This publication contains background readings on consumer affairs for students who are going to participate in the 1980-1981 national high school debate. The debate topic selected by the National Federation of State High School Associations is consumer protection. The three debate propositions are that the federal government should 1) initiate and enforce safety guarantees on consumer goods; 2) establish uniform standards for the regulation of commercial advertising; and 3) establish uniform standards for testing and marketing all products with potentially carcinogenic effects on humans. The first group of articles attempts to cover the area of consumer protection in general from a broad perspective giving historical information as well as addressing current issues. The next three sections contain background materials and essays on each of the debate positions. The articles included in each group begin with those dealing with the subject in general and then move on to those with a more specific focus. Those articles which deal with a pro and con aspect of an issue are grouped together so the reader can readily consider both sides of an issue. The compilers caution that, while the selections were chosen to reflect an overall balance on the debate topic any specific entry may represent a single point of view. Additional resources are listed. (Author/RM)
How Can the Interests of United States Consumers Best Be Protected?

National Debate Topic for High Schools
1980-1981
Pursuant to Public Law 88-246

Best Copy Available

Compiled by the Congressional Research Service
Library of Congress

U.S. Government Printing Office
Washington : 1980
58-658
AN ACT To provide for the preparation and printing of compilation of materials relating to annual national high school and college debate topics.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That the Librarian of Congress is authorized and directed to prepare compilations of pertinent excerpts, bibliographical references, and other appropriate materials relating to (1) the subject selected annually by the National University Extension Association as the national high school debate topic and (2) the subject selected annually by the American Speech Association as the national college debate topic. In preparing such compilations the Librarian shall include materials which in his judgment are representative of, and give equal emphasis to, the opposing points of view on the respective topics.

SEC. 2. The compilations on the high school debate topics shall be printed as Senate documents and the compilations on the college debate topics shall be printed as House documents, the cost of which shall be charged to the congressional allotment for printing and binding. Additional copies of such documents may be printed in such quantities and distributed in such manner as the Joint Committee on Printing directs.

APPROVED December 30, 1963.
CONTENTS

FOREWORD

INTRODUCTION

HOW CAN THE INTERESTS OF UNITED STATES CONSUMERS BEST BE PROTECTED?


Consumerism Lives... and Grows. E. Patrick McGuire in Across the Board, January 1980.

DEBATE

PROPOSITION ONE—RESOLVED THAT, THE FEDERAL GOVERNMENT SHOULD INITIATE AND ENFORCE SAFETY GUARANTEES ON CONSUMER GOODS.


Crying Wolf. Joan Claybrook in Regulation, November-December 1978...


DEBATE PROPOSITION TWO—RESOLVED THAT, THE FEDERAL GOVERNMENT SHOULD ESTABLISH UNIFORM STANDARDS FOR THE REGULATION OF COMMERCIAL ADVERTISING.


DEBATE PROPOSITION THREE—RESOLVED THAT, THE FEDERAL GOVERNMENT SHOULD ESTABLISH UNIFORM STANDARDS FOR TESTING AND MARKETING ALL PRODUCTS WITH POTENTIALLY CARCINOGENIC EFFECTS ON HUMANS ................. 409


Statement on Regulation of Chemical Carcinogens; Policy and Request for Public Comment. U.S. Regulatory Council in the Federal Register, October 17, 1979 ......................... 435

Toward a Sound National Cancer Policy. American Industrial Health Council comments on the statement of the Regulatory Council, entitled "Regulation of Chemical Carcinogens," November 15, 1979 ....... 447

Food Safety Policy. James S. Turner. Paper prepared for Committee on Agriculture, Nutrition, and Forestry, United States Senate, July 1979 ............................................. 475

The Politics of Cancer. Elizabeth Whelan in Policy Review, Fall 1979 .... 517

Unnecessary Chemicals. Anita Johnson in Environment, March 1978 .... 531

Federal Efforts to Protect the Public From Cancer-Causing Chemicals Are Not Very Effective. Report of the Comptroller General of the United States to the Congress, June 16, 1976 ........... 537


SELECTED BIBLIOGRAPHY ON THE 1980-1981 NATIONAL HIGH SCHOOL DEBATE TOPIC

HOW TO SECURE ADDITIONAL MATERIAL ON CONSUMER PROTECTION ............... 623

PUBLICATIONS RELATING TO THE 1980-1981 NATIONAL HIGH SCHOOL DEBATE TOPIC 626
FOREWORD

"How can the interests of United States consumers best be protected?" is the 1980-1981 high school debate topic selected by the National Federation of State High School Associations. The three debate propositions that have been designated within this topic are:

- Resolved, That the Federal Government should initiate and enforce safety guarantees on consumer goods;
- Resolved, That the Federal Government should establish uniform standards for the regulation of commercial advertising; and
- Resolved, That the Federal Government should establish uniform standards for testing and marketing all products with potentially carcinogenic effects on humans.

This volume begins with a group of articles selected to provide an overview of consumer protection in general. It also contains separate groups of background materials and essays on each of the debate propositions. In choosing items for the collection and for the bibliography, the Congressional Research Service (CRS) attempted to sample the wide spectrum of opinions reflected in current literature on these issues. No preference for any policy is indicated by the selection or positioning of articles herein, nor should one infer CRS disapproval of any policy or article not included.

The coordination and final selection of articles and citations in this document was the responsibility of Mary Ann Keefe, Analyst in Consumer Affairs in the Economics Division. Bruce K. Mulock, Analyst in the Economics Division, Geraldine Carr, Analyst in the Science Policy Research Division, and Legislative Attorney Henry Cohen in the American Law Division, were responsible for selecting references in their fields of expertise. The bibliography was drawn largely from the CRS Bibliographic Data Base with the assistance of Richard Gigax, Senior Bibliographer in the Library Services Division, who also prepared the notes and information on additional resources. Stephen Powitz in the Library Services Division and Mark Jickling, John Colletta, and Gary Hauk in the Economics Division, helped in the administration of the project.

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Good luck to each debater in researching your topic and presenting your arguments.

GILBERT GUBE,
Director, Congressional Research Service.
INTRODUCTION

This manual is designed to facilitate research preparations for the 1980-81 high school debates. Following is information to help the debaters make full use of the material included.

The first group of articles attempts to cover the area of consumer protection in general from a broad perspective giving historical information as well as addressing current issues. These articles should provide some useful concepts and data.

The remaining three groups are quite specific in nature: product safety, standards regulating advertising, and standards for testing and marketing potentially carcinogenic products. The articles included in each group begin with those dealing with the subject in general and then move on to those with a more specific focus. Those articles which deal with a pro and con aspect of an issue are grouped together so the reader can readily consider both sides of an issue.

In using this document, two points of caution should be noted. While the selections were chosen to reflect an over-all balance on the debate topic, any specific entry may represent a single point of view.

U.S. Government documents listed in the bibliography may be found in most U.S. Government depository libraries which can be identified by your public library. The Library of Congress cannot distribute copies of these or other materials to debaters.

Suggestions are included at the end of this volume on additional resources. Finally, there is included a list of relevant publications that are available for purchase from the Superintendent of Documents, Government Printing Office.

If several individuals wish to use the material in this volume, entire sections, articles, or pages can be removed easily by creasing the pages at the spine, then pulling them out.
This year's national high school debate topic has been the subject of many articles and much discussion for over a decade. Although consumer activists are disappointed over the failure to achieve the creation of an independent agency for consumer protection, the consumer movement in the United States has grown from almost nothing, 15 years ago, to an established force for change today. In the federal area there have been notable actions, such as the passage of more than 50 new or expanded laws, regulatory-agency rulings, and creation of consumer affairs offices in all Cabinet-level departments, as well as in most independent agencies. Another indicator is the growth of consumer offices in State and local governments throughout the country. A major national opinion survey conducted in 1977 indicated that most Americans believe the consumer movement has significantly improved conditions in the marketplace in the past 10 years. Seventy-two percent of those polled said they believed their shopping skills had improved; 70 percent felt that labeling and product information had gotten better; and 60 percent believed that the safety of most products had improved.

Notably present in the discussion and debate on consumer protection has been much controversy on issues such as whether protecting consumer interests should be the business of the Government or the job of the marketplace; and a large concern over the cost to taxpayers for operating so many Government functions and regulatory activities.

The following articles discuss these concerns and look into the consumer area in general, assessing accomplishments and failures, looking at particular issues, and projecting what might lie ahead.
CONSUMER PROTECTION: GAINS AND SETBACKS

The American Consumer movement has grown from virtually nothing 15 years ago to an established force for change today. There have been notable successes, such as the many federal laws and regulatory-agency rulings on consumer matters. But the movement also has been frustrated by a number of setbacks in recent years, including Congress's refusal to enact legislation setting up a federal consumer protection agency. In light of the setbacks, some wonder whether the consumer movement will ever again be as powerful and effective as it was in the late 1960s and early 1970s. "To assess such an amorphous thing as the consumer movement is not easy," Arthur E. Rowse, editor of Consumer Newsweekly, wrote recently. "There is no yardstick of progress. One can merely list gains and losses while trying to spot causes."

Many consumer advocates say that Jimmy Carter's election has been a significant gain for the consumer movement. Carter spoke out strongly for consumer issues during the presidential campaign. He stressed his support for a strong government agency to represent consumers. In his presentation to the Democratic Party Platform Committee at the nominating convention, Carter called for "major reforms to protect the consumers of this country." A nationwide program of consumer education and vigorous enforcement of the nation's antitrust laws were two other Carter campaign promises.

During his first year in office, Carter placed some 60 former consumer and public interest activists in important positions in the government, a move highly praised by consumer groups (see p. 136). In his State of the Union Address, delivered Jan. 19, 1978, Carter again said he was "strongly committed" to legislation creating a federal consumer protection agency. But despite White House support, the House voted down the measure on Feb. 8 (see p. 126). White House Press Secretary Jody Powell said the following day, "It was a case of the best efforts on the part of the administration not being able to overcome some very organized and effective opposition" from business groups. Powell promised that "administration efforts on behalf of the consumer...will continue and intensify."


Another positive sign is the growth of consumer offices in state and local governments throughout the country. According to the Office of Consumer Affairs of the Department of Health, Education and Welfare, at least one office or division dealing with consumer affairs has been set up in each of the 50 states, the District of Columbia, Guam, Puerto Rico and the Virgin Islands. The total is 141.1 The number of county consumer offices has grown markedly in the last few years—from only 18 six years ago to 150 today. City consumer departments have grown from 51 in 1971 to 67 today. The Christian Science Monitor reported recently that "more than 600" local, county and state government consumer protection agencies are in operation—a figure that has doubled in the past two years.2

New Jersey has one of the most comprehensive state consumer programs. The New Jersey Division of Consumer Affairs works with some 100 county and municipal consumer offices throughout the state. This Consumer Affairs Local Assistance Network handles consumer complaints, corrects frauds and conducts educational programs. In May 1974, the state created the nation's first Cabinet-level Department of Public Advocate with wide powers to sue in the public interest. The Public Advocate office has rolled back rent increases in state-run housing units and helped get voting rights for mentally retarded persons in state institutions.

Among the most successful of the newer county consumer programs is the Los Angeles County Department of Consumer Affairs, which started operations in April 1976. The agency has received some 80,000 telephone inquiries since that time, and has investigated some 10,000 consumer complaints. Many cities across the nation—including Chicago, Honolulu, Boston, Detroit, Atlanta, Houston and Columbus, Ohio—have complaint centers to hear consumer grievances about city services. Local consumer agencies are "gaining more authority all the time," Business Week magazine commented recently, "and the scope of consumerist activities at the state and county levels is growing accordingly."

Public Perception of Consumer Movement

Consumer affairs offices exist in all Cabinet-level departments of the federal government, as well as in most independent agencies, from the Civil Aeronautics Board to the Small Business Administration. In addition, the government operates the Federal Information Center which provides citizens

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Consumer Protection

with information about the government and helps with specific consumer problems. Located in major cities across the country, the offices are run by the General Services Administration and the Civil Service Commission.

There are other, less tangible, signs of the consumer movement's imprint on American life. A national opinion survey conducted by Louis Harris and Associates for Sentry Insurance indicated that most Americans believe the consumer movement has significantly improved conditions in the marketplace in the last 10 years. Seventy-two per cent of those polled in the February 1977 survey said they believed their shopping skills had improved in the last 10 years; 70 per cent felt that labeling and product information had gotten better; and 60 per cent believed that the safety of most products had improved.

The study also indicated a large measure of distrust of business. Exactly half of those questioned said that consumers do not get a better deal in the marketplace than they did 10 years ago; 61 per cent believed the quality of most products and services has grown worse in the last decade. The main consumer concerns were the high price of products, the high cost of medical and hospital care, the poor quality of products, and the failure of many products to live up to advertised claims. The survey concluded: "In the next few years [the business community] can expect to be vigorously attacked by both consumer activists and elected representatives. And it will be more severely regulated unless there are major changes within the business world." 5

Recent Defeat of Consumer Agency Bill

There have been other gains in the consumer movement in recent years. Increasing numbers of federal, state and local consumer protection laws and regulations have been implemented. Budgets and working capital for consumer groups—both private and governmental—have generally risen, as has the number of persons actively working in consumer groups. Many newspapers and television and radio stations have hired consumer affairs experts. And some businesses have taken voluntary steps to help consumers. Many grocery stores provide open-dating of perishable products. 6 Some give comparative prices for different sizes and brands of the same items. Some food processors exceed government requirements for ingredient and nutritional labeling. Other manufacturers offer expanded guarantees and warranties.

6 Open-dating means that the date by which a product should be sold to ensure freshness is clearly marked on its container.
In spite of these positive signs, the consumer movement has faced some setbacks in the last several years. By far the biggest disappointment has been Congress's unwillingness to enact legislation creating a consumer protection agency. Legislation to establish such an agency was introduced for the first time eight years ago. In spite of a heavy lobbying effort by consumer groups, the House of Representatives Feb. 8 rejected creation of a federal consumer protection agency by a 227-189 vote. The vote came on a considerably scaled-down version of previous consumer agency bills. The legislation nevertheless would have given the agency power to represent consumers in government proceedings. Observers believe that the House vote reflected congressional unhappiness with setting up yet another federal agency as much as it did anti-consumer sentiment.

Some laws passed by Congress in recent years have had unintended effects that have hurt the consumer cause. Several of them, in the words of Arthur E. Rowse, "have boomeranged or failed to come close to original expectations." The Truth in Lending Act of 1968 is one example. It was intended to give consumers useful information about loan and credit charges. But some businesses that had not imposed credit charges took advantage of the law's complicated and ambiguous wording and began to do so. Others increased credit charges. The Senate Banking Committee recently began considering ways to simplify the law.

Another law that has not worked as intended is the 1974 Employee Retirement Income Security Act. Marjorie Boyd has called the act, which was designed to simplify private pension plans, "perhaps the most complicated piece of regulatory legislation ever devised." In order to comply with the law, some small businesses have been forced to make costly investments to set up employee pension plans. Boyd wrote that within two years after the measure became law, some 10,000 companies dropped their pension plans rather than comply with the law's complicated provisions.

The 1975 Magnuson-Moss Warranty Act is another case in point. The measure gave the Federal Trade Commission power to set standards for written warranties on products priced at more than five dollars. The law's vague language, some claim, allowed furniture and appliance manufacturers to stop issuing warranties. Some calculations made at the time of the law's passage indicated that a large number of consumers would benefit from the protections it provided. For example, a study by the National Consumer League showed that one in six consumers would receive a warranty under the law. But these estimates were incorrect, and many consumers have not benefited from the law's protections.

1 The Senate passed a bill in 1970 but it was blocked in the House Rules Committee. The House passed a bill in 1971, but the Senate version was killed by a filibuster in 1972. Consumer-protection agency bills were nearly enacted in the 89th (1973-74) and 94th Congresses, but the opposition of Republican administrations and business groups proved too powerful. See Congressional Quarterly's Congress and the Nation, Vol. IV, p. 434.


* Named for Sen. Warren G. Magnuson (D Wash.) and Rep. John E. Moss (D Calif.).
some warranties and weaken existing ones. Other consumer-oriented rulings have proved unpopular with the public and, according to Chuck Fager, they "have produced, or have been manipulated to produce, widespread skepticism about the federal government's capacity to write effective consumer legislation in many areas."10

A Department of Transportation regulation requiring auto manufacturers to install interlock systems that prevented cars from being started until seatbelts were fastened was widely criticized. Congress passed legislation in 1974 overruling the department's order. The bill stipulated that the interlock system would no longer be mandatory and that existing systems could be legally dismantled. The Food and Drug Administration proposed a ban on saccharin, the only artificial sweetener available in the United States, in March 1977. The announcement drew angry protests from consumers and representatives of the food industry. The FDA ban was based in part on Canadian tests that showed rats fed high dosages of saccharin developed bladder cancer. In November 1977, Congress voted to delay the ban 18 months until further tests were completed by the National Academy of Sciences.

**Criticism of Product Safety Commission**

Consumer unhappiness with government-run programs can perhaps best be illustrated by examining the Consumer Product Safety Commission, an independent agency set up by Congress in 1972. The agency is headed by a five-member commission and has the authority to set safety standards for consumer products and to ban products presenting an unreasonable risk of injury. When the commission was established in 1972, it received widespread support from consumer groups.

Since then, the agency has come under wide-ranging criticism. Its chairman, S. John Byington, submitted his resignation Feb. 8 in the face of complaints that the commission does not act quickly or efficiently.11 Howie Kurtz, a Washington, D.C., investigative reporter, wrote recently that the commission has "been such an abysmal failure that it is at least as responsible as any other government agency for the plummeting popularity of consumer protection."12 Jo Thomas of *The New York Times* wrote that the commission "is almost universally regarded as feeble, tardy and reluctant in banning or recalling dangerous products and in setting Federal safety standards."13

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11 Byington will leave office June 30, 1978, four months before his term expires.
Strong indictments of the Consumer Product Safety Commission also have come from government investigatory units. A General Accounting Office (GAO) report took the commission to task for not developing and issuing safety standards promptly. During its first four years, the commission issued standards for only three products—swimming pool slides, architectural glass and matchbooks. The GAO report said that the commission took an average of 834 days to develop those standards, far more than the 330 days Congress specified in the 1972 legislation setting up the agency.

A report by the U.S. Civil Service Commission also was highly critical of the consumer commission. The report found that it "violated personnel laws, regulations and requirements" in 30 cases by giving preferential treatment and personal favoritism to hired consultants. The report blamed Commission Chairman Byington and his former top administrative aide, Albert Dimoff, for the violations.

A third highly critical report was made public Feb. 1, 1978, in The Washington Post. The newspaper reported that a 170-page internal commission report said that the commission had been ineffective in performing its main function—reducing product-related injuries to consumers. "Overall, consumer product-related injuries requiring emergency medical treatment have increased by 44 per cent in the CPSC's five-year history," the report stated. Several factors were cited for the commission's poor performance, including "political or leadership disagreements among the commissioners...tensions between staff and commissioners...staff performance...[and] the effects of having no permanent Executive Director for so long." The report did praise some of the commission's work, especially the development of toy safety and crib construction standards.

Consumer Product Safety Commission officials have defended the agency. Byington said recently that "the critics overlook the fact that the very existence of the agency has been a positive factor in terms of improved safety. There have been dramatic improvements in the whole area of outdoor power equipment.... The standards adopted by the industries have been tightened substantially. Toys are another area where the industry itself has made dramatic improvements."16

Two rulings by the commission have been particularly unpopular. The first, in 1972, required that children's sleeping gar-
Consumer Protection

ments be treated with flame-retardants. Then, in 1977, the agency banned use of one of the chemical retardants, Tris, after determining that it could cause cancer. The two actions angered both manufacturers and consumers. Parents faced higher prices for children's sleepwear in 1972 when the chemical flame retardants were added. Manufacturers protested the ruling that allowed purchasers of Tris-treated garments to have their money refunded. Sleepwear producers say the costs of developing new flame retardants will mean even higher prices.

The commission also has been criticized for not moving quickly against asbestos, which some tests indicate can cause cancer. The agency recently issued a ban on the asbestos coating on artificial fireplace logs. But it took two years to do so. Asbestos is an ingredient in many other products, including children's modeling clay and papier maché. Some time this year the agency is scheduled to issue safety standards for power lawn mowers, gas space heaters, Christmas lights, contact adhesives, communications antennae and baby rattles. The agency also plans to hold regional hearings to let consumers around the country have some voice in influencing rulemaking. But criticism continues and the Consumer Subcommittee of the Senate Commerce, Science and Transportation Committee will be looking into the agency's operations in hearings scheduled for Feb. 24 and 27.

Activities of Nader Groups

C ONSUMER CONSCIOUSNESS is due in large part to the activities of Ralph Nader, a 43-year-old who was virtually unknown to the public only 12 years ago. 'If I were to do a social history of the 1960s and 1970s, I'd write it in terms of Ralph Nader,' Carol Tucker Foreman, Assistant Secretary for Food and Consumer Services at the U.S. Department of Agriculture and former head of the Consumer Federation of America, said recently. "He influenced more people than anyone else." 17

David Ignatius, who worked as a Nader lobbyist in 1973, has written that Nader's career can be divided into four stages. A look at these stages reveals some of the successes and failures of the U.S. consumer movement since the mid-1960s. Nader's career as the nation's foremost consumer advocate began in November 1965 with publication of his book Unsafe at Any Speed: The Designed-in Dangers of the American Automobile.

Although he attacked the whole Detroit automobile industry for emphasis on profits and styling over safety, Nader concentrated his fire on the Chevrolet Corvair, "one of the nastiest-handling cars ever built." The book became a best-seller, and the demise of the Corvair was attributed to its influence.

Meanwhile, congressional support was growing for passage of auto-safety legislation, and Nader testified on behalf of such a bill early in 1966. On March 6, 1966, newspapers published Nader's complaint that he had been under investigation by private detectives hired by the auto industry. Three days later, General Motors conceded that it had initiated a "routine investigation" of Nader to find out if he had any connection with damage suits that had been filed against the company because of defects in the Corvair.

In a nationally televised hearing on March 22, GM President James M. Roche told the Senate Subcommittee on Executive Reorganization that there had been "some harassment," and publicly apologized to Nader. Final passage of the National Traffic and Motor Vehicle Safety Act of 1966 came five months later. After the General Motors apology, Ignatius wrote: "The Nader legend was born. An aroused citizen had waged a successful guerrilla campaign against the world's most powerful corporation."10

The second phase of Nader's career lasted from 1968 to 1970. An organizational period, it featured the opening of the parent Nader organization, the Center for the Study of Responsive Law, in June 1969. The center is a Washington-based tax-exempt organization. It operates on a yearly budget of some $300,000, much of it provided by foundations. The center is perhaps best known as a staging area for the activities of "Nader's Raiders"—groups of young people who gather in Washington during the summer months to ferret out information from government and business groups for subsequent reports.

The Center for the Study of Responsive Law has produced reports on the Federal Trade Commission, the Interstate Commerce Commission, the Food and Drug Administration and on antitrust enforcement, occupational safety and health laws, air pollution, airline safety, nursing homes and the medical profession—among others. The exposés of waste and inefficiency that some of the reports documented won Nader and his raiders the title of modern-day muckrakers. The successes of Nader's organization helped the consumer movement in general to grow rapidly.

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Nader and Congress

Ralph Nader has never been shy about criticizing those who he believes act contrary to the interest of American consumers. When the proposed consumer protection agency bill failed in Congress last year, Nader spoke out harshly against some liberal House members for their lukewarm support.

This year for the first time Nader's major lobbying organization, Congress Watch, will be working in congressional districts throughout the country during the 1978 House campaigns. Congress Watch Director Mark Green said recently that the local groups "will be a way to get information on to people...about what their representatives are really doing, as opposed to what they may say they're doing and to mobilize public support for our issues.... We're still thinking about whether to make formal endorsements; we might."

Nader summed up his position on politics in this way: "Liberal versus conservative is no longer the real dividing line in politics; the actual distinction is between the 'corporatists,' those who support and expand the power of corporations, and 'consumerists,' those who are working to expand the power of the people. The abuse of power by large corporations is the number-one issue in our society and we intend to make it the major political issue in 1978."

During the third phase of his career (1970-1972) Nader began the push for federal legislation setting up a consumer protection agency. Congress's unwillingness to do so, after months of intense lobbying by the Nader organization, led to a second major Nader undertaking: the formation in November 1971 of a 1,000-member team to conduct a yearlong study of Congress. The authors of the Congress Project set out to rate each member of Congress running for re-election in 1972. Nader characterized the effort as "the largest study of Congress ever conducted—an effort to share with citizens a better understanding of how the members and committees of our national legislature operate both among themselves and in relation to outside forces working on the Congress."

"Everyone who had anything to do with it—Ralph Nader included—now admits the Congress Project was something of a boondoggle," Ignatius, who himself helped with some of the profiles, wrote. The main problems were the large volume of work and the short time to complete it. All the work was scheduled to be released before the November 1972 elections and the massive effort to complete the project was further hampered by administrative and organizational problems.

Ralph Nader and Robert Fellmeth, writing in the introduction that accompanied the profiles, "Ralph Nader Congress Project, Citizens Look at Congress," August 1972.
Little new information was contained in the profiles. There were no sensational revelations or charges. The *New York Times* commented that the profiles were "unlikely to furnish any damaging information that could not have been obtained elsewhere with a little digging."

The other significant undertaking during the "third phase" of Nader's career was the establishment of the Public Interest Research Group (PIRG) in 1970. The PIRG, which has been described as Nader's public-interest law firm, has satellite organizations on 145 college and university campuses with some 500,000 student members. Aside from student fees at the various colleges, the organization's budget is met by Nader's lecture fees and book royalties. Nader also donated the proceeds from an out-of-court settlement on an invasion-of-privacy suit against General Motors—estimated at some $270,000 after taxes and attorney fees.

**Litigation, Lobbying and Organizing**

The fourth phase of Nader's career began in 1972 and lasted into 1976. Ignatius described the period as one in which Nader embraced "the traditional tools of interest-group representation: litigation, lobbying and grass-roots organizing." Nader succeeded in setting up a relatively smooth bureaucracy, Ignatius wrote, "with a sensible delegation of authority, leaving him free to ruminate on the future."

In 1972, Nader established the tax-exempt Public Citizen, an umbrella-group, which directly supports four other Nader organizations: (1) the Citizen Action Group, which includes the Public Interest Research Group; (2) Congress Watch, a full-time lobbying office with a yearly operating budget of $145,000 and seven full-time lobbyists, which succeeded the Congress Project; (3) the Public Citizen Litigation Group, set up with a staff of eight attorneys to act in legal suits for consumers, especially in Freedom of Information suits; and (4) the Health Research Group, which studies and researches health issues.

Headed by Dr. Sidney Wolfe, the Health Research Group has petitioned the Food and Drug Administration to act against certain-drug manufacturers and it was successful in helping ban the artificial food coloring, red dye No. 2. The Health Research Group conducts policy-oriented research on such issues as unnecessary surgery, comprehensive health planning, hospital construction and operation, mental illness, nutrition, drugs, pesticides and carcinogens, dental health and the education and training of health professionals.

Since 1976, articles in national news magazines and major...
Consumer Protection

newspapers have examined Nader's career and questioned his effectiveness and power and that of the entire consumer movement. The debate over Nader's effectiveness was sparked by the 1976 publication of the book *Me & Ralph: Is Nader Unsafe for America?* by David Sanford, then managing editor of *The New Republic*. In his self-described "rare and controversial view" of Nader, Sanford conceded that Nader had done an admirable job working for American consumers, especially in influencing Congress to pass important consumer legislation. But the book concentrated on Nader's personal life—his personality, living habits and financial affairs. Sanford presented an overwhelmingly negative picture of Nader, accusing him of acting in his own self-interest rather than for consumers.

Some Nader supporters said the book was part of a personal vendetta against Nader. Theodore Jacobs, a Nader aide, wrote that Sanford's "allegations about Nader are based on double and triple hearsay and consequently suffer from inaccuracies and misrepresentations." Mark Green, the director of the Congress Watch project and a long-time Nader associate, called it a "pastiche of gossip, innuendo and error about Ralph Nader." Nader himself termed the book "a dirty trick."

Debate Over Nader's Influence and Power

Questions about Nader's effectiveness and speculation that he had lost influence and power continued through 1977. Two incidents fueled the controversy. The first was the largely negative reaction by political commentators and sports columnists to the formation of FANS—the Nader-sponsored *Fight to Advance the Nation's Sports*. The purpose of the group, Nader wrote, was to allow sports fans to "exercise some fundamental consumer rights to know and to shape the product of service they are buying." Among the issues to be confronted were the high and growing cost of tickets, the high-priced, low-nutrition junk food sold at sports arenas and television blackouts. Nader said FANS would eventually focus on bigger issues, such as excesses by sports corporations and the overlap and conflict of schedules of different sports.

"The owners and the players each have their own protection organizations. It's time the fans have one of their own," Nader said.

*References*

said as he and lawyer Peter Gruenstein announced the formation of the organization Sept. 27, 1977, in Washington. An editorial in The Washington Post Sept. 29 criticized FANS’ formation, saying that Nader was overextending himself: “The idea that organizations can speak for groups of people is getting out of hand. . . . [B]eing a sports fan, after all, is a little different from being a food buyer—or a taxpayer. You don’t have to be one if you don’t want to.”

Newspaper columnist George F. Will also attacked the organization. “FANS is like many organizations that are concocted by ‘consumerists’ skillful at making work for themselves,” Will wrote. “It is the assertion, by a few persons who have appointed themselves to speak for many strangers, of concerns that few consumers share. . . .” Television commentator Eric Sevareid chided Nader for concerning himself with food at ballparks. Sevareid said Nader “would drive out the odor of peanuts and popcorn from ballpark and football stadium and spray the joints with astringent fumes of the germicide called Social Responsibility.”

The controversy over FANS is not crucial in terms of assessing the strength of the entire American consumer movement. But the reaction to its founding illustrates that Ralph Nader—who for much of his career had been extremely popular and rarely criticized except by conservative supporters of big business—can no longer count on general public acceptance of his every move.

Another round of anti-Nader criticism followed soon afterward. The uproar came after Nader publicly upbraided Joan Claybrook, head of the National Highway Traffic Safety Administration, who had been one of Nader’s closest associates when she served as his chief congressional lobbyist. Nader charged that Claybrook had “etched a trail of averted or broken promises” and demanded her resignation in a long letter made public early in December 1977. He accused her of betraying consumers by supporting a Carter administration decision to give auto manufacturers six more years to install air bags in cars.

Nader’s outburst drew wide attention. Ross K. Baker, a professor of political science at Rutgers University, wrote that Nader’s attack on Claybrook and other outbursts at government officials was symptomatic of Nader’s unwillingness to realize that the federal government must be responsive to all in-

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11 Former Congress Watch lobbyist Nancy Chasen described Claybrook in 1976 as “undoubtedly [Nader’s] most trusted employee—more so than anybody. She has extremely direct access to him. There is no issue that she is left out of.” Quoted in Sanford, op cit, p. 80.
Consumer Protection

Interests—not just to consumers. "Having succeeded to a remarkable degree in placing people identified with consumerism and public-interest activity in the Carter Administration," Baker wrote, "the zealots on the outside are attacking and repudiating their erstwhile colleagues for their moderation in the pursuit of reformist objectives."28

Has Nader's overall impact been significantly reduced by the Sanford incident, the creation of FANS and the Claybrook attack? Nader denies that he has lost any power. "There are two ways you can judge it," Nader said recently. "First, consider who we are up against. If we can come up neck and neck against the biggest coordinated lobby of trade groups ever, as we did on the consumer protection agency bill last fall, that's real power.... Second, you judge by whether a group wins its battles, and achieves what it's aiming at; or if you lose, by how close you come. And in those terms we've also been doing well."29

Rep. Toby Moffett (D Conn.), one of the leading voices for consumers in Congress, said recently that although Nader himself may be losing some influence, his lobbyists are becoming more effective. What Nader is doing, Moffett said, is "creating what I call an information stalemate. Ten years ago, you had information pouring in from the special interests but nothing to counter it. What Nader has done is even up the odds on information...."30 While there may be disagreement on whether Nader himself has lost power and influence, there can be no doubt—as Moffett indicated—that the Nader organization is an established, effective voice for consumer causes.

Future of American Consumerism

President Carter came to office last year with wide support from the nation's consumer leaders. Ralph Nader described Carter's views on consumer issues as "a breath of fresh air" compared to those of Presidents Nixon and Ford. Nader met with Carter Aug. 7, 1976, and pronounced Carter's positions on consumer issues "better than [those of] any candidate that has achieved the nomination of any major party in recent decades."31 Speaking at a Nader-sponsored Public Citizen Forum in Washington, D.C., two days later, Carter said he wanted to challenge Nader "for the title of top consumer ad-

vocate in the country." Other national consumer leaders, including Kathleen O'Reilly, executive director of the Consumer Federation of America, also praised Carter's positions on consumer issues, especially his support for the proposed consumer protection agency and class action lawsuits by citizens. A group called Consumers for Carter, which included Bess Myerson, former New York City consumer affairs commissioner, formed to help the Carter presidential effort.

After the election, Nader's support for Carter faded somewhat. Nader found fault with Carter's initial Cabinet appointments, especially Energy Secretary James Schlesinger, and Treasury Secretary W. Michael Blumenthal. Nader accused Schlesinger of favoring nuclear energy at the expense of solar energy and conservation. Blumenthal, Nader told reporters, is not "someone who has had a record of strong commitment...to using the Treasury Department as something other than a plantation for bankers, trying to get genuine tax reform and trying to use the leverage of monetary policy and the Treasury's resources for housing and other purposes." Nader did praise some of Carter's appointments, including Secretary of Labor F. Ray Marshall, Secretary of Health, Education and Welfare Joseph A. Califano Jr. and Secretary of Agriculture Bob Bergland.

Public Interest Activists in Government

Generally, there has been high praise from other consumer leaders for the large number of appointees with consumer backgrounds in the Carter administration. Important positions have gone to former public-interest lawyers, consumer advocates, civil-rights workers and environmental activists. Juan Cameron reported that some 60 former public interest advocates hold important positions in the federal government.

One of the former consumer advocates in the Carter administration is Peter Schuck, HEW's Deputy Assistant Secretary for Planning and Evaluation, who previously served as Washington director of Consumers Union (see p. 139). Schuck said recently that he, like many others newly appointed to government positions, faced problems with the vast size and procedural difficulties within the government bureaucracy. "It's a very stimulating experience, but it has also confirmed my worst suspicions about how difficult it is to get things done in a bureaucracy," Schuck said recently. "There are just so many bases to touch, so many groups to be conciliated."

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13 Juan Cameron, "Nader's Invaders are Inside the Gate," Fortune, October 1977, p. 252.
14 Quoted in Newsweek, Jan. 12, 1978, p. 22.
Robert Greenstein, a former lobbyist for the Community Nutrition Institute, now is a special assistant to Agriculture Secretary Bergland. As a public-interest advocate, Greenstein worked to liberalize food stamp laws. He was assigned the same task when he entered government. "I never dreamed I would get involved in this, much less be one of the principal advisers on the new food stamp legislation," Greenstein said last fall. He is credited with writing an important change in the new food stamp law that allows qualified recipients to receive stamps without paying for them.

Changes at the Federal Trade Commission

The former consumer advocate with perhaps the most potential to influence the marketplace is Michael Pertschuk, chairman of the Federal Trade Commission. As chief of staff of the Senate Commerce Committee, Pertschuk earned a reputation as a campaigner against unfair business practices and for consumer rights. Pertschuk has promised to make the FTC, which enforces the antitrust laws either through voluntary compliance or court action, a voice for consumers. "We want to make sure consumers are better off than they were before as a result of our actions," Pertschuk said recently.

Pertschuk took over as FTC chairman in May 1977. He has instituted several changes since then. The commission now allocates funds to consumer group representatives to attend FTC rule-making hearings, something the groups had not been able to afford to do in the past. Pertschuk has overseen a general reorganization of FTC procedures aimed at enabling the commission to move quickly to obtain injunctions and get penalties by direct court action.

Pertschuk has been criticized by both business and consumer representatives. Consumer groups say the commission has not moved quickly enough under Pertschuk and that the commission has not significantly aided the consumer cause since he took over in May 1977. On the other hand, businesses generally do not like his pro-consumer outlook. "We are not happy with him," Barry A. Friedman of the U.S. Chamber of Commerce said recently. "He's taken a strong pro-consumer position... that potentially could harm business."

The future of the American consumer movement hinges on many factors. The pivotal question, Arthur E. Rowse of Consumer Newsweekly wrote recently, is whether organized consumers can "ever build up enough power to forge significant im-

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* Quoted by Juan Cameron, op. cit., p. 253.
Consumer Protection

provements in the marketplace and society." One measure of the consumer movement's strength is the fate of the Consumer Protection Agency Bill. Many agree with the assessment of Rep. Benjamin S. Rosenthal's (D N.Y.), "I think we have heard the last of it, at least for a time," Rosenthal, a sponsor of the bill, said Feb. 9. "The margin of defeat was significant, and I don't see any basis for us to recover..."

Size and Shapelessness of the Movement

One thing that contributed to the bill's failure is a problem that has plagued the American consumer movement from its beginnings 15 years ago—the movement's inability to present a totally united front on most issues. The consumer movement, almost by its definition, is as fragmented as the myriad needs the consuming American public has. The Nader organization, with 100 people working full-time in Washington on a yearly budget of some $1.1 million, is the closest thing to a national consumer organization. But the principal Nader organization, Public Citizen, is involved with many different issues and does not directly involve the public.

Lee Richardson, former president of the Consumer Federation of America and now head of HEW's Office of Consumer Affairs, said recently that ultimately "we may need a national membership organization. Without one, it is a little bit scary. Other interests such as labor and women have built up solid constituencies with chapters and affiliates across the country. We are a long way from the kind of organization consumers need."38

There are several national consumer groups, but none represent the constituency of which Richardson speaks. The National Consumers League, Common Cause, Consumers Union of the United States and the Consumer Federation of America are the principal national consumer groups. The largest one, the Consumers Union, has been active since 1936, publishes the magazine Consumer Reports and has some two million members.

There is no question that the consumer movement has had an important impact on the American marketplace in the last 15 years. While there is no unified national consumer organization, there is a large and growing number of federal, state and local consumer-oriented government offices. And the Carter administration has proven to be very responsive to consumer demands. These signs strongly indicate that today's consumer movement will remain an important voice for change for years, if not decades.

Opponents of the consumer reform movement and even some friendly observers have seized on a recent slowdown in gains, including defeat of the consumer agency bill and diminished media interest, to proclaim that consumerism is dying out.

But those who think or hope so are wrong—because the nation has an underlying public demand for such reforms. They're needed to redress the personally and socially harmful injustices of the marketplace and stem the great waste of personal and national resources needed for other purposes.

In fact, all opinion surveys and other signs indicate that the public is far ahead of many government and business leaders in understanding the need for consumer protection.

Gallup polls the past two years found that most people considered the cost of living to be the nation's biggest problem. Several Harris polls found a majority of Americans favored the consumer agency Congress killed. Among other surveys, one by the Sentry Insurance Co. also found strong public feeling that consumer reforms are needed.

Further indicators of the public's consumer awareness are the many local groups that have sprung up around such specific issues as utility rates. And while Congress has seemed more resistant, state and local authorities have become increasingly active on behalf of consumers.

The public's consumer concerns are noticeably high in this year of record-high food prices and overall living costs. Moderate-income families are especially frightened by sudden sharp increases in food prices. They worry that a time may come when they may not be able to feed their families adequately on the money they have to spend.

So rather than consumerism dying out, as some would believe, we may need to be prepared for new interest at the local levels. This is where the real consumer movement is, and while it often seems leaderless and merely grumbling rather than articulate, it...
often responds to serious inflationary pressures with serious activity such as picket lines and pressures on Congress.

Trade union leaders have a special stake in effective consumer reforms because explosive price runups hit wage earners particularly hard and can quickly erase hard-won wage gains and abruptly erode already tenuous living standards.

From 1972 to June 1978, non-agricultural workers had what seems like a handsome rise in their gross average weekly earnings, from $136.16 to $205.46. But real buying power in terms of spendable, constant average weekly earnings, from $96.64 to $93.21.

Financially inexperienced workers have been manipulated and coerced into serious financial losses by rigged credit laws and powerful modern selling pressures and often into garnishment and sometimes even loss of jobs and homes.

But if consumerism is far from dead, it is true that the representation of consumers has narrowed somewhat and the choice of barricades has not always been the most effective.

So many issues recently have been raised in the name of consumerism that the limited resources of the consumer movement are noticeably strained, and the attention of the public and public officials has become diffused. New professional consumer advocates and specialized consumer organizations have sprung up and gone off in many directions—sometimes with little or no first-hand background on particular issues.

Young lawyers and others with little economic background have acted as consumer spokesmen on complex matters of meat grading, nutrition, vitamins, health foods, food costs, agricultural policy or life and auto insurance.

Sometimes because of the lack of experience of the new spokesmen or the time to sift through conflicting arguments, a few activists have been able to represent their personal views as those of many organizations.

A few of the hundreds of issues raised as consumer needs really are fostered by insurance, vitamin, health food or other commercial interests. They can sometimes mislead the inexperienced consumer activists who are themselves burdened with too many issues.

Some other issues may be only dimly related to primary consumer problems or may be largely political. While most of the issues raised do have importance to consumers, there is a noticeable lack of priorities and a diversion from what may be the most urgent needs.

Earlier, and during the period of greatest gains, the main representation of the consumer had been by community organizations like unions, co-ops, women's organizations, settlement houses, credit unions, education, housing co-ops, anti-poverty councils, church and senior groups, etc., and by spontaneous local groups that sprang up to meet specific crises like jumping utility or food prices.

These organizations have deep grassroots and ordinary people who had been victimized were brought forth in an effective drive to secure truth in lending, garnishment control, better drug regulation and other needed protection. Unions and some of the other community groups also were establishing group drug buying and optical services even before the 1959 hearings by Sen. Estes Kefauver focused attention on high drug prices.

The community organizations were also more effective because they have their own financial bases and were less hampered by the need to raise funds. In contrast, the new professional consumerists increasingly have sought grants from various government agencies. And some of the newer groups have expired especially since Consumers Union had to curtail its grants to such organizations because of its own financial problems.

The question of the possible effect on government grants on the independence of the consumer organizations has been raised. Perhaps of more concern is that some of the voluntary consumer organizations have turned to business organizations for funds to attend the many conferences that now take place and for other organization purposes. For example, phone companies, utilities and house-to-house sales associations have provided funds for such purposes for consumer groups or their representatives in recent years.

Officials of several Washington-bred consumer organizations also have accepted fees for consulting with the American Council of Life Insurance, the largest insurance trade association. Such support has not been concealed, though it is not always widely publicized, and this writer has no evidence that it has influenced any of the organizations or individuals involved.

Competing interests and conflicts among some of the new professional consumerists also have attracted attention. Unions have no interest in the politics of the consumer movement. Their interest is simply to help workers get fair value for their dollars, and have reasonable protection in the marketplace from manipulation, deception, and product hazard.

But to approach that goal there is a need to maintain and expand their interest and representation of consumers and not leave this area primarily to the new professional consumerists.

The defeat of the consumer agency bill affirms the need for a mass base and people-organizing and communication skills. Some of the activists assumed a threatening posture against reluctant Representatives, which only made the latter dig in even harder. Meanwhile, while the general public never did get a real understanding of the real purpose and need for the bill, and small businessmen were unnecessarily frightened.

It should be realized that the business of influencing the government has become Washington's second-largest industry, as Lee Richardson, acting director of the U.S. Office of Consumer Affairs, has pointed out. Today, some 3,000 corporations have offices in Wash-
ington compared with about 50 only 15 years ago. The area also now is headquarters for about 1,600 trade associations, 13,000 lawyers and numerous consulting firms, all involved to some extent in the work of influencing the government, Richardson observes.

What are the consumer's main needs? The problems are many, especially in a deceptively affluent society marked by mass production methods but a wasteful, complicated marketing system. But there have been useful gains as well as setbacks.

Modern consumer problems began to proliferate right after World War II. Congress removed wartime price controls prematurely and set in motion a long inflation that lasted from time to time but never really stopped. Consumers also suffered quick defeats — such as the removal by Congress of the wartime requirements for labels on canned foods.

The proliferation of merchandise itself during the 1950s brought such problems as undependable, quality, excessive prices, undependable guarantees, product safety hazards, duplication, the hard sell of TV, the use of easy credit and obsolete credit laws as levers of coercion, home improvement deceits, referrals plans, domination of government agencies by their client industries, and the like.

The real period of consumer redress began about 1962 when the Kefauver drug amendments were passed and President John F. Kennedy appointed the first consumer council. The major gains were achieved during the 1960s and early 1970s when truth in lending, truth in packaging, auto and product safety and other landmark legislation was enacted, and government agencies such as the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA) also moved to provide more consumer protection.

During that period other consumer legislation included cigarette labeling, controls on interstate land sales as well as closer regulation by the states, and expansion of meat and poultry inspection.

Perhaps the greatest gains were made in the area of greatest previous exploitation—consumer credit. Progress also has been made on the state level, both in supplementing and sometimes pioneering in various reforms. Some 40 states and many cities and counties now have consumer protection agencies or consumer divisions in their attorney general's office.

Despite the growing diffuseness of consumer representation, further gains have been made even in the most recent years — though a number look more like fringe benefits than some of the major advances of the 1960s and early 1970s. The recent gains include new regulations at federal and state levels to further strengthen the defenses of credit buyers; a reinforcing of the right of consumers to know beforehand the prices of some of the services they must buy, such as prescription medicines, eyeglasses and funerals; the providing of more information for buyers on energy consumption of cars and appliances; and the quest, still not wholly successfully, to relieve some of the dispute over warranty service by requiring more
credit practices. Among the advances: Congress enacted the consumer co-op bank bill which
brought relief to many organizations, including labor, and has increased the administration's
ability to provide nationwide representation in government. Moreover, the President's consumer assistant, has
announced a program to increase the scope of the present consumer office and of consumer representation in
government agencies.

As in the earlier reform years, the greatest recent advances have been in redressing damaging
credit practices. Among the advances:

**Equal Credit** This recently enacted law prohibits creditors from denying people credit because of sex,
mariage status, race, age, or receipt of public assistance
benefits. Among other practices the law bars are
several previously used to deny women access to credit on their own account.

Another important area has been recent efforts by
government agencies to spur greater price competition.

These efforts, usually in the form of legal suits, have
been aimed at both actual price fixing on a wide vari-
ety of industrial and consumer products, and the
follow-the-leader type of price setting for which some
industries have long been criticized.

In 1976, a price fixing device long used by
companies was finally eliminated when Congress
repealed the so-called "fair trade" laws in the 21
states which had been in force. The state "fair trade"
laws, enacted during the depression of the 1930s,
permits manufacturers to set the retail prices for
their products even if some retailers were willing and
able to charge less. The climate of the depression made
it desirable to stop undercutting by firms for a tem-
porary advantage, but that climate had long since
passed before the "fair trade" laws were repealed.

Court decisions, rather than legislation, have pro-
duced some other useful advances. One, which opened
up price advertising of professional services, was the
1976 ruling by the U.S. Supreme Court which re-
moved laws in 34 states prohibiting pharmacists from
advertising the prices of prescriptions drugs. Virginia
unions joined with consumer groups to win this court
suit.

The ruling was based on the First Amendment
guarantee of free speech. Justice William J. Rehn-
quist, who cast the only dissenting vote in the 7-1
decision, argued that the ruling "cannot be limited
merely to dissemination of price alone, and can-
sion possibly be confined to pharmacists without like-
respect extending to lawyers, doctors and all other pro-
fessionals."

The consumer agenda—or shopping list of consumer
needs begging for attention—remains long even after
the advances of recent years.

Many of the consumer issues recently raised are
serious. Some may be peripheral. Earlier consumer
issues were mainly related to economics and prod-
uct safety. Now, there have been added equal rights,
the environment, overuse of chemicals in food, and some-
times special pleading, as by people connected to the
health food industry.

The other most urgent needs might well include
these largely economic areas:

- Housing costs are the most pressing problem
and by far the largest item in the consumer budget.
Unfortunately, some of the government's activities
are inadequate. Absent from the Carter Administra-
tion's inflation plan was any proposal to reduce the
present steep mortgage rates of 9 to 10 percent.
Moreover, the Federal Reserve Board has continued
on a tight-money, high-interest policy despite the
recent change in leadership at the federal level.

Too, a number of federal agencies are playing the
mortgage lenders' game by supporting such illusions

**AFL-CIO AMERICAN FEDERATIONIST**
as variable mortgages and graduated payment plans. These schemes ultimately mean that home buyers would have to pay still higher costs.

- Food costs are another leading problem, especially since the new 1978 surge in prices. At present, 60-62 cents of the consumer's food dollar goes to those handling food between the farm and market—a "spread" that should be reduced.

Several of the Washington-based consumer organizations are making a valiant and useful effort to get the government to take steps to stimulate competition in the food industry. These efforts need support and additional expertise.

- In an age of processed foods, consumers also have the right to more facts than they now get on ingredients. The FDA and the Department of Agriculture have said they are interested in requiring additional information on labels, but they have been very slow to take any real action.

- Heavy installment buying and borrowing at high finance charges is a continued problem. Already, total consumer debts are over $240 billion. Such heavy use of credit often leads to serious overindebtedness and the new familiar train of garnishments, often followed by debt adjustment plans and bankruptcy. A big consumer debt load always is a recessionary threat.

- But even among families who don't become seriously overindebted, constant payment of high finance charges on installment purchases frequently results in a hidden loss of perhaps 4 to 5 percent of a family's entire income.

- Inadequate health insurance, compared to today's soaring medical and hospital fees, are a persistent dilemma along with the need to control such costs through better delivery of health services. Large medical bills also happen to be one of the leading causes of overindebtedness and sometimes bankruptcy.

- In an age of proliferating merchandises—sometimes of undependable quality that wastes the consumer's and the nation's resources—minimum-quality standards are a pressing, long-term need. Some beginning steps have been made in this direction, with government grades used on many foods (though improvements need to be made in the grades themselves); in the new grading system just announced for tires; in the few product safety standards so far developed; and in the new energy consumption labels required on cars and appliances.

- Auto insurance costs, and sometimes the difficulties in getting any coverage, are another troubling area for workers. No-fault auto insurance laws have failed to restrain rate increases in states which enacted them, and serious reforms of the industry and its marketing methods itself seem to be needed.

Those are some of the main consumer needs which may require priority attention. But consumers and their allies also need to be aware of the need for improvement in some of the legislation already enacted.

- The new warranty law is not helping much with some of the worst problems, like car warranties. As one of the original commissioners, I would judge the Consumer Product Safety Commission has been hampered by political appointments of people with little background in this area, as well as some who didn't even believe much in the need for the agency. So merely enacting legislation doesn't necessarily solve the consumer problem. The new legislation may need public as well as congressional oversight.

Too, some general legislation and existing government bodies can be more effective on the consumer's behalf—as the FTC recently demonstrated with its notable change in the holder-in-due-course doctrine. While consumer redress is not simplistic and actually will never be fully completed, useful advances have been achieved. They can continue to be if community organizations help provide the mature leadership and the grassroots support as before.
TOWARD A NEW CONSUMER PROTECTION

ROBERT B. REICH‡

Consumer protection is everywhere in retreat. Congress has rejected the Food and Drug Administration's proposed ban on saccharin,1 and several courts and state legislatures have attempted to block the FDA's attack on Laetrile.2 The Consumer Product Safety Commission's recent ruling that swimming pool slides must carry danger warnings3 has elicited widespread ridicule, brought a reversal in the federal courts,4 and contributed to rumors that the Commission itself will be abolished. Congress has rescinded the

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2 The decision of the United States Supreme Court in United States v. Rutherford, 99 S. Ct. 2470 (1979), rejected an attempt to defeat the FDA's efforts to regulate interstate distribution of Laetrile, but made no findings as to the drug's safety or effectiveness. While the Rutherford decision appears to clear the path for further FDA involvement in the Laetrile controversy, it does not affect the validity of the various state legislative and judicial pronouncements on the legality of Laetrile. Despite the FDA's call for evidence of Laetrile's safety and effectiveness, seventeen states have legalized the drug. Pro-Laetrile campaigns were defeated, however, in fourteen states in 1978. [1978] FOOD DRUG COS. L. REP. (CCH) ¶ 42,292.


4 Aqua Slide 'N' Dive Corp. v. Consumer Prod. Safety Comm'n, 569 F.2d 831 (5th Cir. 1978).
Department of Transportation's safety-belt/ignition interlock rule, removed its authority to require helmets for motorcyclists, and expressed distaste for its "air bag" regulation. Congress has also rejected the proposed consumer-protection agency. And the Federal Trade Commission's proposal to control television advertising of sugared cereals for children has prompted the Washington Post to accuse the agency of becoming the "national nanny." These events contrast sharply with those of just a few years ago, when Ralph Nader first argued that automobiles were "unsafe at any speed" and the consumer movement demanded and received protection against business malfeasance and nonfeasance. Why the difference? What has changed?

Unfavorable economic conditions offer one explanation. Since 1973, oil embargoes, soaring prices, recessions, and high unemployment have plagued the country. Consumer protection was fine when the economy was buoyant, but in times of belt-tightening it is regarded as an unaffordable luxury, since its benefits are often less immediately apparent than its costs. When auto sales declined drastically during the 1974 recession, for example, Ford and Chrysler asked for a moratorium on federal safety and environmental standards. Chrysler threatened to close a Detroit auto plant employing 5,000 people in one of the city's poorer neighborhoods if the volume of auto sales did not increase. Eventually the industry got its way.

Greater sophistication in the business community about lobbying and grass-roots politicking may also account in part for the decline in political support for consumer protection. Trade associations have a larger number of lobbyists and a more sophisticated approach to lobbying. In addition, the business community has become more effective in using grassroots politicking to influence legislation. This increased sophistication has made it more difficult for consumer activists to mobilize public opinion in support of consumer protection legislation.

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7 In 1977, the Senate sustained the Department of Transportation's decision to require air bags on 1984 models by a vote of 65 to 31. 123 Cong. Rec. S17016 (daily ed. Oct. 12, 1977). The following year, however, Congress tacked on a rider to the Department's appropriations bill which provided that no funds could be used to enforce or implement the airbag requirement. Department of Transportation and Related Agencies Appropriation Act, 1979, Pub. L. 95-335, Title III, § 317, 92 Stat. 435. The House has added an identical amendment to the 1980 appropriations bill. 125 Cong. Rec. H8066 (daily ed. Sept. 18, 1979).

8 The bill to create the agency was defeated by a vote of 227 to 199. 124 Cong. Rec. H828 (daily ed. Feb. 8, 1978).


10 R. NADER, UNSAFE AT ANY SPEED (1965).

ciations have flooded Washington in the past few years. Since 1969, four hundred corporations have opened Washington offices.\textsuperscript{12} And it is estimated that corporations and trade associations account for eighty-five to ninety per cent of about $1 billion a year spent on grass-roots efforts.\textsuperscript{18}

There is, however, another critical factor. Underlying the economic and political shifts of recent years has been a growing public unease about the function of consumer protection. It is not so much that the goal worries people. Ask the average consumer whether he wants unsafe cars, carcinogenic drugs, adulterated foods, dangerous toys, or advertising intended to exploit the gullibility of his four-year-old and he will answer with a resounding "no." But ask him whether government regulators should intervene to remedy these problems and his response is likely to be ambivalent. Increasingly, the public debate about consumer protection has centered less upon the question of which marketplace evils should be cured than upon the propriety of having the government administer the remedy. In its crudest form the question has become: whom do you trust less—big business or big government?

To take sides in this debate would be foolish—recent history offers no particular reason for trusting in either big business or big government. Moreover, some government regulation will always be needed to make sure that consumers are getting what they pay for, even if it is limited to inspecting the scales at the checkout counter and testing for contaminants in beef.

Yet the current crisis in consumer protection points up the need for a reexamination of the fundamental questions. That some form of consumer protection is conceded to be necessary only begins the inquiry. Why do consumers need protection? When should the government intervene to protect them? How should it do so? The government's current answers to these questions have yielded a regulatory policy fraught with difficulties. The need for consumer-protection regulation is seen as arising from the sale of unsafe, unhealthy, or inefficient products. Relying on risk-benefit analyses, existing policy calls for government intervention whenever the cost of making a product better is less than the benefit to consumers of the extra margin of safety, health, or efficiency thereby achieved. Typically, government intervention takes the form of requiring

\textsuperscript{12} Id. 527; Washington Information Boom, DUN'S REVIEW, March 1979, at 60.

manufacturers and sellers to bring their products in line with minimum official standards, or in some instances, of banning sales altogether.

The paternalism and potentially limitless opportunity for government intervention implicit in such an approach have, in turn, engendered a growing skepticism about the legitimacy of consumer protection, and thereby worked to the advantage of those organized interests hostile to the consumer movement.

This Article offers a way out of the current impasse by proposing a nonpaternalistic approach to consumer protection that takes account of the market's structure and its incentives. The need for consumer protection lies not in the existence of "bad" products, but in market relationships which make it unlikely that sellers will take efficient steps to prevent consumer mistakes. This will occur in markets where sellers do not have a significant stake in maintaining goodwill. It follows that the current regulatory method of directly supervising the quality of the product misses the mark. The least costly and most effective strategy for consumer protection is to increase the stake which sellers have in building and maintaining goodwill.

No discussion of consumer-protection policy can afford to ignore antitrust considerations. Part I of this Article discerns the origins of consumer protection in regulatory efforts to restrain competition within temporarily unstable markets. Part II analyzes the contemporary "purchasing agent" model of consumer protection, whereby government directly assesses a product's costs and benefits and the costs and benefits of improving product quality. Because the "purchasing agent" model lacks any connection to the dynamics of the market, it is unable to provide a basis for integrating consumer-protection and antitrust policies, a problem explored in part II by examining four kinds of market restraints typically condemned by antitrust law without consideration of their potential for significant consumer benefits.

Part III sets forth a new, market-oriented analysis of why consumers need protection. Parts IV and V address the when and how of government intervention: Part IV identifies four market situations that reduce incentives to maintain goodwill; part V outlines a number of strategies for increasing the seller's stake in goodwill.

This Article does not consider the possible effects of consumer purchases on third parties. If one dwelled only on such effects, some justification for government paternalism might be discovered. After all, a child's dangerous toy can injure his friend as easily as himself, and not even the rational consumer is likely to weigh this possibility fully in his purchasing calculations.
program consistent with the basic concerns of antitrust, as well as consumer-protection policy.

I. CONSUMER PROTECTION AND MARKET INSTABILITY: GOVERNMENT AS FRANCHISOR

The American economy has paid lip service for two hundred years to the twin laissez-faire principles of vigorous competition and consumer self-reliance, the latter embodied in the maxim caveat emptor. But whenever major businesses faced unstable and uncertain markets, and consumers likewise confronted risky market decisions—when, in short, rapid social or technological change threatened long-standing and established business-consumer relationships—the government attempted to achieve stability by regulation. Government franchising in various guises served to promote consumer as well as private interests by restraining the operation of market forces. The murky origins of consumer protection are thus intimately bound up with protection of certain businesses from competition.

During the latter part of the eighteenth and the beginning of the nineteenth century, some of the nation's most rapidly changing and expanding businesses—banks, insurance companies, and steamboat, turnpike, and bridge operations—received exclusive franchises from state governments, assuring them both stable custom and freedom from local competition. In return, these businesses were vested with public responsibilities. In 1809, the Virginia Supreme Court of Appeals, upholding legislation amending the charter of an insurance company, made this quid pro quo explicit: "[acts of incorporation] ought never to be passed, but in consideration of services to be rendered to the public." A few years later, New York's Chancellor Kent justified on a similar basis the finding of an implied monopoly in a corporate charter: "The consideration by which individuals are invited to expend money upon great, and expensive, and hazardous public works, as roads and bridges, and to become bound to keep them in constant and good repair, is the grant of a right to an exclusive toll." The government thus

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17 President of the Newburgh and Cochecton Turnpike Road v. Miller, 5 Johns. Ch. 100, 111 (N.Y. Ch. 1821), quoted in M. Hornitz, THE TRANSFORMATION OF AMERICAN LAW 1780-1860, at 126 (1977).
agreed to restrict competition in these financial and transportation markets, so vital to a developing economy, in exchange for capital investment and a guarantee to the consuming public of safety and reliability.\textsuperscript{17}

The period between 1870 and 1914 saw a great expansion of economic activity and the development of new markets in consumer goods and services; it also brought destabilization in the form of depressions and sharp upturns. A willingness to sacrifice competition in some industries in return for secure investment opportunities and consumer protection led to regulation. Principles of consumer and business protection, demanding government intervention and control over trade, coexisted peacefully with the principles of a free-market economy, which required unfettered contact among sellers and consumers. Tensions were avoided in large part because government intervention focused on particular markets where rapid growth, coupled with technological or social change, made participation risky for both business and consumers. Under those circumstances, unfettered competition rendered the outcomes of business-investment and consumer-purchasing decisions less predictable, and government regulation more palatable. Regulation thus served to fence in those providers who had been sufficiently bold or farsighted to make the initial investments, and to fence out the Johnny-come-latelies who otherwise would seek to exploit the new demand.

By the mid-1880s, for example, the established railroads faced new competition. They first reacted by attempting to create voluntary pools and agreements to prevent rate-cutting and raiding of established territories. These efforts failed, however, because of the legal unenforceability of such arrangements and the inability of the railroads to act in concert.\textsuperscript{18} Finally, the established railroads advocated and helped to create the Interstate Commerce Commission.\textsuperscript{19} In addition to promoting the railroads' private interests, federal regulation was intended also to end rate discrimination and to provide farmers, merchants, and consumers with consistent and

\textsuperscript{17}See M. Horwitz, The Transformation of American Law 1780-1860, at 109-39 (1977), for a discussion of the legislative and judicial roots of such agreements to restrict competition.


\textsuperscript{19}C. Kolko, supra note 18, at 28-44.
A NEW CONSUMER PROTECTION

high-quality rail service. Similarly, from its inception the Civil Aeronautics Board served to protect the fledgling aviation industry against new entrants; but it served also to protect passengers from the potentially unsafe consequences of untrammeled competition.

A parallel development marked the growth of state occupational licensing statutes. By 1900, Wisconsin had restricted entry into ninety trades, enacting occupational licensing requirements for attorneys, teachers, peddlers, public showmen, pharmacists, dentists, and doctors. By 1915, druggists, osteopaths, midwives, embalmers, barbers, plumbers, accountants, real estate brokers, employment agents, and stockbrokers were added to the list. By the 1950s, aircraft dealers, land surveyors, investment advisors, motor-vehicle salvagers and wreckers, cemetery salesmen, hunting and fishing guides, auto salesmen, auto auctioneers, and operators of commercial driving schools were among the occupations in Wisconsin governed by new or substantially revised legislation.

Typically, li-


Although the commission [ICC] proceeded cautiously and some railroad executives failed to live up to the spirit of the new regulations, the commission's rulings had an immediate stabilizing impact on the transportation industry. By conducting investigations, collecting statistical data, and disseminating its findings widely, it made large strides toward forcing sounder financial practices on the railroads and encouraging them to rationalize their rate structures. Rate differentials between competitive and non-competitive points were reduced sharply. In some circumstances, the roads used the act as an excuse for resisting the demands of shippers for special favors. In countless subtle ways, it compelled railroad men to recognize some of their public responsibilities.


22 See Council of State Governments, Occupational Licensing Legislation in the States 20-27 (1952), attributing the post-Civil War licensing legislation to the assumption by the states of "the responsibility of regulating the professions as a means toward greater protection of the public from incompetency, fraud, and quackery" and to the sponsorship of such legislation by occupational associations seeking to protect their levels of compensation and status. Id. 20-21. See also W. Horowitz, Occupational Licensing in Arizona (1968).

23 L. Friedman, Contract Law in America 162 (1965).

24 Id. 163-65. For surveys of similar movements in other geographic areas, see H. Alderfer, Professional Licensing in Pennsylvania (1962); M. Carrow, The Licensing Power in New York City (1968); W. Horowitz, Occupational Licensing in Arizona (1968).

25 L. Friedman, Contract Law in America 170-71 (1965).
Licensees were required to meet certain standards, of safety and reliability; in return they received protection from potential competitors who did not meet these standards. Such legislatively imposed occupational entry barriers usually were sustained by the courts as reasonable exercises of state police power.

Although intended to protect from competition certain industries and occupations—interests which were able to mobilize political support for entry restrictions far more easily than consumers could have mobilized against them—the advantages that accrued to consumers from these measures support a theory of mutual benefit. Consumers in effect accepted higher prices in exchange for security against marginal operators, who might otherwise have taken advantage of rapid changes to defraud or endanger them.

These moratoria on competition often tended to last far longer than necessary to cope with any temporary market instability. Licensees and franchisees found the fruits of monopoly to be enjoyable; they relinquished them, if at all, only after a political struggle. Most "professions" today remain sheltered from competition, long after the need to attract and reward high quality work or to protect consumers from poor quality has abated.

Deregulation of interstate trucking has proved difficult, although little justification can be found for maintaining entry barriers in that industry. Indeed, perhaps the realization of the political difficulty of removing an exemption from the competitive economy once granted, explains the shift in the focus of consumer protection in recent years from the performance of particular markets to the merits of particular products.

28 The relationship between consumer protection and restricted entry is well illustrated by the reaction of one Indiana barber to the licensing of his profession: "[I]t takes legislation to protect us from scab prices, pestilence and disease." Id. 163.

27 See, e.g., Baccus v. Louisiana, 232 U.S. 334 (1914) (ban on sale of drugs by itinerant vendors or peddlers); Crowley v. Christensen, 137 U.S. 86 (1890) (liquor licensing); Dent v. West Virginia, 129 U.S. 114 (1889) (physician licensing); Slaughter-House Cases, 83 U.S. (16 Wall.) 36 (1873) (exclusive slaughter-house license). Notions of substantive due process surfaced occasionally to void various licensing statutes. Yet, even in these instances, the courts restricted their holdings to professions bearing little relationship to public health. See, e.g., New State Ice Co. v. Liebmann, 285 U.S. 262, 277 (1932) (manufacture and sale of ice not sufficiently affected by public interest); State v. J. P. Harris, 216 N.C. 746, 6 S.E.2d 854 (1940) (licensing of dry-cleaning business unnecessary for public protection).


II. CONSUMER PROTECTION AND PRODUCT INADEQUACY: GOVERNMENT AS PURCHASING AGENT

In the early days of consumer protection, the unstated principle guiding government interventions to protect consumers was to control the market instability which caused businessmen, investors, and consumers to feel particularly insecure in their relationships. The principle which has emerged during the last decade, however, has little to do with such instability. Instead, the government has increasingly assumed the role of purchasing agent, assessing the merits and demerits of particular products on behalf of consumers. Meanwhile, competition policy, as shaped by the courts and antitrust enforcement agencies, has taken off on its own course, somewhat oblivious to consumer-protection interests.

Corresponding to these developments, an analytic dichotomy has grown up between consumer-protection and competition policies. Law schools, for example, typically treat the two in separate courses; even when they are conjoined within the broad subject area of "trade regulation," they are treated as presenting quite separate issues. More serious for public policy, decisions to intervene in the economy on behalf of consumers have failed to take proper account of the market's structure and its incentives. As a result, the scope of government interference has acquired a limitless potential, and the government has sometimes intervened even though consumers themselves believe they need no protection. The following sections will serve to expand and clarify these points.

A. Assessing the Costs and Benefits of Particular Products

Within the last fifteen years Congress has enacted a startling amount of legislation governing the quality of particular products. Foremost has been product-safety legislation, including: The Poison

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10. One commentator theorizes that modern consumer-protection regulation has created long-term, collective contracts between consumers and producers which are administered by regulatory agencies. These "administered contracts" entail rules which allow adjustments and compensation for unexpected costs. The rules also allocate anticipated risks and benefits and identify the circumstances in which the contract may be terminated. See Goldberg, Regulation and Administered Contracts, 7 J. ECON. 428 (1978).

11. For the view that competition policy in the Antitrust Division of the Department of Justice is indeed shaped by myriad factors unrelated to consumer-protection interests, see S. Weaver, Decision to Prosecute: Organization and Public Policy in the Antitrust Division (1977). On the basis of extensive interviews with Division personnel, Weaver concludes, for instance, that Division attorneys adhere to a procompetitive stance, refusing to recognize that the value of competition may have to be balanced against other social or economic interests. Id. 169.
Prevention Packaging Act; the Lead-Based Paint Poisoning Prevention Act; the Consumer Product Safety Act; the Highway Safety Acts; and the National Traffic and Motor Vehicle Safety Act. Other legislation has extended government involvement in product packaging, labeling, and disclosure, and product warranties. Entire agencies, such as the Consumer Product Safety Commission and the National Highway Traffic Safety Administration, have been established to assay products posing "unreasonable risk" of injury. Older agencies, such as the Federal Trade Commission, have grown increasingly bold in regulating particular products deemed inadequate or unsafe.

Mindful that consumers often bear the costs of consumer protection legislation, these agencies have applied increasingly elaborate risk- or cost-benefit analyses to products within their jurisdictions. In their role as "purchasing agents" they are assessing the health consequences of new drugs, foods, and cosmetics; the safety of toys, automobiles, and appliances; and the durability, efficiency, and reliability of a host of other consumer products. Regulatory tools are then fashioned for controlling the dissemination of products according to their relative risks and benefits. In its recently unveiled

91 See Regulating the Product (R. Caves & M. Roberts eds. 1975) for a collection of papers addressing the effect of various control mechanisms on product quality.
A NEW CONSUMER PROTECTION

In general, government intervention under this "purchasing agent" model is presumed to be desirable whenever product risks are reduced by the proposed regulation to a greater extent than costs are added.47 The greater the disparity between these two measures, the more extreme the regulatory response. Outright bans of products are thought to be necessary whenever the risk and mag-
nitude of physical or economic harm thereby avoided is deemed substantially greater than product benefits foregone. Regulators have placed within this category unvented gas space-heaters, lead-based paint, saccharin, and certain drugs. Design specifications or performance standards are thought to be appropriate when the disparity between product risks and benefits is less, but nevertheless significant, as with "childproof" aspirin bottles, flame-resistant sleepwear, nitrates in bacon, rotary lawnmowers, and auto seat belts and airbags. Bans on advertising may be justified in cases where the risk-benefit difference is still less determinative, but the risks remain of major concern, such as television advertising of cigarettes, children's cereals and candy, or alcohol. Mandatory disclosures in advertising or on labels are thought appropriate when risks and benefits, although substantial, are closely balanced, as, for example, with food ingredients, blood from paid or volunteer donors, and energy efficiency of home appliances.

This "purchasing agent" model of government intervention is, of course, open to the charge that it imposes additional costs upon members of the consuming public who, because they can use dangerous products more carefully or skillfully than others, or can make repairs more cheaply, or because they care less about physical and economic harms than other people do, would prefer not to pay more for the safer, healthier, more reliable, or more fully labeled product. Moreover, according to this argument, it is unnecessary to impose the costs of consumer protection on these voluntary risk-takers for the sake of protecting those risk-avoiders whose preferences more closely resemble the government's; presumably those risk-avoiding consumers would have opted for the safer, healthier, more reliable, or more fully labeled product on their own.

But this view ignores the fact that the market for consumer goods is less than perfect, and often cannot be relied upon to generate the degree or quality of information consumers need in order to make rational purchasing decisions. Product choice in some markets remains limited: risk-avoiding consumers seeking a safe automobile have no opportunity to choose a safer, more costly bumper from the restricted range of offerings produced by an

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48 Professor Richard Wilson has urged that, based upon linear extrapolation from animal testing, activities or products which create a 1-in-100 chance of death or serious injury with each discrete usage should be banned, while those which create a risk of less than 1 in 100,000 should be regarded as acceptable. For activities or products between those two levels, public education and warnings are appropriate. Testimony of Richard Wilson Before the Occupational Safety and Health Administration (Feb. 10, 1978) (OSHA Docket No. H-090) cited in Hutt, supra note 44, at 582-83.
A NEW CONSUMER PROTECTION

oligopolistic industry. Moreover, even under competitive conditions, sophisticated advertising and promotional techniques may well manipulate and ultimately distort consumer demand.

A more sophisticated analysis, however, reveals flaws in the "purchasing agent" model which stem from its antagonism to certain fundamental principles of American political economy. First, even if the government's calculations could exactly predict the quality of products and information that rational consumers would choose in a perfect market, the very insistence that government planners and policymakers intervene on behalf of consumers implies that consumers are unable to take care of themselves. Substitution of the choices of bureaucrats for those of consumers carries with it a not so subtle implication that consumers are relatively powerless, if not incompetent, when faced by the combined force of corporate greed and Madison Avenue hype. That message is apt, at the very least, to offend consumers' self-esteem. A saccharin ban implies that consumers cannot be trusted properly to weigh the risks of saccharin, just as a ban on television advertising to children implies that parents cannot be trusted to control their children's viewing. The charge of "big brotherism" in this context may come less as a total rejection of consumer protection than as an affirmation of a preferred self-image of competence. Consumers are not dumb; they recognize that bureaucrats, too, are fallible people, not necessarily more competent than the consumers they purport to protect.

Second, a consumer-protection policy based on a bureaucratic calculus of risks and benefits has no principled limits. Once it is accepted that the government can intercede between consumers and sellers whenever intervention can produce "better" purchasing decisions, no obvious stopping-place can be found. Such a rationale opens the entire economy to scrutiny. It suggests that products are "unsafe" or "defective" whenever the cost of making them safer or more durable is less than the value, as measured by regulators and policymakers, of the extra safety or durability thereby achieved. Similarly, it suggests that sellers should be required to provide more

46 Albert Hirschman's juxtaposition of two consumer complaints to Ford and General Motors, with each consumer threatening to purchase from the other manufacturer in the future, is a telling illustration of the consumer's bind. Without regulation, an oligopolistic market cannot be relied upon to satisfy both the risk-avoider and risk-taker. See A. HIRSCHMAN, EXIT, VOICE, AND LOYALITY 27 n.7 (1970).


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or higher quality product information whenever the cost of generating and communicating it is less than the value to the consumer, again as measured by regulators and policymakers, of acquiring it. At bottom, the risk-benefit rationale for intervention approximates the kind of calculation that consumers traditionally make when they choose a product, choose to do without it, or decide to consult first with friends or Consumer Reports before purchasing. But, because bureaucrats rather than consumers undertake the calculation, the risk-benefit rationale becomes a veritable slippery slope.

Instead of merely correcting those market imperfections which prevent consumers from making rational purchasing decisions, the "purchasing agent" approach to consumer protection goes much further; it replaces the decisions of consumers in the marketplace with government edicts, a method whose premise is fundamentally incompatible with the liberal assumption that each person is the best judge of his or her own needs.

If this underlying contradiction escaped attention fifteen years ago when consumer protection began focusing upon the merits of particular products rather than the stability of particular markets, perhaps it was because there were enough egregious abuses to justify ad hoc government interventions without appeal to any overreaching principle. The list of horribles included unsafe automobiles, teratogenic (fetus-deforming) drugs, deceptive advertisements, injurious rotary mowers, and schemes to sell worthless real estate. But the bureaucracy of consumer protection has grown in the past few years. The occasions for intervention have now extended beyond those most serious cases to instances which may be less compelling on their facts and more in need of a new and principled rationale. The current rationale is simply too grandiose and overreaching to coexist peacefully with principles of a free-market economy.

B. Accounting for the Consumer-Protection Potential of Various Market Restraints—An Unfulfilled Need

As the focus of consumer protection has shifted from markets to products, its rationale has lost any logical connection with the existence or nonexistence of competition. Accordingly, no coherent theory has emerged to explain how, and under what circumstances, various restrictions on competition might help ensure or inhibit the fulfillment of consumer expectations. Competition policy, aimed relentlessly at market power in any guise, has not had to compete with, or comprehend, a market-based rationale for consumer protection because none has been articulated. This has
A NEW CONSUMER PROTECTION

Unfortunately left courts and policymakers free to ignore situations in which certain restrictions on competition can work to the benefit of consumers. A brief survey of the current status of four potentially pro-consumer market restrictions—market division agreements, tying arrangements, occupational licensing, and trademark protection—shows that existing law and policy lack the basic analytical tools needed to understand the interplay between competition and consumer protection.

1. Market Division Agreements

Market-division agreements can make it profitable for an outlet within one vicinity to cooperate with outlets in others. Because such agreements ensure that each outlet's investment redounds to its own benefit rather than to the benefit of "free riders" selling the same product nearby, each has an incentive to promote the product and maintain uniform quality. Notwithstanding this potential consumer benefit, market-division agreements have been deemed illegal. In United States v. Sealy, Inc., for example, the Supreme Court determined that the territorial agreements by which Sealy limited its manufacturer-licensees to sales in designated territories "gave to each licensee an enclave in which it could and did zealously and effectively maintain resale prices, free from the danger of outside incursions." Finding this a sufficient connection with price fixing, the Court applied the rule of per se illegality to hold the agreements "unlawful under § 1 of the Sherman Act without the necessity for an inquiry in each particular case as to their business or economic justification, their impact in the marketplace or their reasonableness." Application of the per se illegality test thus

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33 Id. 356.
34 Id. 357-58. The Sealy majority found the challenged arrangement a thinly disguised horizontal agreement among Sealy's manufacturer-licensees. Sealy was owned and directed almost entirely by the owners and operators of its licensees. Consequently, according to the majority, the agreements were in substance, if not in form, agreements among the manufacturers operating as equals in a competitive market. As horizontal restraints, the licensing agreements were subject to a more stringent standard—traditionally, a per se standard—than applied to vertical restraints.

In a lone dissent, Mr. Justice Harlan argued that Sealy's territorial divisions were vertical restraints and not, therefore, illegal per se. He noted also that such agreements tended to increase general market competition by sharpening Sealy's competitive edge, especially since Sealy did not dominate the relevant market. Id. 361 n.2. See Pitofsky, The Sylvania Case: Antitrust Analysis of Non-price Vertical Restrictions, 78 Colum. L. Rev. 1 (1978), for a discussion of the distinction between vertical and horizontal restraints, as well as mention of the consumer benefits from certain types of market restraints.

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caused the Court to ignore the potential benefits from the market-
division agreements, including the possibility that they would help
to ensure the uniformity of products appearing under the licensed
name and trademark. This test ignored also the district court's
findings, never disputed by the government, that the agreements
permitted national distribution of the uniform product and made it
profitable for each licensee to contribute to national advertising,
research, and promotion.66

The Supreme Court recently determined, in Continental T.V.,
Inc. v. GTE Sylvania, Inc.,67 that some vertical market divisions are
legal, in part, because they serve to "promote interbrand competi-
tion by allowing the manufacturer to achieve certain efficiencies in
the distribution of his products." 68 Although it remains to be
seen what sorts of market-division agreements or other vertical re-
straints will pass muster, presumably those which create efficiencies
in maintaining product quality within the distribution process
should no longer be deemed illegal per se—particularly if the
manufacturer has no reasonable alternative means of ensuring
quality.69

2. Tying Arrangements

Tying arrangements, like agreements, to divide markets, also
may protect consumers from poor maintenance or servicing of
products. But the courts have tended to strike down these arrange-
ments without regard to potential consumer-protection benefit. In
United States v. Jerrold Electronics Corp.,69 for example, the court
found illegal a tying arrangement through which Jerrold sold whole
antenna systems only on condition that it install and service them
itself and replace any parts with Jerrold equipment. Although the
court did recognize that the arrangement guarded against unsatis-
factory performance resulting from system installation and servicing
by companies lacking the requisite knowledge and skill, the court
perfunctorily determined that this did not justify the tying arrange-
ment in the already mature community-antenna industry.69 In

66 Id. 358-62.
68 Id. 54.
69 Vertical restraints have been upheld where they are related to product
safety, have no anticompetitive effect, and are ancillary to the seller's main
purpose of protecting the public from harm or itself from product liability. Id. 55
n.23. See Tripoli Co. v. Wella Corp., 425 F.2d 932 (3rd Cir.) (en banc) cert.
denied, 400 U.S. 831 (1970). See also Pfitzsky, supra note 54.
69 Id. 557, 558.
drawing its conclusion, the Jerrold court assumed, but certainly did not prove, that consumer-protection interests would be served adequately by independent servicing. It ignored the considerable goodwill interest that any manufacturer, whether in a young or mature industry, has in maintaining its own product; the independent serviceman can always blame his failures on product quality, a luxury the manufacturer does not enjoy.

8. Occupational Restrictions

Occupational restrictions, in the form of state licensing laws and so-called “ethical” restraints imposed by professional associations, have traditionally been justified on the assumption that they protect consumers. But such restrictions have increasingly come under antitrust fire. The Federal Trade Commission has challenged certain state occupational licensing laws as unfair trade practices. Both the Commission and the Antitrust Division of the Department of Justice have challenged “ethical” restrictions on the delivery of professional services. Although these challenges have attempted to compare the benefits of competition with the costs to consumers of inadequate service, which might follow the lifting of restraints, there has been no method for deciding which licensing statutes should be challenged in the first place. Because consumer-protection policies have lacked any dynamic market theory, it remains unclear when natural market incentives alone can be relied on to protect consumers without licensing, or when licensing may be the most efficient means of doing so.

Indeed, the Supreme Court has rejected any balancing of the benefits to consumer protection when “ethical” restrictions are challenged under section 1 of the Sherman Act. In National Society of Professional Engineers v. United States, the government brought a civil antitrust action against the professional association; the association’s canon of ethics prohibited competitive bidding by its members, and the government alleged that this restriction violated the Sherman Act. As an affirmative defense, the association

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contended that the canon was a reasonable restraint of trade because it minimized the risk to public safety that competitive bidding would induce engineers to cut prices and provide dangerously low-quality services. The district court granted an injunction against enforcement of the canon, and the court of appeals affirmed.65 Acknowledging that there was a risk that competition would cause some suppliers to market a defective product and that the association had provided ample documentation to support its position,66 the Supreme Court nevertheless unanimously affirmed. The Court reasoned that restraints of trade under the Sherman Act may be deemed reasonable only insofar as they promote competition, not because they protect consumers from dangerous products. "The judiciary cannot indirectly protect the public against [potentially defective products] by conferring monopoly privileges on the manufacturers."67

4. Trademark Protection

Notwithstanding their potential importance to consumers in ensuring consistent quality and reliability,68 trademarks also have been the object of antitrust attacks. In one recent FTC order, an administrative law judge found that Borden, Inc. had unlawfully maintained a monopoly position in the processed lemon industry.69 In addition to a preponderant market share, the judge found to be "strongly demonstrative of monopoly power" the "overwhelming dominance of the ReaLemon brand, . . . its acceptance over the years by the trade and the public as the premium brand" and the premium price it commanded.70 Ignoring the fact that this premium price may well have represented what consumers were willing to pay for consistent quality, the judge's reasoning proceeded strictly according to competition theory: "the heart of the monopoly power preserved and maintained by respondent Borden lies in the ReaLemon trademark and its dominant market position. For competition to enter the processed lemon juice industry, the barrier to

65 The district court made no finding as to the risk that competitive pressures would result in the design of inefficient and unduly expensive structures, finding instead that the canon was illegal on its face. Id. 694-96.
66 Id. 694.
67 Id. 695-96.
70 Id.
entry which inheres in the ReaLemon trademark must be eliminated. Accordingly, the judge required Borden to license use of its ReaLemon trade name.

Although the remedy of compulsory licensing was rejected by the full Commission on appeal, that action merely reflected the Commission’s view that licensing was unnecessary to curb Borden’s monopoly. Like the administrative law judge, the Commission made no attempt to evaluate the possible value of trademark protection to consumers.

This, then, is a brief survey of the present state of consumer-protection/competition policy. Under a “purchasing agent” model, government has increasingly intervened to regulate distribution of particular products or services, restrained only by a balancing of the costs and benefits of intervention. Objections to the paternalism inherent in this approach are compounded by its illimitable sweep. Antitrust policy, on the other hand, has ignored the goal of protecting consumers against such “bad” purchases, possibly because no criteria have been proposed for deciding under what circumstances undercompetitive markets protect consumers more or less efficiently than fully competitive ones.

Having now considered the evolution of consumer protection, a rethinking of its fundamentals is in order. What criteria should guide government decisions to intervene on behalf of consumers? Once a decision to intervene is made, what form should the intervention take? Before these questions can be answered, however, it is necessary to arrive at an understanding of why consumers need protection, and what the goal of government intervention ought to be.

III. THE GOAL OF CONSUMER PROTECTION

Consumer-protection policy has suffered at bottom from a confusion about goals. An implicit assumption of the “purchasing agent” approach is that consumers cannot be trusted to make rational purchases. Therefore, to protect consumers, government...
must intervene to monitor the quality of products and services sold in the market. In essence, the "purchasing agent" rationale is an extension of paternalistic government efforts to protect consumers from the consequences of their own appetites—such as preventing consumers from buying sex, marijuana, pornography, or liquor.

An approach to consumer protection more sympathetic to liberal free-market principles that govern the American economy is possible. The problem lies not with "bad" products or irrational consumers, but in certain market conditions which do not provide sellers with sufficient incentive to prevent rational consumers from making costly mistakes. A consumer-protection rationale focusing on the likelihood that consumers within particular markets will misestimate physical or economic risks attendant upon their purchases can provide a strong basis for government intervention, untainted by paternalism.

A. Hidden Costs and the Costs of Information

Consumers bear several related costs when they purchase goods or services, only the most visible of which is the purchase price. Other costs are often hidden: the product may cause bodily injury, impair health, or damage property; it may require expensive or time-consuming maintenance or have to be totally replaced in a relatively short time; it may require enormous amounts of fuel; or it may be inadequate to perform the tasks that the consumer has in mind, requiring the consumer to forego those tasks or spend more to perform them.

The rational consumer would will wish to minimize the product’s total cost (its purchase price plus these hidden costs), while at the same time receiving a product that fulfills his needs. But to accomplish this goal, he must bear still other costs. First, he must define his needs. Diagnostic information, which identifies and measures such particular requirements, can be expensive. To avoid gastric upset, the consumer may, for example, have to undergo a battery of tests to determine what foods his stomach cannot abide; similarly, to avoid the possibility that a newly purchased waterbed will crash through the ceiling, the consumer may have to employ a structural engineer to measure the tolerance of his upstairs floor. Second, after discovering his particular needs, the consumer must learn the capabilities of different products to fulfill those needs.

The "rational consumer" is of course a fiction; no one contends that consumers are actually as rational as this hypothetical person. Nonetheless, the concept can be useful in predicting general patterns of behavior.
Product-testing information, revealing, for example, the contents of a particular can of food or the fully inflated weight of a particular waterbed, also can be costly. Third, for the diagnostic and product-testing information to be useful, the consumer must have meaningful access to it in a timely manner. Communication, in the form of product advertising and consumer searching, is then a third related cost.79

For some purchases, the combined costs of diagnosis, product testing, and communication may exceed any savings in the total cost of the product sought. But it would be nonsensical for a consumer to expend more resources trying to locate a product than the potential savings available from its use. If, for example, a consumer has discovered three adequate lawnmowers of equal price, the best of which would save him one dollar in convenience and quality, there is no reason to spend more than one dollar to discover which of the three is truly best. Accordingly, a rational consumer will purchase product information only to the point at which the marginal cost of obtaining that information is likely to exceed any marginal gain in the total value of the product.77 Thus, the "best" purchasing decision is not best in absolute terms, but only relative to the cost of the diagnosis, product testing, and communication necessary.

79 A slightly different typology has been used by Nelson, who distinguishes between "search qualities"—qualities of a product that the consumer can determine prior to purchase—and "experience qualities"—qualities that the consumer cannot determine prior to purchase. Nelson, Advertising as Information, 82 J. Pol. Econ. 729, 730 (1974); Nelson, Information and Consumer Behavior, 78 J. Pol. Econ. 311, 312 (1970). Darby and Karni use the term "credence qualities" to describe qualities that cannot be evaluated through normal use of a product, but can be assessed only by gaining additional costly information. Darby & Karni, Free Competition and the Optimal Amount of Fraud, 16 J.L. & Econ. 67, 68-69 (1973).

77 This model of course simplifies both the economics and the psychology of consumer search. The marginal-value/marginal-cost calculation is not strictly applicable to non-searchers. Given the presence of at least some consumer searchers, non-searchers can secure the benefits of product information without sustaining any costs, as producers are likely to compete for the searchers' business while offering the same terms to non-searchers. See Salop & Stiglitz, Bargains and Ripoffs: A Model of Monopolistically Competitive Price Dispersion, 44 Rev. Econ. Stud. 493, 493-95, 501 (1977); see also Rothschild, Models of Market Organization With Imperfect Information: A Survey, 81 J. Pol. Econ. 1283 (1973). But the notion that producers will compete for searchers' business may not extend fully to those markets in which hidden costs are excluded from the purchase decisions of all but the most scrupulous searchers. In these instances, producers may compete only as to price, with poor quality or substandard performance prevalent throughout the market. See text accompanying notes 81-86 infra.

to make it. That some consumers may accept high total costs, in
the form of dangerous, inadequate, or high energy-consuming prod-
ucts, does not necessarily indicate that the market is functioning
inefficiently, for such a choice may reflect a rational trade-off
against even higher information costs.

It follows that a range of less costly products, with “cost” again
including potential hidden costs, will require less costly attempts
to ensure that the purchasing decision is a proper one. If the price
of the product is low, and the possible adverse consequences of a
bad choice are minimal, the consumer’s own diagnosis may be com-
pletely adequate (“I know what kind of food agrees with me”); as
well as his own search (“Let’s see if there’s a restaurant in the neigh-
borhood”); and his own testing (“It looks like a dive, but I’ll
try it once”). Alternatively, consumers might rely on the judgment
of trusted friends, who are aware of their particular needs (“You’ll
love the ambiance, but don’t eat the goulash”). If the product
proves worthy, then the cost of diagnosing, testing, and locating it
in the future can be greatly reduced by merely repurchasing it. In-
deed, the business value of the “goodwill” derived from an estab-
lished trade name or marketing technique is that consumers are
willing to pay a premium for what they save by avoiding costly di-
agnosing, product testing, and searching.\footnote{To be sure, adver-
siting may be used to establish goodwill. Although the product
image created by advertising may substitute for product quality, “infor-
mative advertising” may serve a useful purpose when employed by new entrants
to identify an established producer who has chosen to “rest on his laurels” rather
than maintain consistent quality. Boyer, Informative and Goodwill Advertising, 56
Rev. Econ. Stat. 541 (1974).}

Occasionally, of course, it is more reasonable to look elsewhere
for reliable information. When an incorrect purchasing decision
could pose high risks to health or property, or could result in sub-
stantial economic loss, self-diagnosis or self-testing is unwise. Pru-
dence would dictate, for example, that one seek expert advice about
the need for maintenance or repair of complex machinery such as
an automobile, home plumbing, or one’s own body. Similarly, it
is advisable to refrain from ingesting unidentified pills or investing
a small fortune in an untested machine “just to see if it works,” and
to rely instead on tests performed by others. Indeed, it is often
necessary for sellers to offer new products at a discount or to guaran-
tee “complete satisfaction or your money back” in order to offset
consumers’ understandable reluctance to sail such uncharted seas.
By the same token, if the sources of diagnostic or product-testing
information are scattered, but the group of consumers who want the
information are identifiable and can be reached through some common medium, it may be more efficient for the sources to communicate their information than for the consumers to spend their own time and resources trying to locate the sources. For example, a shipper specializing in Caribbean cruises could locate prospective purchasers by advertising in the *New Yorker* far more efficiently than prospective purchasers could locate him by writing to shipping companies.

Some sources of diagnostic and testing information sell nothing but such information, with the consumer paying primarily for reliability and good judgment. Consumer guides, independent testing laboratories, newspaper reviewers, and various types of appraisers fit within this category, as do, on a slightly more general level, training manuals, adult-education courses, and how-to-do-it books. Because property rights in such information are limited, however, and difficult to enforce against a recipient who is apt to share the information freely with others, often only those sources who also have a pecuniary interest in the products under scrutiny can bear the direct cost of developing and communicating diagnostic and testing information. Some of these information sources function in effect as agents, and select products on behalf of consumers. In exchange, they charge consumers a premium for the quality of their selection. Travel agents, stock brokers, realtors, and department stores all bear most of the direct costs of developing product information and then pass these costs on to the consumers who find it more efficient to rely upon such intermediaries than to carry on their own diagnoses, tests, and searches. Alternatively, reliable information about product risks or inadequacies can sometimes be derived from competitors, for whom the cost of developing such information may be less than the expected revenues generated from sales of their own product.

Because they have direct access and control, sellers often can generate test information about their products more efficiently than any other source. They can run tests as a routine step in the production or marketing process, and they are aware of the particular product characteristics that require most careful attention. Similarly, sellers of maintenance or repair services often can generate diagnostic information more efficiently than other sources because they can both diagnose and respond to a particular need in a single transaction.

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B. Minimizing Consumer Misestimation of Hidden Costs

With this understanding of the role of product information in purchasing decisions, it becomes apparent that rational consumers will select the source of information that is both least expensive and most reliable, relative to the total product cost at stake. The sources of such information likewise can be expected to bear the direct cost of producing it only insofar as consumer demand yields adequate revenues. In this way, the information market should generate approximately the "right" amount of reliable information to enable consumers to make adequately informed purchasing decisions.

Under perfect marketing conditions, then, government intervention to protect consumers would be unnecessary. One could assume that consumers get just the amount of product information they need, and that they make rational trade-offs between product information, product quality, and purchase price. But consumers may, for a variety of reasons, underestimate the risk of economic loss or personal injury attendant upon their purchasing decisions. Sufficient product information may be unavailable or, if available, may be misconstrued. Or consumers may overestimate the reliability of the diagnosis or product-testing information received. Either way, they will miscalculate how much additional information they need—how much care they should exercise—before purchasing.

The problem then lies not in a particular product or service which appears to be inadequate, defective, unhealthy, inefficient, or unsafe. All these adjectives convey relative concepts which lack meaning outside the particular set of expectations which frames the transactions. Manufacturers and sellers make countless decisions to substitute lower cost for a higher-quality product or product information, and there is nothing inherently wrong about these decisions. Rather, problems arise when consumers, unaware of such substitutions, are unpleasantly surprised by poorer quality (higher hidden costs) than they bargained for. Skateboards, kitchen knives, waterbeds, "gas-guzzlers," and hang-gliders all can have disastrous consequences, but they present little justification for government intervention because consumers are apt to know of their risks and costs at the time of purchase.80 On the other hand, life-insurance policies,

80 With regard to some products, consumers know only of the existence of risks. They remain uncertain as to their distribution and unable to assess these risks accurately because all relevant information is possessed by the seller. The ways in which "imperfect information" may lead to market failures are discussed in Akerlof, The Market for "Lemons": Quality Uncertainty and the Market Mechanism, 84 Q.J. Econ. 488 (1970).
home insulation, drugs and food additives are more obvious targets for government intervention because consumers are likely to underestimate the riskiness and costliness of these products.

To be sure, the magnitude of the potential risk and the gravity of the harm are important considerations in deciding the appropriateness of intervention. A relatively small chance that consumers will underestimate these measures may nevertheless require intervention if risk and harm are substantial. The point is that it is the ignorance of consumers, rather than the product's intrinsic risk, which triggers the inquiry into the need for government action.

Misestimations of reliability of information or risk of loss could be reduced, if consumers or sellers, or both, were required to exercise more care in their transactions; but how much care, and who should exercise it, are complex issues. The ultimate question is not whether caveat emptor or caveat venditor is the correct principle, but under what circumstances and to what extent one principle is to be preferred to the other. If consumers and sellers could bargain with each other over the allocation of this responsibility, free from the costs of transacting those bargains, presumably they would allocate the responsibility to the party in the best position to minimize the likelihood of misestimations. In fact, buyers and sellers in large-scale commercial transactions do bargain over such responsibilities and risks. In the real world of unequal bargaining power and lack of coordination among consumers, however, liability rules may be necessary to allocate responsibility between the parties. Common law causes of action sounding in contract or tort in effect require the seller to bear the cost of fulfilling consumer expectations that his product is fit for ordinary use and not unreasonably dangerous, unless the seller gives warning that the product is being sold "as is" or presents unusual risks. But in other circumstances, the costs of private litigation are likely to be prohibitive, and more direct forms of government regulation may be desirable.

Viewed in this light, the purpose of government intervention should not be to protect consumers from purchasing "bad" products. Rather, the goal of consumer protection should be to minimize the likelihood that consumers will misestimate product risks and hidden costs, by placing the responsibility for avoiding such misestimations on sellers and manufacturers when they are better able to do so than consumers. This principle stands in sharp contrast to the "purchasing agent" model, which allows the government to intervene whenever it decides that the costs of a given product, including hidden costs, outweigh its benefits. Here, intervention is appro-
appropriate only when it cannot be presumed that sellers will voluntarily seek to prevent consumer misestimations.

IV. WHEN IS INTERVENTION APPROPRIATE?

A proper allocation of responsibility between sellers and consumers to prevent misestimations of product risk is likely to occur automatically in markets where sellers are concerned about developing and maintaining goodwill, and where consumers can easily discover hidden costs after they have purchased the product. Under those circumstances it is simply unnecessary for government to intervene to protect consumers. By contrast, intervention may be appropriate when sellers are unconcerned about goodwill or when hidden costs can be passed on to an unsuspecting public with no detrimental effect on goodwill.

Consumers are often willing to pay a premium for trustworthiness and the chance to avoid costly diagnosis, testing, and searching among unknown products. For the seller who capitalizes on it, this willingness to pay more for a trusted product can ensure a stable or growing market. To preserve his market, however, the seller will have to incur costs of maintaining product quality and consumer satisfaction. At the least, he must inform consumers of potential hidden costs, when it is more efficient for him than for the consumer to discover and draw attention to them, so that consumers can make informed trade-offs between quality and price.

Such a private ordering of responsibility cannot be presumed, however, when sellers have no particular stake in maintaining goodwill. Indeed, under these circumstances, it may be in their interests to mislead consumers, to fail to disclose hidden costs, or generally to sell products that fail to meet consumer expectations. And it is here that government intervention may be appropriate.

Sellers are apt to be unconcerned about goodwill when consumers' surprise and disappointment at the product's hidden costs have no bearing upon future sales. This is likely to occur if 1) consumers do not know of the existence of these costs; 2) consumers know of their existence, but are unable to attribute their cause to the particular product or seller; 3) the seller is not dependent on repeat purchases or "word of mouth" reputation; or 4) the seller, because of market power or collusion with other sellers, knows that the consumer has no real choice as to source of supply.

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81 See text following note 78 supra.
A NEW CONSUMER PROTECTION

A. Difficulty in Detecting Hidden Costs

There are some products whose hidden costs may easily go undiscovered. High energy costs due to faulty installation of home insulation, or poor-quality insulation, are difficult for the average consumer to detect, since the monthly utility bill provides no easy method of calculation. Manufacturers and sellers of insulation therefore have little incentive to test their product's energy-saving potential or to provide consumers with truthful information. Similarly, poor nursing-home services may be difficult for the purchaser to discern, because the purchaser is often not the elderly beneficiary. Moreover, the patient is often too enfeebled to judge or complain about the quality of care. Accordingly, nursing-home operators may have little incentive to maintain adequate quality control, or truthfully to inform prospective purchasers and patients of the level of service provided.

Ignorance of hidden costs also underlies consumer dissatisfaction with what is suspected to be unnecessary work performed by auto mechanics or doctors. If diagnostic or testing information is sold in conjunction with the service, the consumer may be unable to judge the accuracy of the diagnosis or the necessity of the operation or repair work. But, because it is normally more efficient to bundle diagnosis and treatment together rather than require that the mechanic or doctor put the subject back together between diagnosis and treatment, the consumer often is reluctant to undertake the extra expense of separating the two and getting a “second opinion.” The consumer can assess whether such unbundling is worthwhile only if he is aware of the risk and cost of the bundled as against the ‘unbundled diagnosis and treatment—risks and costs which the seller often has no interest in disclosing.’

B. Difficulty in Attributing the Cause of Hidden Costs

Many products have hidden costs which are not readily traceable because the costs appear at such time or in such form that their magnitude or cause cannot be discerned. For example, carcinogenic

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82 One particularly tragic example of risky and costly bundling recently came to light in Japan, where physicians are permitted to sell drugs directly to patients on their own prescriptions. The drug Clioquinol, used throughout the world since 1899 in antidiarrheal medicines, has been found to cause a severe and crippling nervous disorder when ingested in large quantities. Only in Japan has the drug had these widespread harmful effects, because Japanese doctors have prescribed larger daily doses for longer periods than physicians in any other country. This might be explained by the bundling of diagnosis, prescription, and retail sales, which gives Japanese physicians a strong financial incentive to over-prescribe. See Wash. Post, Mar. 18, 1979, § A, at 1, col. 5.
properties of certain food additives, drugs, or cosmetics may not become apparent for years after use, and even then it may be difficult to attribute the problem to particular products. Hence, manufacturers and retailers will have little incentive, notwithstanding their interest in maintaining goodwill, to test for carcinogeneity. Indeed, if consumers cannot know of a product's carcinogeneity, manufacturers and sellers may have little incentive to develop safer products. The cost of research and development is not likely to be offset by increased sales, since skeptical consumers will probably discount advertisements of non-carcinogeneity, knowing they will never be able to verify them.

Sometimes hidden costs can be traced to particular products, but the products themselves cannot be attributed to particular manufacturers or sellers. The identification of a defective product with its manufacturer becomes difficult if the manufacturer frequently changes models or promotes a new image, as is often the case with automobiles and household products, respectively. And, even if identification is possible, the past disappointment of consumers may be overborne by promises of new and improved products. Alternatively, if the manufacturer fears that consumer dissatisfaction with one of its brands will jeopardize others, the manufacturer may attempt to conceal its corporate identity and induce the consumer to believe that there is no connection between brands. For example, corporate sellers frequently hide their identity when they sell "seconds" at lower quality and lower price than their name-brand goods.

When consumers are unaware of hidden costs or cannot attribute their cause to a particular product or seller, they are unable to act on their dissatisfactions. They cannot alter their own buying behavior or that of their friends and neighbors, because they do not know what needs to be altered. As a result, seller goodwill is not in jeopardy and sellers have no incentive to remedy the problems. This suggests that government intervention may be appropriate. It also suggests that consumer complaints are poor indicia of which markets are most in need of government intervention; the complaints themselves are evidence that consumers are able to discover the causes of their dissatisfaction, an important first step in eliciting a market response.

C. Non-repeat Sales

If the seller is not particularly concerned about repeat purchases by the same consumer or other consumers within the same
geographic area, then he has no goodwill incentive to discover and communicate hidden costs. So-called "fly-by-night" sellers, moving rapidly from city to city; mail-order houses, telephone solicitors, and door-to-door sales networks that rely upon ever-new geographic markets; and sellers of "once in a lifetime" products, such as exotic vacations or tracts of land, often do not depend on repeat purchases. Because consumers and their neighbors rarely have prior experience with these sellers, the latter reap no particular benefit from a reputation for trustworthiness. Rather than invest in building such a reputation by ensuring that consumers get the value of their bargain, it is often more profitable for such sellers to invest in ways of overcoming the reluctance of consumers to contract with the unknown. For example, the seller may offer a discount. Or, frequently, the seller will provide large commissions to its sales force, a guarantee of aggressive, if not ruthless sales practices.

D. Low Level of Competition

The value to the seller of goodwill is intimately related to the competitive structure of the market. Sellers may have an incentive to warn consumers of hidden costs in their competitors' products if their own hidden costs are lower, and thereby to build up their own goodwill. But the cost of developing and communicating such information may be greater than revenues expected from increased sales. This may be particularly true if the seller's product has similar defects and the warning merely induces consumers to shift to other product lines, or if the product is so similar to others that any newly won sales will be widely shared. But, even if it were profitable in the short run to communicate such information, competitors might be unwilling to do so for fear of triggering competition in an oligopolistic market, or of creating opportunities for entry or expansion of sales by new entrants. More fundamentally, if there is tacit or explicit collusion among sellers, or excessive concentration, goodwill may cease to be an important factor, since patronage can often be guaranteed without it. Under these circumstances, the seller has no particular reason to worry when consumers underestimate the hidden costs of his products. Nor will he have any particular incentive to reduce

83 Mail order companies continue to generate a high number of consumer complaints. Over 15% of the complaints received by offices of the Better Business Bureau in 1978 involved mail-order purchases; door-to-door sales followed closely behind. See Statistical Summary of Better Business Bureau Activity (1978).

these costs. He can reap the fruits of his monopoly either by raising prices or reducing quality control, and is free to choose the latter out of sheer laziness. The owner of a so-called "company store" or ghetto supermarket, often a local monopoly, is apt to be less concerned about fulfilling his customers' expectations than he would be in a more competitive situation. Lack of competition may also explain the frustration consumers experience at the hands of indifferent government bureaucrats and unhelpful employees of public utilities. To be sure, in some cartels, non-price competition may substitute for more readily policed price competition, and sellers may invest in means of enhancing their goodwill at the expense of their cartel compatriots. But, the mutual interests of cartel members will not be served if these campaigns degenerate into "octane wars" or "tar and nicotine derbies." There are therefore strong disincentives for investment in goodwill in markets with low levels of competition.

These four factors—detectability, traceability, reliance on repetitive sales, and level of market competition—often interact. Thus, the likelihood that purchasers of new automobiles will underestimate the frequency and cost of repairs resulting from "piston scuffing" and will not be warned by sellers of this potential "defect" is high because 1) it may be difficult for consumers to detect this problem; 2) it is often difficult to attribute subsequent breakdowns to this factor rather than poor servicing; 3) most consumers are relatively inexperienced in purchasing automobiles, and dealers and manufacturers, although eager for repeat purchases, nevertheless have steady streams of first-time customers and of new lines and models for which they can claim superiority over all former ones; and 4) the industry is highly concentrated, offering consumers a relatively narrow range of real options, all of which attempt to have repair problems of one sort or another.

This is not to say that government intervention is necessarily appropriate whenever one or more factors are present. It may be less costly for consumers to discover and repair a "defect" when it occurs than it is for manufacturers or dealers to warn all purchasers of its likelihood, to repair it free of charge, or to improve the manufacturing process so that such "defects" do not occur. The point is that the proper allocation of responsibility for consumer misestimations is less likely to occur automatically through market forces.

55 Id. 665.
56 See note 49 supra.
when there are greater difficulties in cost detection and attribution, less dependence on repeat purchases, or higher levels of monopoly power and collusion. Where such impediments exist, one cannot presume a proper allocation of responsibility to avoid misestimations of risk. Government policymakers may therefore justifiably attempt to balance the costs of intervention against the benefits to consumers of more fully informed purchasing decisions.

The lesson for consumer-protection policy is clear. Whether one is considering a legislative or regulatory solution to a perceived consumer problem, the first step is to ascertain whether and to what extent any one of the four impediments outlined above is present in the product or service market under scrutiny. If the impediments are nominal or non-existent, it can be presumed (absent special instances of consumer incompetence or vulnerability, for which government paternalism may be widely accepted, such as addicts, young children, or cancer victims) that the market is efficiently allocating between consumers and sellers the responsibility for avoiding misestimations. If, however, a substantial impediment blocks the market's natural allocation, it may be appropriate for the government to intervene. Whether intervention is, in fact, appropriate, and if so, what form it should take, are questions which can then be answered only by weighing the costs and benefits of government action.

V. How Should Government Intervene?

Consumers need protection not because unsafe or defective products are being sold, but because the market may sometimes shield the seller from responsibility for the consumer's misestimation of product risks. This suggests a general approach to intervention that avoids taking direct control over product quality or seller conduct. Since the problem lies in the ability of sellers in certain markets to dispense with goodwill, the solution will usually be to increase the importance of goodwill to those sellers. Such a strategy would begin by overcoming whichever, market factors have made goodwill irrelevant.

This general approach to the method of government intervention is borne out by a cost-benefit analysis that aims for the least costly remedy. The cost of a particular intervention has two components: the cost to the government of enforcement, and the cost to the seller of compliance, some or all of which may be passed on to the consumer in the form of higher prices. Exerting direct control over the quality of products or seller conduct typically entails high enforcement costs. New products and models, new advertising
campaigns, and new ingredients, are all introduced into the economy at an overwhelming pace. It is simply not feasible for the government to police any but a small fraction of these initiatives. By contrast, a consumer-protection strategy aimed at creating goodwill incentives would involve smaller enforcement costs because it focuses directly on the market and only indirectly on the product.

Similarly, compliance costs are higher for regulatory measures that directly control product quality and seller conduct than they would be for a strategy of enhancing market incentives. In addition to the cost of filing compliance reports with the government, a program of direct controls inevitably raises the quality, and the price, of some products higher than consumers are willing to pay. The alternative approach outlined here, by contrast, would preserve the efficiency of the market: sellers would invest in goodwill only to the extent that consumers were willing to pay a premium for trustworthiness.

To be sure, there may be some products with substantial hidden costs which society simply does not wish to entrust to the market, regardless of the sellers' concern to maintain goodwill. The likelihood of consumer harm from the sale of certain dangerous drugs, unsafe toys, or virtually worthless real estate may be so great relative to benefits that, notwithstanding proper motives on the part of sellers, a total ban is justified. Such instances will be rare. By and large, government strategy designed to protect consumers should aim first to foster sellers' stake in goodwill.

How can this stake be enhanced? Possible strategies follow directly from the four impediments to goodwill described in part IV. Consumers' difficulties in discerning the hidden costs of the product, attributing their cause to the product or seller, or discovering the nature of such hidden costs on the basis of previous purchases or local gossip, all correspond to a set of strategies designed to overcome such information impediments. The impediment resulting from low competition levels requires a different set of strategies which bear a curious relationship to the first.

A. Overcoming Information Impediments

When manufacturers and dealers are shielded from responsibility because of the difficulty of discerning or attributing to them subsequent hidden costs, consumer-protection strategy should aim to establish causal connections between the product and the subsequent cost. If, for example, the efficacy of a particular home insulation is hard to discern, mandatory disclosures, such as average
yearly energy savings, might be appropriate. By the same token, if it is difficult for consumers to attribute unsatisfactory purchases to a large manufacturer or conglomerate whose identity is obscured by a multiplicity of products and subsidiaries, then perhaps the conglomerate should be required to disclose its identity on all its products. And if subsequent health problems cannot readily be traced back to certain drugs, mandatory disclosure of the risks of ingesting the drugs might provide a solution.87

Because such cause-and-effect information is apt to be complex, however, consumers often will have difficulty using it effectively. Thus, an appropriate strategy might aim to facilitate independent "information brokers," who can process and simplify the information according to the needs of consumers. For example, manufacturers or sellers of home insulation might be required to offer the services of, or warn consumers of the need for, an energy "auditor" who could independently appraise the home's insulation needs and calculate potential energy savings from various kinds of insulation. Similarly, when diagnosis and treatment are bundled, as with auto mechanics and doctors, an appropriate strategy would be to develop a market of independent diagnosicians who would offer only diagnoses. These individuals would have an incentive to warn consumers of the risk and cost of unnecessary treatment. They might also refer consumers to specialists they knew to be reliable, a role perhaps played in simpler times by family doctors and local garage mechanics. The government may need to subsidize such diagnosicians, however; property rights in the information disbursed by these individuals would be quite limited, rendering their services susceptible to use by "free riders." 88

When sellers are shielded from responsibility because they are not dependent on repeat purchases by the same consumer or by others within the same locale, methods should be devised to make them accountable for their improprieties. For example, companies that sell by mail-order or from door to door might be required to maintain up-to-date files of consumer complaints and to inform prospective purchasers about the incidence and subjects of consumer dissatisfaction.89 Alternatively, these companies might be required to maintain broad warranty and insurance coverage. Finally, responsibility might be placed upon a third party who, because it deals repeatedly with the seller, is better able than individual con-

87 See Pinto, Beyond Nader, supra note 84, at 673-75.
88 See text accompanying note 79 supra.
89 For an alternative remedy, see FTC Mail Order Rule, 16 C.F.R. § 435 (1979).
consumers to hold the seller accountable for defective products or poor service. If, for example, consumers were legally entitled to invoke against a creditor who financed their purchase of shoddy merchandise the same claims and defenses they have against the seller, the creditor surely would have a strong incentive to monitor the performance of the sellers with whom it deals. So long as this rule is limited to creditors who have regular business dealings with the seller, it may be a way of maintaining seller accountability far more efficient than setting minimum standards for the purchased goods. A similar remedy would require sellers of products with particularly high hidden costs to sell only through fixed location dealerships or department stores, where reputational stake is likely to be higher than in mail-order or door-to-door sales operations.

These strategies for overcoming impediments to goodwill may be inadequate or overly cumbersome. Ensuring that particular disclosures are provided, that offers are made of auditors and warranties, or that third parties are adequately policing the transaction can pose a substantial enforcement burden. In seeking to make sellers accountable for the consequences of their sales, it may therefore be more efficient for the government to create and enforce what might be termed "property rights in trustworthiness." Such property rights, which could take the form of licenses or certification, trademarks, or exclusive-sales agreements, would allow higher-quality sellers to differentiate themselves from poorer ones more efficiently than the market would otherwise permit.

Government licensing or certifying can function as an efficient method of quality control when mere reputation cannot. Certain products that have risks difficult for consumers to assess, such as prescription drugs or firearms, are sold only through licensed screeners who can help the consumer to understand the delicate trade-offs involved. Such licensed screeners are well-situated to test products for risks that would elude individual consumers, and can put their knowledge of past consumer product complaints to good advantage in advising on subsequent purchases. Moreover, the licensing or certifying authority can establish minimum professional standards, and can review consumer complaints against licensees in a single revocation hearing. A preferred means of ensuring con-

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90 This theory has been embodied recently on a more general level in the FTC's Rule 433. See FTC Preservation of Consumers' Claims and Defenses Rule, 16 C.F.R. § 433 (1979).

91 It is interesting to note in this connection that Montgomery Ward complained to Firestone about the poor quality of its radial tires as early as 1976, two years before the National Highway Transportation Safety Administration ordered a recall. Product Safety: Tired Out, NEWSWEEK, Aug. 21, 1978, at 61.
A NEW CONSUMER PROTECTION

Consumer protection and business investment in the past, licensing today is being considered by several state legislatures for nursing-home operators and other occupations.\footnote{92 See, e.g., S. 680, Pa. Gen. Assemb., 163d Sess. (1979), an act providing for licensing of nursing homes.}

Certification also may foster competition in product quality. If the high cost of credibly communicating distinctions of product quality makes sellers reluctant to inform consumers that the hidden costs of their own are lower than those of their competitors' products, the government can encourage comparisons by developing standar-dized comparative measures. For example, once the Federal Trade Commission developed a uniform standard for measuring the tar and nicotine content of cigarettes, manufacturers of cigarettes with lower tar and nicotine had an efficient means of communicating their comparative advantage. As a result, manufacturers began to compete vigorously to produce and advertise cigarettes of even lower tar and nicotine content.\footnote{93 In 1967, when FTC testing of tar and nicotine content was begun, only 5.5% of the advertising and promotional expenditures of cigarette companies were devoted to cigarettes yielding 15 milligrams or less of tar. 32 Fed. Reg. 11,178 (1967). Ten years later that percentage had jumped to 49.4%. FEDERAL TRADE COMMISSION, ANNUAL REPORT TO CONGRESS ON CIGARETTE ADVERTISING, Table 11 (1978). The extent to which public demand for low-tar cigarettes over this period was influenced by the ready availability of an easy comparative measure, and how that demand affected advertising and promotion decisions remains undetermined. The potential to foster competition in product quality may similarly exist for other markets affected by Commission certification efforts. E.g., 16 C.F.R. §§ 259.1-259.2 (1979) (automobile mileage-per-gallon ratings); 10 C.F.R. § 409.1 (1970) (durability and power-consumption ratings for lightbulbs).}

Trademarks and brand names can provide sellers an important incentive to establish goodwill and provide an easy means of identifying trustworthiness. Sellers obviously would have little incentive to invest in quality control and promotion if any other seller could capitalize on the investment, and consumers would be unwilling to pay a premium for the quality control and promotional information if they had no way of knowing which product embodied it. Trademark protection makes it profitable for sellers to invest in quality control and promotion to the extent that consumers are willing to pay a premium for them. Consumers profit too, provided that the premium they pay still allows them to save on the total cost of the product, including hidden costs, as well as the costs of diagnosing, searching, and testing it.\footnote{94 See text accompanying notes 75-78 supra.}

Occasionally sellers will contract to transfer their property rights in goodwill to other sellers or several sellers will pool their collective goodwill. These sales agreements can be profitable if the
cost to the sellers of maintaining overall quality control, which presumably rises with the number of outlets, is less than the premium that consumers are willing to pay. The Quality Inn trademark, for example, has become for consumers a valuable assurance of quality for which they are willing to pay a premium. So long as that premium exceeds the cost to each independent proprietor of his share of system-wide promotion and inspection responsibilities, the pooling arrangement will be profitable.

Other forms of exclusive dealing arrangements may also serve to ensure manufacturers or sellers that their goodwill remains unimpaired and quality consistently high. Agreements by which dealers provide certain customer services in return for a manufacturer's grant of an exclusive-sales territory can serve as a device for efficient quality control. By this means, manufacturers can prevent injury to their goodwill from careless or shoddy retail servicing, and dealers can capture the benefits flowing from their investment in promoting and servicing a manufacturer's product. Similarly, manufacturers or sellers may limit those permitted either to service their products, or to provide spare or component parts. Such a restriction may ensure that the product will be maintained in good working order and that faulty components will not jeopardize it. Inadequate servicing or faulty components might otherwise undermine a seller's goodwill, particularly if difficulties in attributing the cause of subsequent problems were to lead consumers to lay the blame at the seller's door.

B. Overcoming Market Concentration and Collusion

If sellers have little stake in maintaining goodwill because of market concentration or collusion, the obvious consumer-protection strategy would be to foster competition. Such a plan may necessitate a reversal of the strategy of increasing sellers' stake in goodwill by promoting property rights in trustworthiness. Government licensing, trademark and brand-name protection, exclusive-sales agreements, and product tie-ins of servicing or component parts

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95 The premium may rise with the number of outlets since opportunities for consumers to save on the costs of diagnosis, search, and test are increased.
96 As more hotels qualify for membership, the consumer's premium is likely to grow since the trademark becomes more widely recognized and opportunities for consumers to take advantage of it increase, but the total costs of inspection and promotion also are likely to rise. Theoretically, system-wide expansion should cease, when the costs of inspection and promotion reach the highest premium that consumers are willing to spend in return for potential savings.
97 See text accompanying notes 51-58 supra.
98 See text accompanying notes 59-60 supra.
restrain competition by erecting barriers to market entry. All have been the focus of antitrust enforcement. In a market characterized by low levels of competition, therefore, enforcing property rights in trustworthiness may backfire, and reduce sellers' stake in goodwill rather than increase it. On the other hand, if in more competitive markets promotion of property rights in trustworthiness enhances the importance of goodwill, then singleminded pursuit of an antitrust strategy, without regard to its effects on information impediments, will likewise exert a negative effect on consumer interests.

How then is the choice to be made between those strategies designed to overcome information impediments and those designed to correct competitive impediments? The preceding analysis suggests several rules of thumb.

1. If products entail substantial hidden costs, attribution and reputation problems make it unlikely that consumers can rely upon seller goodwill, and the market is not particularly concentrated, the balance may tip toward the creation and enforcement of property rights in trustworthiness. Under these circumstances, trade-name promotion, government licensing, exclusive-sales agreements and tying arrangements may be motivated primarily by the desire of sellers and consumers to trade in trustworthiness rather than by sellers' desire to collude. Accordingly, a sensible consumer-protection and competition strategy would foster these property rights. For example, territorial restrictions which encourage dealers to hire well-trained salespersons would be permissible for distribution of complex audio or camera equipment; prospective consumers of these products are likely to want to purchase this extra help in assessing potential hidden costs, and competition in these markets appears to be quite vigorous. By the same token, government licensing of insurance agents, doctors, or auto mechanics is apt to facilitate these sellers' stake in goodwill by overcoming information impediments to a greater extent than it creates competitive impediments. And vigorous promotion of trademarks by hoteliers will probably encourage responsible service in a relatively competitive industry, thereby providing consumers with protection from flea-ridden, sleepless nights.

2. On the other hand, when a product has substantial hidden costs, but discovery and attribution of these costs after purchase are relatively easy for consumers, and sellers are dependent on repeat

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99 See text accompanying notes 51-73 supra.
100 See Pitofsky, The Sylvania Case, supra note 54.
sales, there is less justification for territorial restrictions, licensing, trademarks, and tying arrangements. Sellers of home appliances, osteopathy, or haircuts, will in all likelihood disappear from the market with relative dispatch if they fail to satisfy their customers. And this self-corrective feature of the marketplace will be particularly efficient if there are no barriers to entry by potential competitors.

3. When it is less clear which impediments—information or competition—are paramount, an intermediate strategy of required disclosures would alert consumers to the quality-control issue, but leave to them the decision whether to invest in trustworthiness. To avoid the anticompetitive effect of a servicing or component tie-in, under these circumstances, the seller could be required to disclose to prospective purchasers the existence of the tie-in and the likely future cost, discounted to present value, of the servicing or components. Consumers could then decide if they wished to pay a premium for this guarantee of continued product quality. Similarly, to avoid the anticompetitive effects of government licensing, unlicensed sellers nevertheless might be permitted to sell their products on condition that they disclose the lack of government approval and any pertinent risks that the licensing was designed to address. Consumers could then choose the unapproved, and presumably less expensive product if they wished. Rather than undertake exclusive-sales agreements, manufacturers could allow certain sellers to indicate that they had been inspected and approved by the manufacturer; other sellers would have to disclose that they had not been so approved. Once again, consumers could decide which they preferred.

4. Finally, when there are little or no hidden costs and products are relatively simple and fungible, as with laundry detergents, paper napkins, aspirin, liquid bleach, and long grain rice, goodwill is unnecessary to ensure that consumers get what they expect. Under these circumstances the cost of adequate diagnosis, testing, and search is so low that consumers have no need to invest in trustworthiness. Here, vigorous promotion of a trade name may actually cause consumers to overestimate the consequences of their purchasing decision, and to pay a premium for the promoted product upon

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105 Porter refers to "goods with relatively low unit price, purchased repeatedly, for which the consumer desires an easily accessible outlet"—and for which research costs outweigh the probable gains from asking price and quality comparisons—as "convenience goods." M. Porter, INTERBRAND CHOICE STRATEGY AND BILATERAL MARKET POWER 24 (1975).
the mistaken assumption that real differences exist among brands. Because trademark or brand-name promotion that artificially differentiates such a product is likely to serve little purpose but to create barriers to competition, an appropriate consumer-protection strategy would be to require the trademark owner to license the trade name to competitors, or to disclose the product's standard "generic" ingredients. Similarly, under these circumstances, government licensing, exclusive-sales agreements, and tying arrangements are unnecessary to present consumer misestimation of hidden costs; they are more apt to protect sellers from potential entrants whose competition might well reduce prices. The best consumer protection strategy would therefore aim at rescinding these property rights. Viewed in this light, the administrative law judge's decision to order trademark licensing in the FTC's ReaLemon case seems entirely defensible.

Conclusion

This Article proposes a nonpaternalistic rationale for consumer-protection regulation, a rationale superior to that which allows government to intervene whenever it appears to regulators that the benefits of intervention exceed the costs. The critical issue for policymaking turns not on the merits of particular products, but on the characteristics of particular markets. Do sellers have sufficient stake in goodwill to ensure that they will bear the cost of avoiding consumer mistakes, when it is more efficient for sellers than for consumers to do so? When market conditions do not facilitate sellers' stake in goodwill and a substantial likelihood of consumer misestimation exists, government intervention may be appropriate.

This analysis of when government should intervene also suggests how intervention should proceed. Consumer-protection regulation should aim at improving market performance by enhancing sellers' stake in goodwill, rather than improving the quality of particular products or product information. This calls for a strategy combining, in differing proportions according to market characteristics, elements of disclosure, property rights in trustworthiness, and competition. Such a market-centered approach to consumer protec-

Studies have shown a strong positive relationship between consumers' perception that unfamiliar brands are risky and the strength of consumers' expressed brand preferences. Other experimental studies have shown that subjects are willing to pay a price premium for brands of bread and beer with which they have experience, even though other brands they could have chosen at less cost were identical in all respects but the labels. For a summary of these and related studies, see Schmalensee, supra note 68, at 1036-39.
tion would require careful analyses of particular industries and sectors, not unlike those that should underlie policy planning for antitrust enforcement. Indeed, data on industry concentration, consumer purchasing patterns, and advertising and marketing should inform decisions to intervene both to protect consumers and to maintain competition. When the two goals conflict, several rules of thumb may help government regulators choose an appropriate strategy to maximize both.

In sum, regulators engaged in protecting consumers should not act as purchasing agents, substituting their judgments for those of informed consumers. They should instead design ways to encourage the market to provide the quantity and quality of product and information that consumers want. A policy which thus seeks to make the market more responsive to consumer desires need not run afoul of the basic principles of competition policy. Both have at their core the same fundamental purpose: the enhancement of consumer welfare.
THE CONSUMER ADVOCATE
VERSUS
THE CONSUMER

During the last century, recurrent waves of anti-corporate fervor have swept the
United States. Although the particular issues debated vary with each era, much of
the agitation has focused on allegations of corporate abuse of consumers. Once
again, we are riding such a wave, and once again the problem of protecting con-
sumers intrigues us, this time in the movement known as "consumerism."

There can be little doubt that consumerism is an idea of considerable force.
For the media, it attracts audiences; for publishers, it is the source of sales; for
some manufacturers, it provides a profitable blessing for their wares; and for
politicians, it wins votes. That legislators who cast their vote against bills carrying
the stamp of consumerism do so at their peril is reflected in the fact that such legis-
lation generally clears Congress by a wide margin. Thus, a bill establishing a Con-
sumer Protection Agency (CPA) passed the Senate in 1970 by a vote of 74 to 4,
and a similar bill gained House approval in the current Congress by 300 votes.

One of the distinctive developments during this era's agitation over the con-
sumer has been the birth of the consumer advocate, the self-appointed vigilante
of the economic system. Although he is to a large degree indistinguishable from
the muckraker of the past, his concept of his role encompasses more than the
exposure of corporate malfeasance and extends to active representation—in courts,
agencies and legislatures—of his view of the consumer interest.

The central role the consumer advocate plays in consumerism is demon-
strated by the proposals for governmental action which have emanated from the
movements, in particular the call for the creation of a consumer protection agency
empowered to intervene in the proceedings—formal and informal—of virtually
all other federal agencies in order to "represent the interests of consumers." This
proposal seeks, in short, to institutionalize the consumer advocate as a federal
agency and to put the force of government behind the ideology of the movement
known as consumerism. As a result, a judgment as to the merits of the proposal

1 See generally, U.S. Congress, Senate, To Establish a Consumer Protection Agency,
Hearings on S. 1177 and H.R. 10835 before the Subcommittee on Executive Reorganization
and Government Research of the Committee on Government Operations, 92d Cong., 1st
2 S. 1177, Sec. 202 (1), H.R. 10835, Sec. 203(b)(1).

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Consumer Advocate Versus the Consumer, Washington, American Enterprise Institute for
Public Policy Research (1972), 16 p. American Enterprise Institute for Public Policy
Research Special Analysis no. 26.
must turn on the validity of the concept of consumer advocacy and of the ideology
that spawned it.

I. The Ideology of Consumerism

Defense of the consumer interest is an attractive cause, for all of us are consumers.
Indeed, it has long been the creed of those who believe generally in laissez-faire
that consumer interests should not be subordinated to producer interests, which,
when recognized and protected by government, generally lead to monopoly and
restriction of output. It is also the case that in an economy heavily dependent on
technology and media advertising, problems of the accuracy and availability of
information and the safety of products are inevitable. What distinguishes the con-
sumer advocate is his bleak view of the dimensions of those problems and the
reasons we face them.

Expositions of consumerism generally begin with a description of the plight
of the consumer in the United States today. According to the consumer advocate,
the American consumer is in the grip of corporations “able to divert scarce re-
sources to uses that have little human benefit or are positively harmful.” Beset on
the one hand by products of apparent and advertised safety which in fact endanger
his life and limb, the consumer finds on the other that many products are also of
considerably less utility than advertising had led him to anticipate. That very same
advertising induces him, moreover, through the sophisticated use of applied psy-
chology, to waste his limited funds on items he really does not need.

The consumer’s plight is of comparatively recent origin, and stems largely from
the complicated technology of today’s products. Senator Gaylord Nelson tells us:
“Once, the consumer was the final arbitrator in marketplace decisions, but with
our society becoming more and more complex, due to increased industrialization
and specialization, economic power has shifted gradually away from the American
consumer.” In other words, the consumer can no longer rely on his sense for
adequate information about the safety and usefulness of his purchases, and is at
the mercy of Madison Avenue. Manufacturers, moreover, are not generally likely
to make the information he desires available lest it hurt their sales.

The list of unsafe, shoddy or unneeded products seems endless. Unsafe automo-
hiles, tires with no durability, flammable fabrics, dangerous or worthless drugs,
fraudulent repairs, worthless warranties, leaky pens, adulterated food, bread without nutrition, beef stroganoff with too little beef, superfluous deodorants, and so on, have all received their share of attention. To the consumer advocate these are not isolated instances of human error. To him they are standard operating procedure in the American economy. His estimates of the dollar value of consumer fraud or consumer abuse suggest a problem of enormous dimensions. Thus, Senator Philip Hart's estimate that $200 billion spent by consumers in 1969 (of total expenditures of $780 billion) purchased nothing of value is part of the consumer advocate's stock in trade.*

All of this occurs, we are told, because of the quest for profit. Much, of course, is made of allegations about monopoly and the lack of competition in the economy. But to the consumer advocate it really does not matter whether there is competition or not, because in either case he argues that the consumer is playing a game he cannot win against his corporate adversary. Thus, Mr. Nader tells us there are "thousands of arrangements that make it possible for corporations to avoid competition so that the value of what buyers receive is often outrageously distorted." On another occasion, however, Nader has found that "company economy is very often the consumer's cost and hazard" and that competition is, "as a result," little more than "racing for the lowest permissible common denominator." 11

The consumer's plight is not caused by the lack of government agencies. Congressman Benjamin Rosenthal has pointed out that "there are approximately 50 Federal agencies and bureaus performing some 200 or 300 functions affecting the consumer." There are also any number of state and local agencies performing similar consumer protection functions. Thus, it cannot be said that a mindless adherence to laissez-faire has left the consumer at the mercy of malevolent producers.

Among the federal agencies directly concerned with consumer affairs, for example, are the following: Federal Trade Commission, Consumer and Marketing Service (Department of Agriculture), Federal Communications Commission, Federal Housing Administration, Federal Power Commission, Food and Drug Administration, Interstate Commerce Commission, National Bureau of Standards, National Commission on Consumer Finance, National Highway Safety Bureau, National Transportation and Safety Board, Office of Consumer Services, the President's Committee on Consumer Interests, and the Securities and Exchange Commission. Indeed, the history of consumerism—consumerism has, after all, been a recurrent theme in American politics for years—is a history of the growth of a large state and federal bureaucracy.

All seem to agree, however, that government regulation has failed. The reasons

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13 Hearings on S. 1127 and H.R. 10035, p. 19
for this failure are numerous but three recurring ingredients can be identified. The first is slow, pure and simple. Too many bureaucrats tend not to work a full day or to be as productive as they might. The "Nader Report" on the Federal Trade Commission (FTC) reported one well-paid official literally asleep on the job. Second, appointments to high positions and subsequent policy decisions are all too often based on partisan political considerations rather than on individual merit and in the public interest. Thus, one of the "Nader Report" indicates that appointments to the Interstate Commerce Commission are federally political plums. and another charges that the location of a Federal Trade Commission office—in Oak Ridge, Tennessee—was solely for political reasons. The third ingredient is more complicated. Over time an agency will tend to respond most favorably to the organized interests which put the most resources into influencing it. The interest of a single consumer in any particular product is likely to be small and organization with other consumers all but impossible. Producers, on the other hand, tend to be better organized as well as more persistent, and therefore, more able to influence agency action. Thus, it is alleged, regulatory agencies are all too often "captured" by the very interests they are supposed to regulate. To an unknown extent, similar forces also operate in the legislative process. Licensing regulations at the local level are often enacted in the name of the consumer but are in fact the handiwork of the regulated interests, and one revisionist historian has attributed much of the legislation of the Progressive Era to similar pressure from business groups.

II. The Cure Offered by the Consumer Advocate

Having completed his description of the sorry plight of the American consumer, the consumer advocate offers a multitude of remedies, of which only the most important can be described here.

First, better people must be appointed to responsible positions in the regulatory agencies, for, in the consumer advocate's view, it is the quality of the people appointed, rather than the nature of the regulatory mission, which has led to the failure of government. Thus, the "Nader Report" on the FTC said: "The real problem of the FTC—and indeed of any faltering agency—can usually be traced to people." (Original emphasis)

Second, the rhetoric of the consumer advocate leans toward measures which hinder the marketing of any product deemed "unsafe," with little regard to its potential benefit. Although there is considerable ambiguity as to what disposition

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17 Feinmeth, The Interstate Commerce Commission pp. 152 & 22
20 Turner, The Business Trust pp. 98 & 104
should be made of common items like matches and knives, the consumer advocate is prone to subject new products to tests which require that safety be established before marketing, no matter what the potential benefits. The danger of a thalidomide being marketed is to him presumptively greater than the danger of a penicillin being suppressed.  

Third, he would outlaw the marketing of products which fail to meet particular quality standards. Stroganoff without a specified percentage of beef is not stroganoff and should not be called such. It is also a loophole in the law to permit a product which appears to be a salad dressing but does not meet salad dressing standards to be sold as a "whip." And he regrets that "in 1970 this gaping loophole in the law is still substantially available to manufacturers, allowing products such as Gatorade, the 'thirst-quencher,' on the market. Since the law has no standards for 'thirst-quenchers,' Gatorade can legally contain whatever the manufacturer chooses, although now he must list the ingredients on the label." The implication of such an approach is that government is to draw up a list of permissible products with requirements as to standardized structure and content. Anything not on the list cannot be legally purchased.

Fourth, the consumer advocate would regulate advertising. It would not do to argue in detail here what has been adequately disposed of elsewhere, but it is clear that the consumer advocate would impose restrictions which would cause the amount of advertising in the economy to decline sharply. Advertisements which emphasize particular qualities of a product, for example, would have to state that the advertised product was not unique, if in fact competitive products also had those qualities. Positive aspects of a commodity, moreover, could not be highlighted without detailing whatever negative aspects might also exist.

Finally, to put the force of government behind his ideological position, the consumer advocate would establish an agency empowered to intervene in the proceedings of virtually all other federal agencies—including, under the most extreme proposals, even informal proceedings. The role of this consumer protection agency (CPA) would be to "represent the interests of consumers" before those other agencies in the hope that the presence and advocacy of an official consumer representative will offset the influence of other organized interests on regulatory proceedings. As Senator Abraham Ribicoff has said, its function would be "to police the departments and agencies to make sure they are doing their job for the consumer." What we are trying to do is put the 210 million Americans in the same position as the adversary involved who is supplying information to the agency, to have that agency head have the same information from the consumer's advocate. The proposed agency would also have power to receive complaints.

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1. Ibid. p 223
2. Ibid. p 64
3. Ibid. p 129
4. Ibid. p 130
7. Ibid.
from consumers and to collect information on consumer matters—and under one version of the proposal it would have subpoena power against "any persons" in the nation.

III. Is the Ideology of Consumerism Sound?

The initial difficulty with consumerism goes to the validity of its factual premises, namely that consumers are needlessly and willfully abused. Of course there are accidents, difficulties about product information and false advertising in a developed economy. But what is the norm for "too many" accidents, "too little" information or "too much" fraud, and how is that norm derived? Elimination of such evils entails costs, and those costs must be weighed against the anticipated benefits. At common law, for example, the calculus of an "unreasonable risk" entails balancing the likelihood of injury, the seriousness of that injury and the cost of avoidance. So too, the value of information to the consumer must be balanced against the cost of collection and transmittal just as the damage caused by deceptive advertising must be weighed against the cost of suppression. These costs, after all, can be substantial. Outlawing the wheel would no doubt save thousands and thousands of lives but no one seems prepared to take the plunge. Similarly, a penicillin unused because of doubts as to its complete safety imposes costs in the form of opportunities foregone.

Very little of the literature of consumerism even hints that a balancing process is involved, but until consumer advocates face that question directly, the allegations of consumer abuse will remain unproven. However the norm is established—and it probably must be on a product by product, case by case, basis—it cannot be no risk of accidents, absolutely total information and completely accurate advertising. To measure performance against such norms is utterly unfair and wholly misleading.

Beyond the tendency of consumer advocates to measure performance against unrealistic norms is the fact that much of the evidence supporting the claims of widespread consumer abuse seems anecdotal and unsystematic. The abuse is assumed to exist and the burden of proving otherwise is put upon those who would dare to deny it, with the strong implication that a denial is evidence of one's indifference to the ills of society. Consumer advocates tend to toss off a lot of quotations and statistics but when one culls "estimates" and polemical arguments from verifiable facts, their work product seems far too thin to be taken seriously as an assessment of a trillion dollar economy.

Skepticism as to the scientific basis of consumerism's factual premises, for example, is not discouraged by the liberality with which Mr. Nader and lesser

99 S 1177, Secs 204, 205, H.R. 10815, Secs 205, 206, 207.
91 S 1177, as introduced, Sec 205(d)(3)
movers of the cause employ Senator Hart's estimate of $200 billion of consumer abuse. But $200 billion seems substantially in excess of total profits for all business and is almost four times total after-tax corporate profits.44

Skepticism further increases in the face of consumer advocates' failure to fashion a theoretical explanation for the phenomena they describe. Mr. Nader is quite revealing when he says "economists for the most part have failed to ... show how corporations ... have been able to divert scarce resources to uses that have little human benefit or are positively harmful." 45 One might as well muse over the failure of scientists to explain why the earth is flat. Will economists ever be able to show that businessmen make money by deliberately failing to satisfy consumers? If consumers desire more safety, more quality and the like, greedy businessmen will find it in their interest to fill those desires and very much to their detriment to willfully ignore them. This is so even in the case of the absolute monopolist. He may have a greater margin to work with than his competitors but he still has little reason to take his "profit" in inefficiency and injuries to others rather than in money. If his product leads to accidents, for example, he will lose both customers and lawsuits. And what about competition? If industries are willfully failing to satisfy consumer tastes, there are vast fortunes to be made simply by producing what consumers actually desire. Consumerism seems to assume, therefore, not that businessmen are greedy, but that they are relatively indifferent to profits.

The lack of a theory to explain the phenomena consumer advocates observe is further demonstrated in the ambiguity they foster as to whether their function is to enlarge the consumer's opportunity to satisfy his tastes or to impose their own tastes on him. When Mr. Nader criticizes the food industry for taking steps to "sharpen and meet superficially consumer tastes at the cost of other critical consumer needs," one may fairly ask whose judgment it is that a taste is "superficial" and whose judgment it is that a "need" is "critical." In the circumstances mentioned it seems rather evident that the judgment in question is solely Mr. Nader's.

This ambiguity as to how the consumer is to be "protected" pervades consumerism. No doubt some consumers are misinformed about the safety of a product and no doubt some products appear to be far safer than they are. No doubt also—as I shall argue later—a considerable amount of government regulation can be justified. But there also should be no doubt that most products are less safe than they might be simply because consumers do not want to cover the necessary extra costs. Both knives and matches can be very dangerous and can be made "safer," but it is rather clear that consumers believe the benefits of greater safety do not outweigh the extra costs. Similarly, there can be little doubt that many consumers fully aware of the risk of, say, convertibles, are quite prepared to bear those risks in exchange for what they regard as countervailing pleasures.

As stated above, a judgment about the reasonableness of a risk entails balance-
ing three factors: the likelihood of harm, the seriousness of that harm, and the value of the interests to be sacrificed to avoid that harm. When a consumer advocate labels a product “unsafe,” it is he who is making that balancing judgment, not the consumer.

Of course, such judgments depend on the information available, but even here the consumer advocate exaggerates the potentials for improving present performance and substitutes his own views for those of consumers. The ease with which the consumer advocate calls for more “information” belies the complexity of the issue he raises. Much of what is called “information” involves questions of judgment, style and taste. Once we pass matters such as weights and measures, product “information” becomes increasingly subjective. “Experts” frequently disagree as to the validity of particular testing standards and methods, a fact which has made the businessman rather vulnerable to attack. When test results are not released, he can be accused of suppressing information; when they are, the charge of misleading tests can be raised. The gross judgments in which the consumer is most interested, moreover, are anything but objective. Which of a number of items is the “best” is not, after all, what is known in ordinary language as a scientific judgment.

Beyond these problems is a conflict between the goal of accuracy and the goal of communication with the consumer. Accuracy pushes toward highly technical language not easily comprehended by a layman (and, if recent reports are correct, lawyers at the FTC), while the need to communicate calls for ordinary words which often cannot accurately portray the intended meaning. Again the businessman is vulnerable to the attacks of consumer advocates because either choice leaves him open to a charge of misleading the consumer.

Information is also anything but costless and the costs of collection and transmittal must be borne like any added cost. The reliability of product testing depends on the size of the sample and the sophistication of the tests. And, if government regulation is involved, legal advice must generally be purchased. Like safety, then, “adequate” information involves costs as well as benefits and is a relative rather than absolute concept.

It is not at all clear, moreover, that the consumer advocate’s craving for unlimited information is shared by the consumer, who must sooner or later bear the cost of collection and transmittal. He must also bear the cost to him in time and effort of absorbing the information, a cost which many consumers may regard as outweighing any potential benefits. Consumers do in fact frequently forego opportunities to learn more about their purchases even when the information is free—reading ingredients, for example—and it seems evident that many prefer lower prices to paying for information. Were this not the case, Consumers Union would be one of the largest organizations in the country and a large number of firms would have entered the field of product testing and information collection. Where there is a demand for information—as on motor vehicles, for example—a glance at a newsstand tends to indicate that it can be purchased. Indeed, if consumers were

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that anxious for more information, competition would—as it often does—compel manufacturers to supply it in most cases, the most obvious exception being where all competing products have the same negative aspect, such as cigarettes. Even there, however, a demand for information would call forth independent testing agencies. Again, therefore, as in the case of safety, the consumer advocate is seeking to impose something on the consumer that he has chosen not to purchase.

The willingness of the consumer advocate to override the tastes of consumers has been demonstrated time and time again. For example, the “Nader Report” on the Food and Drug Administration attacks the producers of white bread in the United States for not making their bread more nutritious. Yet the report also says:

> At one time the battle between makers of white breads and makers of whole wheat and other more nutritious breads was carried into the marketplace. The Ward Baking Company in 1921... produced a highly nutritious nonwhite bread and conducted a vigorous campaign to promote it. However, in 1925 the company ran into economic difficulty and was reorganized. The new owners decided to discontinue the production of the more nutritious bread; white bread meant easier and greater profits."'

There is simply no way to analyze cases such as this except as instances in which consumers do not have the “right” tastes, although the consumer advocate continues to direct his fire at the manufacturers for not forcing items on the consumer that he does not want.

Similarly, the standardization of products will prevent consumers from buying items they might desire when such items do not comply with the government’s list. Those who like Gatorade, for example, would not, if the “Nader Report” had its way, be permitted to purchase it because it presumably does not meet the standard for a “juice,” just as those who would take a risk in order to satisfy some other taste will be prevented from satisfying it by rules which prevent the marketing of goods which seem somehow “unsafe.”

The late Frank Knight put it well half a century ago when he wrote,

> A large part of the critic’s strictures on the existing system come down to protests against the individual wanting what he wants instead of what is good for him, of which the critic is to be the judge, and the critic does not feel himself called upon even to outline any standards other than his own preferences upon a basis of which judgment is to be passed."

When pressed on this question, the modern consumer advocate turns to a favorite target, advertising, and argues that, after all, most consumer tastes have been created by the deceptive techniques of advertising and are not really to be viewed as the true will of consumers. Even accepting that objection at face value, one may, nevertheless, ask in what area of human activity are judgments free of influence by advertising techniques.

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19 Turner, The Chemical Feast, pp 111-112  
**Frank H Knight, Risk, Uncertainty and Profit (Boston: Houghton, Mifflin Co 1921), p 182**
It is all very well for consumer advocates to attack advertising but they themselves merchandise consumerism in a way that puts Madison Avenue to shame. Their activities seem very much geared to media impact and involve a great deal of sensationalism. Consider also the example of how the typical "Nader Report" is merchandised. On the cover, the name Ralph Nader appears twice and in large print. The name of the actual author appears once and in small print. On the back in large red letters is emblazoned: NADER'S RAIDERS STRIKE AGAIN! Nevertheless, except for the use of his name, there is little indication in these books as to what Mr. Nader had to do with their preparation. Furthermore, during congressional hearings in 1969, a Mr. Fellmeth, who has authored two "Nader Reports," was asked whether the reference "Nader's Raiders" was a fair statement. He answered,

I don't think so. I think it is very inaccurate for several reasons. First of all, it is inaccurate because Mr. Nader's involvement is crucial, but not as extensive as that name would imply. At least we are not investigating for him alone in a direct sense. Secondly, we are not raiders. That is a very inaccurate name, with an inaccurate connotation.

Maybe so, but when they ran it up the flagpole.

My colleague, Professor Arthur Leff, has quite rightly noted that the purpose of this kind of merchandising is to sell consumerism the way Colonel Sanders sells fried chicken. The point is simply that one cannot reject the market on the grounds that businessmen are too reliant on advertising, since that is also true of consumer advocates. If we are deceived by advertising, there is no way to judge whether it is business, the consumer advocates, or both, that are deceiving us.

In any event, many of the attacks on advertising are exaggerated because the attackers read every ad literally and needlessly reject any resort to imagery or symbols. For example, splashing Mr. Nader's name over the "reports" is in fact informative to the consumer, both as to the ideological slant and the quality of the books, but it is the very form of merchandising technique the consumer advocate likes to condemn.

Of course advertising is not the source of divine revelation or absolute truth. It is advocacy and well understood to be such by the consumer. Advocacy cannot, however, be suppressed in the name of accuracy without reducing the incentive to advertise and thus depriving society of the valuable functions advertising performs. It enlarges the consumer's choice by enlarging his knowledge and reduces transaction costs by efficiently bringing buyers and sellers together. It is also a critically important weapon of competition. Thus it has been found that heavy advertising tends to be associated with highly competitive rather than concentrated markets.

Fellmeth, The Interstate Commerce Commission. I4
Hearings on S 800 and S 2045, pp. 119-120.
and that those who seek to repress advertising are often seeking to repress competition. Product advocacy, therefore, can be suppressed only at a high cost to the consumer.

That consumerism will likely impose costs is not readily admitted by consumer advocates, who for the most part prefer to let the consumer believe that he can get something for nothing. Too often he is left with the view that increasing product testing by 1000 percent, making cars "safe," keeping all drugs off the market until they are absolutely "safe," forcing companies to spend large sums litigating and clearing things with a government bureaucracy and paying for that bureaucracy itself will cost nothing in out-of-pocket cash, increased taxes or foregone benefits. It is hard to think of a claim of commercial advertising more misleading than that proposition.

On one issue, however, few disagree with the consumer advocates. Government regulation has failed, and the inefficiency and "capture" by regulated interests alleged by the "Nader Reports" is generally conceded. Some agencies, like the Federal Trade Commission, have been just generally slothful. The American Bar Association's commission to study the FTC, for example, found one senior staff member who openly admitted that he preferred to hire older men because they have been out in the world and had come to appreciate that they were not going to make much of a mark. Regulatory failure, however, involves more than sins of omission. Even the FTC has approached "effectiveness" in enforcing statutes within its jurisdiction which are designed to protect producers rather than consumers, and the work of the Interstate Commerce Commission (ICC) is a clear instance of government regulation protecting monopoly interests in the economy. Professor George Stigler may thus well say, "It is of regulation that the consumer must beware."

IV. Is the Cure of Consumer Advocacy Worse Than the Disease?

The Priority Areas for Government Regulation. It is not my purpose here to define with precision the proper role of government in consumer protection. Rather, it is to identify those areas in which market failure seems most likely and the case for government regulation most powerful. One of the harmful effects of consumerism has been to divert attention from the real issues of locating market failure—consumer advocates really say it is everywhere—and of determining in what areas the government ought to cease regulation entirely. But for one or two exceptions they always call for more and more regulation.

First, the government ought to impose safety regulations where parties other than the buyer or seller may reasonably be expected to suffer injury. There is no

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Footnotes:
3. Ibid., p. 45

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reason why I as a pedestrian must bear the risk undertaken by a car owner who purchases low quality brakes, and it is certainly arguable that my son need not bear the risk of my poor judgment as to the safety of his toys.

Second, government must play a role in suppressing false advertising. It ought to enforce legal actions by consumers and product competitors—"the latter have a more substantial incentive to bear the costs of litigation—against false advertisers. Some have also argued that it is appropriate for government to establish an agency like the FTC to seek out and suppress false advertising. Professor Yale Brozen has contended that false advertisers are in effect "free riders" profiting from the reputation of advertisers who are truthful." Because a consumer cannot determine truth or falsity from the face of an ad, the existence of some false advertising casts a cloud over all advertising. For this reason, Brozen argues that affirmative government intervention can be justified. This intervention is to be distinguished, however, from the kind of regulation which in effect requires that advertising give up the function of advocacy of the product, for example, by disclaiming uniqueness or publicizing negative aspects. That kind of regulation discourages advertising generally and thus reduces the amount of information available to the consumer as well as the amount of product competition.

Third, the government ought to establish uniform standards where objective rules can be imposed, for instance, weights and measures. Without such standards, information cannot be easily transmitted. Competition here, moreover, may lead to the creation of confusing and deceptive standards which the consumer cannot interpret and competitors cannot combat effectively. Government may similarly compel sellers to inform the buyer through labeling as to matters such as quantity and ingredients according to uniform definitions. Providing such information is relatively costless and, in the absence of government intervention, definitions of measures and ingredients may not be matters of uniform agreement and understanding. Similarly, certain contract language can be given a fixed legal meaning. A seller surely ought to be free to make disclaimers, but there is no reason to permit him to label them a warranty. Establishing uniform measures and definitions is a far cry from standardizing products, an act which is necessarily anti-consumer and anti-innovative.

Fourth, where there is a high risk of serious harm, the government can seek out and provide information to consumers if that information is unlikely to be available to competitors or independent testing organizations. The sanitary conditions in which food is processed are of great importance to the consumer and really cannot be accurately discovered other than through governmental action. As the frequency and seriousness of the risk decline and the availability of information to competitors or testing organizations increases, however, the justification for governmental intervention diminishes.

Fifth, when a product is by its nature either dangerous or addictive and there are no close substitutes—cigarettes are an example—some role of government may

**See particularly Professor Richard Posner's analysis on this point in Report of the ABA Commission to Study the Federal Trade Commission, pp 104-106**

**Brozen, "The FTC Attack on Advertising"**
be justified in bringing relevant matters to consumers' attention because there is less expectation that competitors will inform consumers about safer alternatives. A limitation to dangerous or addictive products and a strict definition of "close substitutes" seems appropriate because, in all other cases, either competitors or independent consumer information organizations will supply the information desired in timely fashion.

The scope of the regulatory areas sketched above can be debated. Some no doubt have more faith in regulation than others. Skepticism as to government's ability to regulate effectively will vary from individual to individual and many will not accept some of the arguments outlined above or believe in some not mentioned.

Several are clear, however. First, the presumption ought to be against governmental intervention in view of its failure in the past. Regulation has been a failure of such dimensions that it should be undertaken only in clear cases of market failure. Second, market failure does not automatically call for regulation. Markets fail in varying degrees and government intervention cannot be justified unless the benefits exceed the costs. Careful scouting of regulatory proposals is particularly necessary since many of the alleged causes of market "imperfections" seem inherent characteristics of government regulation. Critics of the market remind us of the relative lack of power of the individual consumer over market decisions and his difficulty in acquiring information. Less readily do they point out that this is even more the case when the individual faces the regulatory machinery of government. A harmful ICC ruling is usually less well-known and always less avoidable than a poorly made appliance. The clamor for regulation ignores this because it is based on the naive view that "the people" exercise continuing control over government. This is, of course, contrary both to the theory and practice of representative democracy, which provides only for periodic and very general accountability. The device of the independent agency, moreover—the mainstay of regulation—reduces even this limited accountability to the vanishing point. Identification of market failure, alone, therefore, is not justification for governmental intervention; there must be a further showing that regulation will work and that its costs will be less than its benefits. Third, it is clear that we now have too much regulation, a good deal of which harms consumers by protecting monopolistic interests. How can we truly say we care about consumer protection while we permit the ICC to continue to exist?

Consumer protection entails identifying areas of market failure and carefully tailoring the role of government to them. The scattergun, anti-everything approach of the consumer advocates contributes nothing to this difficult task but merely diverts attention from the important issues, including the critical need to eliminate superfluous or harmful regulation.

The Cure For The Failure of Regulation Is Not More Regulation. The entire case for the creation of an independent consumer protection agency "to represent the interests of consumers" in proceedings before federal agencies rests on the proposi-
tion that the agencies have failed to fulfill their responsibilities. Calling for the creation of the CPA is an astonishing admission of the egregious failure of consumer protection regulation. But surely the mind boggles at the argument that the failure of regulation in the past calls for imposing yet another bureaucratic overlay. If this proposed agency arises from a need, as Senator Ribicoff purports to police the departments and agencies, one may justifiably inquire who or what is to “police” it. How soon will it too be hiring only older men who realize that they are not going to make a mark in the world? Why is this agency not as susceptible to “capture” by organized interest groups as other agencies? It is surely as tempting a target and it cannot be divorced from political pressure any more than, say, the Interstate Commerce Commission. Are we, in a generation, to hear a call for yet another agency, this time to “police” the CPA?

The CPA also has the potential of creating a bureaucratic nightmare—particularly if, as is proposed, the CPA must be notified of and have a right to intervene in every action of other agencies, formal or informal, affecting consumers. As the chairman of the Administrative Conference of the United States has stated, every act of every bureaucrat affecting consumers cannot be written down and sent to the CPA without cripple government. Even if such extreme suggestions are rejected, the proposed CPA will still serve to delay and increase the costs of government action.

All of the arguments supporting the creation of a CPA suggest not a new agency but the elimination of an old agency. If the FTC is moribund, a CPA—whose director and deputy director would be appointed in the same manner as the FTC commissioners—is unlikely to bring it to life. It will merely double the cost. Why should the citizens of this country have to pay taxes for a consumer agency to appeal before the Interstate Commerce Commission to urge that commission to reach the results a competitive market would—that is to say, the very results that would occur if there were neither an ICC nor a consumer agency?

There Cannot Be a Single Consumer Representative. The model on which proposals for a CPA are based is the adversary system of our courts. That model, however, is totally inapplicable to the purposes urged by consumer advocates. The lawyer-client relationship is one of principal and agent in which the principal has continuing power to direct the actions of the agent. A lawyer representing a client also has the duty of absolute and single-minded loyalty to that client and an obligation to make whatever arguments are in his interest. Where the interests of two persons conflict, the lawyer may not seek to represent both in one action.

The proposed CPA is in no way analogous to representation by legal counsel. It is, the principal, not the agent. It, and it alone, would decide when and for what reasons to intervene in the proceedings of other agencies. There is, moreover, no single client or interest for the CPA to represent. It is a fundamental principle of economics that individual consumers put different values on particular commodities. People may differ as to how much beef they like in their stroganoff and

See Hearings on S 1177 and H R 10835, pp 186, 193.
as to how much they are willing to pay for it. Safety and information are not costless, and different consumers will have differing tastes as to how much of each of those they wish to purchase. Intervention against a product which the CPA believes to be "unsafe," for example, is solely in the interest of those consumers preferring to purchase more safety and to the detriment of those preferring a cheaper product, albeit one of greater risk. There is no way around the dilemma created by empowering the CPA to "represent" persons with conflicting interests.

One bill pending in Congress defines "the interests of consumers" in part as "the cost, quality, purity, safety, durability, performance, effectiveness, dependability and availability and adequacy of choice of goods and services offered or furnished to consumers; and the adequacy and accuracy of information relating to consumers goods and services. . ." 5 Such a definition, however, ignores the fact that all of these things can be traded off against each other. There can be more safety and quality for a higher cost and vice versa, and different consumers will prefer different mixes. The proposed consumer protection agency simply cannot "represent" all consumers on these matters.

The very idea that there is such a thing as a consumer advocate is, therefore, little more than a public relations gimmick. It has, however, fed the erroneous and misleading notion that a government agency can be established to "represent" the interests of consumers. All those consumers who prefer a trade-off between cost, quality, safety, information, and so on, different from that determined as "correct" by the agency will remain unrepresented in all of the proceedings. This is a grave danger because the very existence of the CPA will conceal the fact that large numbers of people—perhaps in most cases the vast majority of consumers—are in effect unrepresented and are actually being injured by an agency acting in their name.

Consumer Advocates Against the Consumer. Even if the CPA does not fall prey to sloth and bureaucratic lassitude, even if it is "effective," that effectiveness will consist in imposing a particular ideology of consumerism upon consumers. To be sure, some consumers may be helped but many others will be hurt.

It should be recognized, moreover, that the ideology of consumerism does not provide protection against "capture" of regulatory agencies by special organized interests or inhibit coalitions with those interests, particularly if consumer advocates seek and obtain further restrictive legislation. Emphasis on safety, the suppression of advertising, and the standardization of products all tend to dampen competition between firms and are frequently anti-innovative and restrictive influences. Standardization, although the least restrictive, is all too close to the ICC's determination of adequacy of service in deciding whether to permit new entrants into the transportation industry. Firms already in the market with established names and established products will have an enormous advantage. They will, moreover, quite likely see the opportunity to take advantage of the work of the CPA in order to suppress competitors by blocking innovations. Just as the FTC has been more vigorous in enforcing "protectionist" statutes than other statutes in

\[10\text{H.R. 10835, Sec. 304(5)}\]
its purview, a CPA will find that a coalition with organized interests is the path of least resistance. The very existence of the CPA, moreover, will tend to legitimate action by other agencies which is monopolistic.

Consider the case of the compact car. Had consumerism been an active governmental force in the 1950s, it is quite plausible to imagine that measures would have been taken to prevent the introduction of such cars into the American market on the grounds that they were not safe. All of the steps necessary could have been accomplished by a CPA in the name of the consumer, with the automobile industry working silently in the background. This is by no means an imaginary horrible, for allegations about small cars continue. Such a step would, of course, bring about the very results deplored by consumer advocates in other circumstances. But the very fact that the CPA had helped to bring about the exclusion of the car would serve to legitimate what was in effect governmental creation of a monopoly.

Finally, the existence of the CPA will unquestionably make consumers relatively poorer. There will of course be the deprivation of income and benefits which will occur because of the massive bureaucratic delays caused by the CPA and because of the tax revenues needed to cover these delays and the cost of the CPA itself. Consumers would almost surely be better off without such regulation and with the money they pay in taxes to buy more safety and information.

Beyond that, the delays in putting products on the market and forcing firms to expend resources on clearing new products with the bureaucracy, the heavy governmental burden on products which do not meet some norm of perfection will inevitably increase the cost of commodities. And this increase in costs—dictated principally by the political views of the consuming middle class—is likely to have its most detrimental impact on the poor, who will get more quality only when they can pay the higher price.
Should Executives Be Jailed for Consumer and Employee Health and Safety Violations?

The Consumer Product Safety Commission was established in 1972 to develop mandatory product safety standards and to prohibit the sale of products which do not comply. The Occupational Safety and Health Administration was established in 1973 to develop and enforce worker safety and health regulations. Both agencies were established with the goal of reducing the number of work and product related injuries, sicknesses, and deaths. Much remains to be done. According to the Consumer Product Safety Commission 30,000 people died and 110,000 people received serious injuries from unsafe products in 1976. The Occupational Health and Safety Administration reports that in 1976 4,500 employees died and 1 out of 11 employees received serious injuries from work related causes.

To supplement the work of OSHA, the AFL-CIO has established a Department of Occupational Health and Safety which currently employs ten industrial hygienists who try to help member unions monitor on the job health and safety problems. George H. R. Taylor, Department Director, estimates that 25-30 of these health-engineering technicians will be employed within the next five years.

The CPSC receives help from a different source. The CPSC has established a Consumer Deputy program, in which consumer volunteers with no authority, enlisted and trained by staff in CPSC Area Offices, help monitor retailers to detect non-complying products.

Health and safety issues are being given greater priority by unions during contract negotiations. Also, many local union and joint management-labor health and safety committees are being established within the work place. Clearly, a variety of legislative and private measures are being used to control product and occupa-

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Within the past fifteen years there have been increasing grounds for holding executives personally responsible for an organization's behavior. Over a decade ago in an electrical price fixing case, middle managers were sent to prison. However, the top executives of the companies involved, General Electric, Westinghouse, and Allis Chambers, were not considered by the Court to be personally criminally liable for the price fixing because it was not demonstrated that they intended to fix prices or that they knew that the middle managers engaged in price fixing. [6] Since that time there have been several successful criminal prosecutions, convictions, jail sentences, and prison terms for executives. For example, an executive at an H. J. Heinz Co. factory in California received a six month suspended sentence for unsanitary food conditions in the factory. A Minnesota judge ordered Lloyd A. Fry Roofing Co. to pick one of its top executives to serve a thirty-day jail term for violating air pollution standards. A top executive of a grain company received a three month prison term for conspiring to cheat foreign customers by short-weighting ship loadings. One hundred and sixty one executives were convicted on antitrust violations in 1977. Five were jailed. This number is up from only one the previous year. Most of the convictions resulted in either fines or suspended sentences. [6, 10]

Among other laws, the Federal Food, Drug, and Cosmetic Act, the Sherman Act, the Federal Water Pollution Control Act, and the Occupational Safety and Health Act all have criminal penalties for responsible top executives. Amendments to these and other laws regularly have lengthened prison term penalties. The Justice Department has increased criminal prosecutions of top executives in recent years and is more often seeking prison term penalties for those who are convicted or who plead guilty or no contest. This phenomenon is not confined to the United States. For example, top executives in France, England, Russia, and China are currently serving prison terms for factory worker accidents. [3, 6, 10]

**DEFINING EXECUTIVE RESPONSIBILITY**

Controversy surrounds the crucial issue of how top executive responsibility should be defined. In the June 1975 landmark case of United States v. Park, the Supreme Court ruled 6 to 3 that John R.
Park, the president of Acme Markets, was criminally liable for conduct in a business unit far down in the corporate hierarchy. The case had its origins in November 1971 when the FDA found evidence of rodent infestation in the Baltimore food warehouse of Acme. The FDA informed both Park personally and the company. A second investigation a few months later found some improvement, but still unsanitary conditions. The company and Mr. Park were then charged with violation of the Federal Food, Drug, and Cosmetic Act. The company pleaded guilty and Mr. Park pleaded innocent. Mr. Park contended that as President of Acme which had 36,000 employees, 874 grocery stores, and 16 warehouses, he could not personally supervise all activities. A jury found him guilty despite the fact that: (1) Park ordered a line supervisor to obey the FDA order; (2) Park directed another employee to check on the first employee; (3) Park took these actions in good faith; and, (4) Park was unaware that his orders were not being carried out. The Supreme Court upheld the conviction. [3, 4, 8, 10]

The Court held that an executive is responsible if, by virtue of his position in a company, he had a position of authority and responsibility in the situation out of which a prosecution for a violation might arise. Such an interpretation of responsibility dispenses with more traditional criteria of criminal conduct such as knowledge of the crime or intentional criminal activity. Such an interpretation of responsibility comes very close to absolute liability by virtue of position that permits no defense when a violation occurs. However, the Court's interpretation does not go this far. The Court stated that it does not require "that which is objectively impossible." [3, 4, 8, 10]

The principles established in the Park case may, at least in part, have been reversed recently in the 1978 Supreme Court decision in Ceylon & U.S. Gypsum Co. By a 6-2 vote the Court divided the Sherman Act along criminal and civil lines, requiring proof of intent for the former, but only an anticompetitive effect or purpose for the latter. That is, for a criminal conviction the Court required proof that the executive intended to break the law, while for a civil conviction the Court required only an illegal result that might have been caused without the executive intending to cause a violation. The Court stated that it held the more lenient standard for criminal
convictions because criminal conviction without proof of intent "holds out the distinct possibility of overdeterrence; salutary and procompetitive conduct lying close to the borderline of impermissible conduct might be shunned by businessmen who choose to be excessively cautious in the face of uncertainty regarding possible exposure to criminal punishment for even a good-faith error of judgment." [9]

EXTENDING THE PARK CASE PRINCIPLES

There is great disagreement about whether the Park principles should be extended to the enforcement of all Federal regulations concerned with consumer and worker safety and health. Mark Green, consumer advocate and Director of Congress Watch, strongly supports the U.S. v. Park principles and their extension. Green says, "Legislation is necessary because the political reality is such that judges don't want to convict executive criminals."

A spokesman for Senator Kennedy says that Senator Kennedy supports the extension of the Park principles into the criminal code noting, "The current criminal code does not contain adequate provisions for getting at serious executive crimes."

David Ewing, Executive Editor of the Harvard Business Review and author of Freedom Inside The Organization: Bringing Civil Liberties To The Workplace, disagrees. He argues that the problem of responsibility is a result not so much of the behavior of individual executives who do not fulfill their personal responsibilities as it is with the structure of modern business. Dr. Ewing explains that:

"The big crime is the growth mania found in many businesses. There is too much pressure for profits that cause executives to give orders for both increasing profits and making safe products and working conditions. When both goals can't be reached, many executives are pressured not to want to know about potential dangers."

Dr. Ewing suggests that if the competitive pressure for profits and growth can be reduced, then the problem of unsafe products and...
working conditions would be reduced more through such structural reform of business than through extension of the Park principles.

Meyer Issenberg, a law professor at the University of California, Berkeley, takes a similar position in stressing the structure of business as a more important cause of consumer and worker injuries and deaths than individual top executive culpability. The analogy Professor Issenberg uses is the driver in a hurry who goes through a yellow light expecting and hoping that there will not be an accident. Professor Issenberg compares this situation to the executive under profit pressure who cuts corners on worker and product safety systems with the expectation and hope that no one will get hurt. Instead of prison sentences he recommends monetary fines and reform of the business system.

David Ruder, Dean of the Northwestern University Law School, also emphasizes the structural problems of business as a cause of problems and adds that:

The social disgrace of a criminal conviction for a business executive is worse than for a street criminal and that often the executive's health suffers and many executives die from the stress of criminal proceedings. If the penalties for top executives are too harsh, the society may have difficulty finding competent business leaders to take the necessary risks required in business.

This is similar to the position the Supreme Court took in U.S. v. Gypsum. [9]

Ralph Nader rejects the argument that blame should be laid on the structure of business rather than individual executives. He says:

Those advocating structural reforms instead of personal executive criminal penalties are either naive, trying to deceive the public, or wish to make it easier for executives to increase their profits or cover up their crimes. A white collar criminal should be treated just like any other criminal.

While conceding that there are structural problems beyond individual culpability that cause consumers and workers to be injured and killed, Ralph Nader emphasized that little is likely to change very quickly without individual responsibility encouraged through prison terms, executive suspension, and behavioral sanctions such as requiring executives to spend time working at the scene of the crime, such as the factory floor where a death or injury occurred. Nader also advocates a solution that he credits David Ewing with raising in the current debate, that of firmly protecting employees who "blow the whistle" on executive criminals.
Jake Clayman, Director of the Industrial Union Department of the AFL-CIO, agrees that the structure of American business is a large part of the problem, but stresses that:

Fines don't mean anything to top business executives. While I am not quick to recommend jail sentences for business executives, many workers and consumers are being killed and permanently injured and the Courts have never seriously faced up to executive culpability. Fines don't mean anything. This breeds a kind of feeling that the law isn't applied equally.

In a special report on white collar crime from the Bureau of National Affairs, a legal publishing house, it is similarly observed and documented that Nader and Clayman are correct in noting that many judges have difficulty imposing criminal sanctions on corporate executives except in the most severe cases. However, Norman A. Carlson, former Director of the Bureau of Prisons, points out that criminal penalties even though used sparingly in practice are helpful in compliance and deterrence. "Non-prison alternatives don't have nearly the impact of imprisonment."[10] Similarly, Business Week observes that the use of criminal penalties even when used infrequently "has succeeded spectacularly at executive consciousness raising". [7] It should also be pointed out though that criminal law is much slower and more expensive to all parties.

The President of one large midwestern manufacturing company, who declining to be identified, agreed with Clayman and stated that:

Many executives may have to be more concerned with the process and not just the bottom line, but it's not just executives with a lack of social orientation that are the problem. Stockholders want more profits and growth. It's difficult for executives to stand up and talk. Putting a few executives in jail is more treating the symptom than the cause. But now that I think about it, criminal penalties may be necessary until the social orientation problem is solved.

Despite regulatory efforts, thousands of consumers and workers are suffering injury, sickness, and death from product and work related causes every year. The issue of whether and under what circumstances executives should be jailed for organization violations that cause such harm is unlikely to disappear while so many are suffering so seriously.

The relatively short jail terms that the law permits do not appear too harsh relative to the literally thousands of consumers and workers suffering injuries, sickness, and death from unsafe products and working conditions. Criminal penalties do not appear unreason-
able, in circumstances where top executives knew that there was a reasonable probability that injuries or deaths could be suffered and did nothing to prevent them; when executives ordered corrections, but did not check to see whether their orders were carried out; or, where top executives permitted an information system to continue even though it did not bring "bad news" about potential injury, sickness, and deaths to their attention.

REFERENCES
The Economics of Jailing Executives for Violations of Health and Safety Regulations

In the preceding issue of this journal, Richard Nielsen dealt with the issue of whether executives should be held criminally liable for health-safety regulation violations. His paper reviewed judicial decisions in this country and offered views, both pro and con. The article deserves much credit for pointing out a serious issue; however, it did not provide a framework for analysis of the problem. It is to this task that this note is addressed.

The analysis will attempt to answer three questions. First, are health-safety regulations necessary? Or, alternatively stated, could not an unregulated market arrive at socially optimal standards of safety? Second, are executives in uniquely influential positions to affect safety levels? Third, if the answer to the second question is in the affirmative, are criminal penalties the socially optimal devices to enforce safety regulations? As a starting point, we will begin with an example of a situation where the unregulated market can lead to socially optimal levels of safety. We will then examine the implications of relaxing the assumptions that were necessary to achieve the optimal solution with a view toward answering our three questions.

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2 The socially optimal level of safety will be here defined as that level at which the benefits to society as a whole to either increase or decrease safety are negative.
THE IDEALIZED MARKET SOLUTION

Given the assumptions that all of the costs and benefits of any action are known to all parties, that there are no transactions costs, and that everyone reveals his or her true preferences, the unregulated market can arrive at socially optimal levels of safety. Imagine that a manufacturer has the choice of either building a plant which produces cars with poorly protected gas tanks or of building a plant costing $1,000,000 more which produces cars with better protected gas tanks. Say that 100,000 people each intend to buy one of the cars, and that it would be worth $10.01 to each of them to have a safer car. That is, each would be indifferent between having the safer car, and paying $10.01 less and taking the added risk of the more dangerous car. In this situation, the potential customers would be willing to offer the manufacturer up to $1,001,000 ($10.01 times 100,000 people) to produce the safer car. If they offered him, say, $1,000,500 to build safer cars, then each party, the people and the manufacturer, would be better off by $500. If there were an infinite array of possible plants corresponding to different car safety levels, by repeating the above negotiations, it would be easy to show that that plant which cost exactly $1,001,000 more than our first plant would be built. This would be the socially optimal plant, producing an auto with the socially optimal level of safety.\footnote{If there were n plant designs, each costing $1,001,000 more than the first plant, that plant that could produce cars offering the highest level of safety, ceteris paribus, would be built. That is, only the most efficient plant within each cost range would be considered.}

PROBLEMS WITH APPLYING THE IDEALIZED MARKET SOLUTION

Unfortunately, in the real world, information is not freely and evenly distributed, there are transactions costs, and people are reluctant to reveal their true preferences if they can see some gain from concealment.

Transactions Costs

Loosely speaking, transactions costs may be divided into two parts: the costs of organizing to negotiate and the costs of negotiating. In instances involving health and safety, on one side of the bargaining table is usually a firm and on the other side is a group of workers or consumers or pollution victims. Once both sides are
organized, there is no reason to suspect that the costs of negotiating will be higher for one side than the other. However, the costs of organizing and of remaining organized are likely to be far greater for those dealing with the firm than for the firm itself. The firm, almost by definition, is already a cohesive unit with a fairly simple and dispassionate reason for being, namely to make money. On the other hand, a group of consumers or pollution victims are not likely to even know each other. In addition, their goals and expectations are likely to be highly diverse. Even a group of well organized union workers must take into account the often conflicting and emotional wants of various segments of its membership. These factors make it likely that it will be far more difficult for a group seeking higher levels of safety to deal with a firm than for the firm to deal with a group.

To show how this asymmetry in transaction costs can lead to suboptimal safety levels, suppose that the cost of organizing the consumers in the preceding example is $5.00 per person, and, again, that all costs and benefits are known. Recall that the manufacturer requires a minimum of $1,000,000 in order to be willing to build the safer car. If the consumers want the safer car, they must pay at least $1,050,000 ($50,000 to organize and $1,000,000 to the manufacturer). Since it is only worth $1,000,000 to the consumers to have the safer car, it will not be worthwhile to seek a safer model. If the manufacturer is unable or unwilling to speculate and build the more expensive plant, the more dangerous car will be produced.

Reluctance to Reveal True Preferences

The reader may be wondering why the manufacturer, in such a situation, would not sell safety coupons, costing $10.01, to the potential customers in order to raise the needed funds to produce the safer car. If each person purchased one coupon, the safer car would be produced, nobody would be worse off, and the manufacturer would make a $1,000 return for his trouble. The problem is that each individual would have an incentive to be a free rider, that is, to not purchase a coupon in the expectation that the coupon purchases of

* For those who wish to argue that firms also maximize sales or executives' prestige or whatever, please keep in mind that the main point here is only that the firm's objective function is likely to be simpler than that of a group of workers or consumers or pollution victims.
others would be enough to pay for the safer car. Almost 100 people could refuse to purchase a coupon and still the firm would raise the necessary $1,000,000. Everyone would desire to be one of those 100 people.

Imperfectly Distributed Information

Only in the mind's eye of an economist is all information instantly and costlessly known to everyone. In the real world each one of us is privy to only a small subset of all knowledge. The transfer of information to others involves costs. Moreover, as in the preceding paragraph, there are times when it is advantageous to one party to keep certain information from others. In our example, it is unlikely that the consumers will be aware of the differences in gas tank protection levels between one car and another. It is, however, highly probable that the manufacturer will be aware of these differences. The management, then, has the option of either building the safer car, incurring the costs of informing the public of its cars' superior safety levels, and hoping that the resulting higher price will be sufficient to recoup its costs, or of building the cheaper, more dangerous car and marketing it as though it were perfectly safe. In general, the second choice is the more lucrative. The point is that safety levels are often not readily discernible. A worker may be unaware that he or she is working with radioactive materials; a city might not know that a factory is dumping mercury into its harbor; and consumers may be ignorant to the fact that their cars tend to explode when hit from behind. In each of these instances, however, the management of the firm is likely to have detailed information about the problem and to have an economic incentive to conceal that knowledge.

The Three Questions Answered

We are now ready to apply the results of the above analysis to answering our three questions.

The Need for Health and Safety Standards

In the above analysis it has been demonstrated how the existence of transactions costs, incentives to conceal true preference levels, and imperfect information all conspire to create a situation in which an unregulated market will lead to suboptimal levels of safety. The
need for health-safety regulations follows immediately from the preceding statement. Governments exist to provide services to its society that the market is unable or unwilling to deliver, such as national defense. If free markets are unable to provide the level of safety that society desires, it is the duty of government to dictate that that level shall be provided. As a qualifying statement, I should add that merely because the market will fail, does not mean that government will succeed. Certainly anyone who claims that regulations are typically costless and well thought out is either incredibly naive or has a personal stake in a regulatory body. The point here, however, is that if the society is to have optimal levels of safety, some nonmarket solution is needed, namely some form of regulation.

Are Executives Uniquely Able to Determine Safety Levels?

It has been argued that only managements are likely to be privy to relatively complete data regarding the safety levels of its company's working conditions, effluents, and products. Because of this, it follows that executives are the best possible monitors of safety levels. Particularly when one considers the costs and the potentials for loss and/or concealment of attempting to transfer this information to some other body of regulators, the unique position of executives as the ideal regulators becomes clear.

Are Criminal Penalties Appropriate?

Having decided that executives should monitor safety standards, there remains only the task of creating a system of rewards and penalties that will persuade executives to act as if they had society's welfare uppermost in their minds. Since we are assuming that society, via its government, has already dictated its desired safety levels, we are, essentially, attempting to persuade executives not to violate that standard, either actively or passively. But are there not tradeoffs? That is, should not an executive be allowed to sanction some minor erosion of safety levels below the societal standard, if the financial rewards are great? Unless we are prepared to radically alter our view that each individual has an absolute right to his or her own life we must respond to the negative, because a decision to compromise safety standards is, essentially, a decision to kill or injure for profit. Statistical inference, as well as our common sense,
tells us that if the probability of an injury occurring is increased and if this increased probability applies to a large number of events, such as 100,000 cars, then there will surely be more injuries. Exactly how or how many will be injured is unknown, but that there will be additional injuries is clear to all but the most sublimely optimistic. Unless we are prepared to instruct executives as to how many dollars they must earn in order to perpetrate assault and/or murder on a roughly specified but anonymous group of individuals, we must conclude that society's chosen level of safety must be strictly adhered to.

The use of the words "assault" and "murder" in the preceding sentence probably surprised most readers, but it is essential to understand that this is precisely what is being discussed. Suppose that both the safer and the less safe car of our example were available, with the safer car selling for $10.00 more. Mr. X chooses to save the $10.00 by purchasing the less safe auto. He is not, by this act, committing suicide for the $10.00. He is simply, assuming a slightly higher level of risk. In effect, Mr. X is underwriting himself against a slightly elevated possibility of what is still an unlikely event, i.e., his death or injury due to the weaker gas tank. On the other hand, suppose that Mr. Y decides to manufacture large numbers of the more "dangerous" car. Since the product defect is not readily discernible, Mr. Y conceals the fact and thereby avoids having to charge a lower price, the wrath of regulatory authorities, or both. The benefit of this action is that Mr. Y will make more of a profit and the cost is that some people will be killed and injured. Unless it is assumed that Mr. Y is extremely naive, it must be assumed that he realizes the existence of this tradeoff. Because Mr. Y will be unlikely to know the victims or to hear their screams does not alter the fact that he is knowingly killing or injuring others for personal gain.

In addition to the moral arguments that murder and assault are criminal offenses, no finite system of monetary fines, as would be levied in civil offenses, would provide the same level of deterrent. Bankruptcy laws impose limits on fines. No person can effectively be charged more than his or her net worth. In addition, most financial losses can be insured against in one way or another. This is particularly true for the well-off and the sophisticated, and executives tend to be both. There are, however, no ways to insure against imprisonment. For all of us time is unidirectional and death is a
certainty. Chunks of our lives are priceless in that there exists no market at which we can purchase a replacement. This, then, is the infinite cost that is proper to impose upon executives for the crime of imposing infinite costs on others.¹

¹ Some of the individuals quoted in the Nielsen article expressed the concern that making executives criminally liable for safety violations would seriously lower the supply of executive talent. I confess that I fail to understand this argument unless it refers to cases where the executive would be held accountable for infractions that he or she had no knowledge of. If culpability were limited to willful violations, why would a law-abiding executive fear?
APPLYING ECONOMICS TO AN IMPERFECT WORLD

Alfred E. Kahn

For me, economics with a practical bent there is an immense satisfaction in taking principles out of the textbooks and applying them to the real world. That has been my avowed task as a practitioner of regulation for the past four years.

The economic principles we—my fellow commissioners, board members and I—have been applying are easy to characterize: that economic efficiency requires prices for goods and services to be set equal to their marginal social opportunity costs (that is, the cost to society of the resources that are used to produce additional quantities—resources that will therefore be freed for other uses if and as buyers restrain their demands), and that, whenever it is technologically feasible, competition is the best way to achieve this result, as well as to ensure the optimum rate of innovation and the greatest degree of managerial efficiency— efficiency, as economists now put it. What has been especially intriguing about my experience is that it has embraced two quite different regulatory situations—one, the traditional public utility, where competition seems for the most part not feasible and the economist-regulator is moved to play an active role in trying to produce efficient results, the other, airlines, in which it appears the prime obstacle to efficiency has been regulation itself and the most creative thing a regulator can do is remove his or her body from the market entryway.

But the process of applying these principles—even of simply getting out of the way—
has been far from simple. The state in which the
environment regulation exists is still scribbled
over with the scratchings of lawyers, politi-
cians, the world to which he would apply his
principle is a curiously imperfect and
resistant, and the companies means is one
which would help him thread his way through
the thicket of second best? 

A theory that tells us,
itself that it may be economically efficient
to price at the highest level of marginal
costs in some individual markets, prices in
other markets are above or below that
ideal level. The really challenging problem
defining what the ultimate, economically
rational equilibrium should look like but what
is economically rational in an individual,
second best world and how best to get from
here to there.

Regulating Monopoly

It would be so easy to point to
lor her to the extent the defects of the institution,
regulated monopoly, the byproducts at the extreme, is that
it combines the worst of both worlds' the evils
of monopories with the sluikth of the profit
motive. I should add to this the almost uninter-
acting motives of producers, the products is to use price, typically,
very imperfect means to guide the redistribution of income

The First Problem: Regulated Monopoly Itself

One of the most sobering lessons of my en-
xperience with public utility regulation was the
progressive realization that the most energetic
initiatives were little more than idle efforts
to compensate for the inherent defects of
the institution over which I was presiding.

One of my proudest accomplishments at
the New York Public Service Commission was
the progress we made in requiring the electric
and telephonic companies, in New York to in-
troduce a system of prices related to marginal
cost. For example, the large residential user
of electricity on Long Island, instead of paying
the present flat charge of so many cents per
kilowatt hour, will soon--if the courts allow
the rates variance between $2.5 cents at night
and 40 cents on summer days of the temperature gets above 83 degrees. As a specific ex-
ample of the encouragement that this kind of
pricing will offer to rational choices between
consumption and abstinence. Energy and In-
sulation, the use of fuels in the sun, consider
the introduction of that marginal cost
based 12 T ratio does to the likelihood of
storage cooling being developed and introduced
commercially. Again, the business customer of
the New York Telephone Company now have to
pay for their local calls on a timed basis; they
no longer ignore the fact that additional
minutes of use have a positive marginal cost. Residential rates have shown a similar
pricing system, with the introduction of re-
duced basic charges.

In trying to introduce changes like this we
encountered the same resistance, not just
from large users who thought they would be
harmed by them, but from the utility com-
panies themselves. Why? Why would the electric
companies cling to a declining block rate
structure (whereby more electricity a customer
uses the cheaper each additional "block" of
electricity is) without reference to the time of
consumption? When it appeared, particularly
at times of peak demand, that sales in the final
blocks were at prices markedly below marginal
cost and that the result was to intensify the
financial squeeze to which the companies were
already exposed by the combination of inflation
and regulatory lag?

I can think of only two reasons, first, bu-
tromatic inertia, and second, a lingering as-
sumption that it was in their interest to pro-
 mote additional sales that require additional
investment, in order to build up their rate base.
Both of these phenomena are themselves
social consequence of regulated monopoly
--of the absence of competition and of regula-
tion on a cost plus basis (with allowable re-
 turn reckoned on invested capital) so a plaus-

The plausibility can be made that regu-
lation itself was one of the imperfections
we were trying to overcome. ...
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The Third Problem: Subsidization. The same.
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posed upon long-distance calling interstate revenue requirement, there to be
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tional method has beqn by charging prices mincing this internal subsidization. The tradi-
sion's to des 'strut a least-distorting method If IT-
system.

it will force to subsidy

Similarly, society seems determined to have basic telephone service provided at less
than cost and even warn from the efficiency standpoint through Internal subsidization. The
reasons when they are articulated at all, are usually stated in terms of externalities (my
telephone is valuable to me only as it enables
the public to reach others or "social welfare." A regu-
latory commission can be persuaded, how ever, (1) that there is an absence of cost in unlimited numbers of calls and, possibly to
place some minimum on outgoing ones, but (2) that they provide very little justification for
subsidizing what passes for basic service in most places in the country which typically
includes the opportunity to place an unlimited number of local calls at unlimited duration, at
no extra charge (contrasting the subscriber to the
former, truth basic service, while introducing individual charges for each additional local call and for additional minutes of calling, mon-
izes the mechanics that results from holding
rates below marginal costs and has the addi-
tional satisfying effect of rewarding lower
bits per minute of capacity, willing to exercise some re-
straining in the costs that they impose on the

Economics logic can be fruitfully applied also to devising a least-distorting method of
financing this internal subsidization. The tradi-
tional method has been by charging prices markedly above marginal costs for interstate
calls on the ground, among others, that since
the very costly installation at the subscriber's end is used for both intrastate and interstate
calls, it is only "fair" that both share the re-
sponsibility for covering its costs. The conse-
quence is that every time a telephone or a
switchboard is installed, some 20 percent of the
capital cost is automatically transferred to the
intrastate revenue requirement, there to be im-
poused upon long-distance calling.

Managing n Transition to Competition

During the last fifteen months, I have been
coping with a very different kind of discussion
the transition the airline industry from a regime of rigid governmental protection-ism and antitrust to one of free competition.

What I propose to explain here is my con-
version from a belief that gradualism is desir-
able to advocacy of something as close to total
deregulation as the law will permit, to be
achieved as quickly as possible.

My original attitude was based, first, on
simple intellectual caution. It was based, sec-
ond, on a desire not to discredit deregulation
by showing an insensitivity to the fears of both
Congress and the financial community about
what a sudden total immersion in the waters
of competition might do to the financial health of
the industry, especially since it had just
emerged from five or six years of dismal earn-
I usually thought that since the airline companies had relied on points of origin for their routes, the carriers would naturally be ready to face the competition and meet the additional competitive pressures to which they would be subjected as a result of the competitive opportunities that should shortly be presented.

I must now examine at the outset of the possible deterioration of a radical process the degree of second thoughts that if we were in a competitive position it would be extremely difficult to present so that it would be presented with the same advantage.

Airlines.

The first problem: Unusual competitive situations. The airline industry has been in a state of flux for some time, and conditions have changed from the past. The most important changes were in the different airlines and their respective routes, and the new routes to the cities were long and short in thin markets or thin. Moreover, the ability of one airline to compete successfully on a particular route with another will be greatly influenced by the extent to which it is to the advantage of the carriers and the extent of their services in the cities from which their own feeder routes that they can readily funnel into their own operations and (2) rights to routes going beyond a given city pair route onto which they can feed their passengers, thereby permitting them to latch up their flight schedules on routes where there is competition. Continental Airlines, for example, which has a large system of feeder lines, demands that it would be at a serious competitive disadvantage if carriers within its system could feed into the O'Hare Airport from the East were free to make the comparisons between their routes to the West that contribute the bulk of its profits.

Our uncertainty about the outcome of the competitive struggle is no reason to prevent its taking place...
primary freedom to slough off their artificial handicaps by entering and leaving markets as they please.

Moreover if we cannot predict how these collecting advantages and handicaps of the several carriers are likely to work out under a regime of free entry, it seems to me even less likely that we can hope to achieve the most efficient performance of the transportation function by prescribing how the thousands of markets should be served as the proponents of the status quo would have us do. I find it difficult to see how these uncertainties tilt the balance in the direction of a reliance on predictably ignorant regulation in preference to an uncertain predictable market process.

The second problem: Distortions from Moving Patchwork. Some carriers profess not to worry about their ability to survive a competitive struggle if the CAB were able to deregulate promptly and totally, but they argue strenuously that against one developing totally free entry into markets on a case-by-case basis in the order in which applications happen to be presented to it.

The problems they envisage seem to be of two kinds. First, a Continental or a National among the market by market approach to free entry is subject to waves of competition in particular markets that are important to it, while it may find itself having to wait a long time for its own turn to come. I see no reason to assume, however, that the order of our proceeding would have a rhythmic beat of this kind. In fact, our most dramatic proposals to open large numbers of markets to multiple permissive entry—invoking service to and from the underused Chicago Midway and Oakland airports—have been ones in which the great bulk of the traffic will be merely a spillover of the, therefore, feed and beyond rights will be of little importance, and in which prominent among the applicants are carriers with no such route systems at all.

The second fear is that if only some markets are opened to entry and not others, all the competitive energies of the industry will concentrate on them, resulting in excessive entry and investment. All this comes down to is the destructive competition scenario there seems to be a general belief among defenders of the present regulatory regime that there is something about airplanes that drives business men to say that once the CAB removes its hand from the threshold, they will rush into it.

There seems to be a general belief among defenders of the present regulatory regime that there is something about airplanes that drives businesses men crazy.

markets sell well like lefthanders, without regard to the size of each or how many sellers it can sustain and how many others may be entering at the same time. This does not happen in other industries; there is no reason why it need happen in an air transport.

It remains undeniable, however, that the practical approach-market by market—which may be forced on us by the Federal Aviation Act most involve distortions. So long as the certificate and public convenience and necessity continue to have an exclusivity, and therefore a market value, some of the airlines assure us, they will apply for more licenses than they can operate, and operate under them sufficiently to ensure that they are not taken away, and that they will flood markets with more service than is economic in order to preclude competitive operations by others, in the hope of being able in the future to reap the rewards of the monopoly power they achieve and preserve in this way.

The only rational answer is to demonstrate convincingly that the value of these franchises is going to be zero. Then there will be no valuable pieces of paper to fight for with uneconomic operations and no future monopoly gains to offset against the costs of present predation.

It is of course necessary to convince the companies that this is going to happen, but the way to do that is to open markets to free entry—and that is what we are doing. Moving as rapidly as possible to a system of universal free entry—and exist—is the way also to deal with the asserted inequality of competitive abilities and opportunities during a slow transition: make the transition rapid, move quickly, on as broad a front as possible, to permit all carriers to slough off the restrictions that limited their operating flexibility, to leave the markets they find unserviceable to serve, to enter the markets.
they want to enter. This will not assume a large impact upon the small plane traffic until it is determined whether or not there is enough demand to justify the additional service. The Maryland and Midway were scheduled for roundtrip operation to the benefit of the traveler and at a profit to the carrier. It is hoped that the CAB will continue to approve the use of Midway Airport as a hub. The CAB had consistently approved the establishment of the Midway Airport as a hub. The CAB had consistently approved the establishment of the Midway Airport as a hub.
The problem, however, was the restricted number of flights scheduled. On the first day of the new schedule, the available flights were less than the demand.

The solution was to introduce new flights, which was done without the need for any additional slots. However, this required the coordination of the airlines and the airport authorities. The airlines were required to submit a proposal for the new flights, and the airport authorities would then determine the feasibility of the proposal.

The process was complex, but ultimately it worked. The new flights were introduced, and the airport was able to accommodate the increased demand for air travel.

The lesson from this experience was that airports need to be flexible, and that new solutions need to be found when existing ones are not sufficient. This is a lesson that has been repeated in many airports around the world.
them charges landing fees based on one cut uniformly into scheduled service by the
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pricing principles even modestly So the choices
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The passenger in question is a member of a large group of passengers who have booked a flight on a particular airline. The airline has a policy of overselling flights, which means that they sell more tickets than there are seats available. This practice is used to maximize the potential revenue from ticket sales, even though it increases the risk of overbooking.

The airline's decision to oversell the flight is based on the assumption that some passengers will not show up for the flight. The probability of a passenger showing up for the flight is influenced by various factors, including the time of the flight, the type of airline, and the location of the airport. The airline's decision to oversell the flight is also influenced by the number of available seats and the number of passengers who have booked the flight.

To determine the number of passengers who will show up for the flight, the airline uses a mathematical model that takes into account the probability of a passenger showing up for the flight. The model uses historical data and statistical analysis to estimate the number of passengers who will show up for the flight.

The airline's decision to oversell the flight is based on the assumption that the cost of providing standby service is less than the cost of paying compensation to passengers who are bumped from the flight. The cost of providing standby service includes the cost of providing transportation to an alternate flight, as well as any additional expenses that may be incurred by the passenger. The cost of paying compensation to passengers who are bumped from the flight includes the cost of paying for a hotel room, food, and transportation back to their home.

The airline's decision to oversell the flight is also influenced by the number of available seats and the number of passengers who have booked the flight. The airline may choose to oversell the flight if there are more passengers booked than there are seats available, even though this increases the risk of overbooking. The airline may also choose to oversell the flight if the cost of providing standby service is less than the cost of paying compensation to passengers who are bumped from the flight.

In conclusion, the airline's decision to oversell the flight is based on a combination of factors, including the probability of a passenger showing up for the flight, the cost of providing standby service, and the number of available seats and passengers who have booked the flight. The airline uses a mathematical model to estimate the number of passengers who will show up for the flight, and then uses this information to determine whether to oversell the flight.
tal's Chickenfeed, TWA's No Strings and America's Short Stop are available to all corners in the markets in which they are offered, regardless of size, shape, length of stay or previous condition of servitude; the only control is that -just like interruptible off-peak sales of gas and electricity - the number of discounted seats varies from flight to flight depending upon their timing relative to the system peak. British Caledonian has divided its planes on transatlantic flights into three compartments with fares, each based upon a single explicit load factor and therefore in the degree of the transports' ability to separate and charge for their different customers, that is, and such is that differentiation, based upon the presence or absence of cancelation penalties, stopovers, prohibited routes and in some cases all of their genuine costs - charging for them.

And that is probably the most telling indication of the tendency to market and the resulting ATM predictions are accurate for the future, the more that the would-be entrants will have to look into the list of priorities will look for them.

Epilogue: Who Bears the Burden of Proof?

The logic guarantees that no town will lose service, even temporarily, that no carrier will be subjected to unequal competitive pressures because it may have inherited a less favorable route structure than its rivals, that there will, furthermore, be no wastage of fuel, no excessive entries into any market, no injurious discrimination, no bankruptcies, no loss of seniority rights, no danger of increased concentration and no impairment of scheduled service. Or they will oppose free entry, unless and until the advocates can predict in complete detail how the new pattern of operations will look and get the authority to leave the task of the future to system to its every detail to the new Civil Aeronautics Board that strictly enforces its ability to make those predictions. The opponents and the Antitrust Committee would have us commit ourselves to a process whereby the prices schedules, the cancelation penalties, the path of seats, sales for heightened service, and travel agents, and lawyers.

What has been even more illuminating to me is that the whole of the entire comprehensive I have rejected is the conclusion that the only way to save - but also the way to measure the transition - is to make the transition as smooth as possible.
The Mystery of the Dissatisfied Consumer

Complaint letters and opinion surveys only give us clues about why some consumers are unhappy. More information is needed for a good solution.

By George S. Day
Repair services, direct mail, toys and automobiles contribute disproportionately to consumer hostility.

But agencies need to be examined more closely. For example, when consumers are served by companies that were really doing what they were supposed to be doing, they were not interested in some products marketing techniques for products and services. As marketing agencies became increasingly involved in specific areas, people who were not interested in the specific market were not interested by appraising products in the short-term market. As well, ads for furniture and appliances in the long-term market appeal to needs and aspirations. But magazines may appeal to users in some areas, but not in others. People who were not interested in the specific market were not interested in the specific products.

As a result, the marketing of these products is not a very good representation of what people think of these products in general. But there are some specific experiences of consumers that have been identified. For example, for the most part, consumers believe that the product is more valuable than the price. Sometimes, the product was not as good as expected. But still, the price was just too high. It could not afford the more powerful products. Some people said that the price was too high. Others believed that the product was not as good as expected. But still, the price was too high. Some people said that the product was not as good as expected. But still, the price was too high.

This is an example of how marketing is very good. The product was not as good as expected. But still, the price was too high. Some people said that the product was not as good as expected. But still, the price was too high. Some people said that the product was not as good as expected. But still, the price was too high. Some people said that the product was not as good as expected. But still, the price was too high.
Hunting her refrigerator turned out to be more aggravating than she had originally expected. In all three cases, the problem was with the consumer—not the manufacturer—but the consumer appears disatisfied.

On the other hand, there are situations where the consumer is indeed being abused and doesn’t know it. For example, when food additives cause bad side effects. It is also difficult for a consumer to know whether claims made in a company’s advertising are honest or deceptive. Thus, whether a consumer’s reaction is available or not necessarily a good reflection of the product’s quality.

National surveys can be used to measure consumer experiences. But often these surveys raise more questions than they answer. Even because businesses and government look for different things when conducting such surveys. Business leaders like to express pride in the large percentage of customers who are satisfied. Some government agencies want to minimize abuses in the marketplace and focus on the large numbers of customers who are unsatisfied.

The most thorough example of the satisfaction-oriented approach favored by business comes from a comprehensive consumer survey program conducted by General Electric. As of 1972, GE had asked 80,000 customers to describe their overall satisfaction with some 665,000 individual appliance products, on a five-point scale ranging from extremely satisfied to extremely dissatisfied. According to GE, 90 percent of those questioned were extremely satisfied or very satisfied. To be sure, the proportion varied somewhat by product, category, appliance, and service. But in any case, the high level of satisfied customers does not seem to violate much common sense or consumer behavior. A similar trend is evident in another government survey of 1.000 households asking each to think about the problems they had had within the past year with packaged food products and health and beauty aids. After each household had time to think about the mailing and presumably to come up with some dramatic examples of product defects, Neilsen surveyors interviewed each housewife by telephone.

The results? Out of the 1.000 respondents, 100 couldn’t recall a single defect and a further 100 reported only package defects. The remaining 800 households reported a total of 6,117 product defects. In numbers, that is a lot of households, but a lot of product defects. In numbers, that is a lot of satisfied households, but a lot of product defects. But the number is miniscule when you consider that each household buys hundreds of packaged food products and health and beauty aids in the course of a year.

On the other hand, you probably buy more packaged goods than food. Let’s suppose a housewife buys a package of flour wrong beans at her supermarket. She comes home...
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over 47
L opt. os the persnytc anti finds a dead antpoltltics
lanai's. het. mist: the 1:61C't, ..1%
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son 25 percent of LIU terol ledb roblcrn,
pottecl no stnoplautts sstth aof of !het, re-
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52,, moth,*

...
A buyer who is happy
with an 8-speaker stereo
may become dissatisfied
when a 12-speaker model
comes on the market.

small group of consumers who might be
unbeknownst reluctant test samplers. For
example, a new talcum base in a bath
powder was tested on a small sampling of
people and caused no problems. Once it
was on the market, though the manufac-
turer received dozens of complaint letters
from people who were allergic to the new
product, apparently none of them had
been included in the test sampling. Simi-
larly, the development of the safety cap
upon bottles long before the govern-
ment thought to require it, can be attrib-
ted to consumers who wrote letters to
drug companies expressing concern about
the ease with which children were open-
ing bottles.

Many complaint letters present a disorientat-
ed and incomplete picture. People who write
such letters are not types of shoppers.
They are most likely to be high-school
aged, accident-prone and fussy. They then
don't have more free time or other hands
than the types of shopper who, as teens with
puberty and interests, have often been
told. Most shoppers, rather than
demand satisfaction from a company
simply which holds a shop in different
states. Now income shoppers are especi-
ally unlikely to complain, even when they
have strong grounds for complaint, be-
cause they don't know how to go about
it.

In a study conducted by one
manufacturer's own informal studies,
indicated that the head office of
chain stores is almost an
isolation from consumers as are the
head offices of manufacturers. Many
complaints are simply swept into the
store clerk's department manager
and go no further. They never even
get to the attention of the store
manager, much less the store's corporate
headquarters. And if the store's corporate
headquarters is any indication, there
may be less complaining behavior
than among the public. At the very
tiniest moment, a consumer
rebellion is brewing.

There are potential benefits to en-
couraging consumer complaints by the use
of telephone surveys, as complaints in-
cluded in packages and other improved
consumer action devices. But regardless
of the effect of such measurement, it is
clear that consumer complaints cannot be
allowed to serve as the sole source of in-
formation about consumer dissatisfaction.

Suggested Reading

- Marketing Science Institute
- Marketing Science Institute
STATE PROTECTION OF THE CONSUMER:
INTEGRATION OF CIVIL AND CRIMINAL REMEDIES

Paula W. Gold * and Robert D. Cohan **

State legislation which protects consumers can be found in two major areas: (1) civil statutes specifically enacted to protect consumers, and (2) existing criminal laws. An effective program of enforcement must integrate both. This article will survey the broad range of civil and criminal sanctions currently available to most state enforcement agencies for consumer protection.

The most comprehensive civil statutes for consumer protection are modeled after the Federal Trade Commission Act, which generally prohibits unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.

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Criminal enforcement arises under either traditional criminal statutes, for instance, larceny by false pretenses, or criminal statutes specifically enacted to protect consumers, such as the Model Penal Code sections dealing with unfair and deceptive business practices.

Unfortunately, only a handful of states have developed comprehensive civil and criminal legislative programs designed to protect consumers. Therefore, many state prosecutors are hampered by laws which are inappropriate and unrealistic. Regardless of whether the legislative framework in which the enforcing authority operates is an up-to-date, comprehensive one or a patchwork interrelation of laws, it is essential that the state coordinate civil and criminal remedies to deter unfair and deceptive practices and compensate victims in a timely and efficient manner.

I. CIVIL PROSECUTION

Fifty jurisdictions have enacted some form of "baby FTC act." These acts fall into two general categories: (1) those without civil penalties for initial violations which provide only for a penalty in a contempt proceeding for the violation of an injunction, and (2) those which impose either civil penalties and/or criminal sanctions for initial violations.

A. Statutes Without Civil Penalties for Initial Violations

Less than half of those states which have enacted consumer protection statutes modeled after the FTC act, including Massachusetts, do not provide for the assessment of civil penalties for initial violations, even though a consumer protection act which provides such penalties is far more effective than one which does not. Although aggressive enforcement of a consumer protection act without civil penalties for initial violations can protect con-

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2 FTC Fact Sheet, supra note 2.
numers in many areas, states like Massachusetts are hindered in
affording full protection to their citizens. None of the available
equitable remedies act as a deterrent to those who intend to pur-
sue unfair and deceptive trade practices. A state with a con-
sumer protection act which imposes civil penalties possesses a
meaningful deterrent to initial violations of the act.

Under the Massachusetts Consumer Protection Act, the At-
torney General may seek: (1) an assurance of discontinuance;  \(^5\)
(2) an injunction restraining the use of unfair or deceptive acts
or practices;  \(^6\) (3) in the case of corporations which habitually
violate injunctions, the dissolution, suspension or forfeiture of
the corporation's franchise or its right to do business within
the Commonwealth;  \(^7\) and (4) restitution for persons who have
suffered ascertainable loss.  \(^8\) Neither an assurance of discontinu-
ance, nor an injunction, imposes a penalty for the initial viola-
tion of the Act; nor does the first violation trigger corporate
disenfranchisement. Each remedy seeks to insure future com-
pliance. Furthermore, where the assurance of discontinuance
or injunction runs against the corporation but does not run
against individual corporate officers, the corporate officers can
dissolve the corporation and reorganize under a new corporate
structure not subject to the assurance of discontinuance or in-
junction, thereby avoiding the penalties for future violations.  \(^9\)

An order of restitution is also of limited effectiveness in de-
terring initial violations. It is of no value where the operator
is judgment-proof as a result of the dissipation of his assets
or bankruptcy proceedings; and, even if the operator does have

\(^4\) See Annual Report of the Consumer Protection Division to Attorney General
Francis X. Bellotti, 1976.
\(^9\) See Hearings on S.670, The Consumer Fraud Act Before the Consumer Protec-
tion and Finance Subcommittee of the House interstate and Foreign Commerce
Committee at 3-4 (August 11, 1976) (statement by John M. Nannes, special assistant
to the Assistant Attorney General, Antitrust Division); for a discussion of individual
liability of corporate officers in Massachusetts, see generally 13A Mass. Prac. §§
643-46.
sufficient assets to comply with the order, restitution is only available for those defrauded consumers of whom the state is aware. The operator may retain the remaining illegally gained profits and, at most, is required to return only what he has earned through his unfair and deceptive practices. As a result, the operator may view restitution as simply another cost of doing business, and he will not be deterred from his fraudulent activities.

For the foregoing reasons, the legal effect of a consumer protection act without any fine or penalty for initial violations has been likened to a "dog bite" statute which entitles a dog to one free bite, regardless of the damage caused, before sanctions will be imposed. Fraudulent operators will not be deterred so long as they believe the only sanctions to which they are exposed are restitution and a court order prohibiting a recurrence of the act.

B. Statutes With Civil Penalties for Initial Violations

Statutes which impose civil penalties for initial violations provide a significant deterrent to unfair and deceptive acts or practices. Twenty-seven states and the Virgin Islands have enacted such legislation. By eliminating illegal profits through

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10 In reference to actions brought by the Attorney General, Mass. Gen. Laws ch. 93A, § 4 states in pertinent part, "... [the] court may ... make such other orders or judgments as may be necessary to restore to any person who has suffered any ascertainable loss by reason of the use or employment of such unlawful method, act or practice any moneys or property, real or personal, which may have been acquired by means of such method, act, or practice." (Emphasis added).


12 See Comment, Civil Penalties — More or Less!, 40 Gonzalez L. Rev. 669 (1975) [hereinafter cited as Civil Penalties — More or Less?]

the imposition of appropriate civil penalties, the incentive to initiate illegal acts may disappear. Civil penalties may be further justified as punishment for wrongdoing to the victim, society, and also may serve as a source of revenue to help offset the cost of consumer protection to the taxpayer. In addition, because the sanction is civil in nature, practical procedural problems associated with criminal prosecution may be avoided.

Two important elements determining the effectiveness of a statute which imposes civil penalties are the burden of proof and the maximum permissible assessment of damages.

1. **Burden of Proof**

State statutes impose varying burdens of proof. Twelve of the states which impose civil penalties for initial violations require proof that the violation was willful, intentional or knowing. Fifteen states do not require any showing of intent; the

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10 See Compton v. United States, 377 F.2d 408, 411 (8th Cir. 1967).

11 See notes 53-57 infra, and accompanying text.


13 See also for California, Lexin, Consumer Fraud At The San Diego District Attorney's Office & San Diego L. Rev. 47, 51 (1970) [hereinafter cited as Lorenz].
Virgin Islands incorporates both approaches by imposing a greater penalty where the law is knowingly violated.\textsuperscript{20} The authors believe that proof of intent should not be required when the business community knows or in the exercise of reasonable care should know of its obligations. For example, knowledge of legal obligations imposed by unambiguous statutes, regulations, or case law should be presumed. However, it is unreasonably burdensome to impose upon a merchant the threat of penalty without any showing of intent to violate the law when the prescribed conduct is not clearly and unambiguously defined. Table I, below, categorizes the different burdens of proof required.

2. Assessment of Penalties

The maximum permissible assessment varies from a high of $50,000 for each violation in Illinois, to a low of $300 for each violation in Maryland. Two states, Maryland and New Jersey, impose one penalty for the first offense and allow a higher penalty for each subsequent offense.\textsuperscript{21} Table I indicates the maximum permissible penalty in these states.

It should be noted that even the smallest maximum assessment can have a deterrent effect if judges impose multiple penalties for multiple offenses; however, a small penalty simply will not deter the constantly dishonest business operator.\textsuperscript{22} Assessments imposed are frequently criticized as being much lower than the profits made by violating the law.\textsuperscript{22} Large corporations can readily absorb penalties which are too small or pass them on to the consumer or stockholder in the form of higher prices and lower dividends.\textsuperscript{24}

\textsuperscript{20} $350 civil penalty for each violation, $500 civil penalty for a knowing violation. V.I. CODE tit. 12A § 104.
\textsuperscript{21} Maryland: $300 for each first violation and $500 for each subsequent violation. Md. ANN, CODE COMM. LAW § 13-410. New Jersey: $2,000 for each first violation and $5,000 for each subsequent violation. N.J. STAT. ANN. § 56: 8-13.
\textsuperscript{22} LORENE, supra note 19 at 50; Staff Studies, supra note 11 at 392.
\textsuperscript{24} Consumer Protection By Prosecution, supra note 11 at 89
In determining the size of the legally permissible assessment there are three issues to consider:

1. The importance to the public of deterring unfair and deceptive practices;
2. The amount of the damages that could be caused by violations of the consumer protection act; and
3. The size of the penalty necessary to deter future violations.25

The authors agree with those who believe that if the maximum permissible penalty is much below $5,000, its deterrent effect decreases substantially.26

**TABLE I**

<table>
<thead>
<tr>
<th>Maximum Permissible Penalty For Each Violation</th>
<th>Proof Required That Violation Was Willful Intentional, or Knowing</th>
<th>No Showing of Knowing Intent Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>$50,000</td>
<td>Oregon</td>
<td>Illinois &amp; Minnesota</td>
</tr>
<tr>
<td>$25,000</td>
<td></td>
<td>Hawaii, New Hampshire, Texas, Vermont, Wisconsin</td>
</tr>
<tr>
<td>$10,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$5,000</td>
<td>Arizona, New Mexico, South Carolina, West Virginia</td>
<td>Alaska, New Jersey (second offense)</td>
</tr>
<tr>
<td>$2,500</td>
<td>Nevada</td>
<td>California</td>
</tr>
<tr>
<td>$2,000</td>
<td>Connecticut, Georgia, Kentucky, South Dakota</td>
<td>Kansas, Nebraska, New Jersey (first offense), Washington</td>
</tr>
<tr>
<td>$500</td>
<td>Mississippi, Montana, Virgin Islands</td>
<td>Maryland (2nd offense)</td>
</tr>
<tr>
<td>$350</td>
<td></td>
<td>New York</td>
</tr>
<tr>
<td>$300</td>
<td></td>
<td>Virgin Islands</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Maryland (1st offense)</td>
</tr>
</tbody>
</table>

25 See Civil Penalties - More or Less, supra note 12 at 670.
27 See note 13 supra; see also, for California, Lorence, supra note 19.
II. CRIMINAL PROSECUTION

An effective consumer protection program must involve not only civil actions but criminal prosecutions as well. Criminal prosecution is the public enforcement weapon which affords the greatest deterrent effect. Members of business and professional communities generally abhor being branded criminals regardless of which law they may have violated. Conviction strips the offender of his cloak of respectability and may bar him from the pursuit of his chosen career. The effectiveness of criminal sanctions is vividly displayed by the pressure the business community exerts against use of these sanctions. Furthermore, criminal conviction results in a sentence which cannot be avoided by a judgment-proof operator. These sen-

28 See Ball and Friedman, The Use of Criminal Sanctions In the Enforcement of Economic Legislation: A Sociological View, 17 Stan. L. Rev. 197, 216 (1965) [hereinafter cited as BALL]; Geis and Edelertz, Criminal Law and Consumer Fraud: A Sociological View, 11 Am. Crim. L. Rev. 989, 1005 (1975); Givens, Roadblocks to Remedy in Consumers Fraud, 24 Case W. L. Rev. 144 (1972). For example, since 1968 the Fraud Division of the U.S. District Attorney’s Office for the District of Columbia has had to indict only one home improvement scheme. This was attributed to a number of successful prosecutions in the late sixties believed to deter potential offenders. Rothchild and Throne, Criminal Consumer Fraud: A Victim Oriented Analysis, 74 Mich. L. Rev. 661, 693 (1976) [hereinafter cited as ROTHCHILD]. See generally National Institute of Law Enforcement and Criminal Justice, Exemplary Projects: Prosecution of Economic Crime.

29 BALL, supra note 28 at 217; Staff Studies, supra note 11 at 391.


81 BALL, supra note 28 at 217; e.g. Testimony of Albert B. Perlin, Jr., on behalf of the National Retail Merchants Association before the Subcommittee on Consumer Protection and Finance of the House Committee on Interstate and Foreign Commerce regarding 8. 670 (August 9, 1976). The issue is whether criminal sanctions ought to be imposed on those who violate the legal but not the moral code. BALL, supra, note 28 at 190. However, consumer fraud well merits severe punishment. The victim has lost more than property, he has lost the security in transactions with other members of society which is gained only through fair dealings. Consumer Protection by Prosecutors, supra note 11 at 91. This loss of confidence in the free market system makes the legitimate businessman a victim as well. Testimony of Louis J. Lefkowitz, Attorney General of New York, before the Executive and Legislative Reorganizing Subcommittee on Government Operations (April 29, 1966), (reported in Placement of State Consumer Protection Programs, Consumer Protection Special Report, February 1976, National Association of Attorneys General at 1 n.1; See also RAMSEY CLAIR, CRIME IN AMERICA 38 (1970).
tences also provide some satisfaction to defrauded consumers who demand equitable retribution where restitution is unavailable.

A. Traditional Larceny Statutes

In the absence of specific statutes which provide for criminal prosecution of economic crimes, larceny by false pretenses may be construed to prohibit unfair and deceptive trade practices. The value of such statutes to prosecutors and their effectiveness as a deterrent to economic crime depends on the extent of the burden of proof placed on the prosecution and the maximum permissible sentence and/or fine. As Table II indicates, the maximum permissible sentence and/or fine varies from a low in Hawaii of one year and/or a $1,000 fine to a high in Arkansas of twenty years and/or a fine of $15,000 or twice the pecuniary gain from the illegal act.

**TABLE II — Larceny Statutes**

<table>
<thead>
<tr>
<th>Maximum Sentence</th>
<th>Maximum Fine In Addition</th>
<th>Maximum Fine In Alternative</th>
<th>No Fine</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 years Arkansas ($15,000)</td>
<td>Arizona ($10,000)</td>
<td>Oregon ($10,000)</td>
<td>Virginiaˈ</td>
</tr>
<tr>
<td>15 years Utah ($10,000)</td>
<td>Wisconsin ($10,000)</td>
<td>New Hampshire ($2,000)</td>
<td>Maryland ($1,000)</td>
</tr>
<tr>
<td>14 years Idaho Montana</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>State or Territory</th>
<th>Maximum Fine In Sentence</th>
<th>Maximum Fine In Addition</th>
<th>Maximum Fine In Alternative</th>
<th>No Fine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorado</td>
<td>10 years ($30,000)</td>
<td></td>
<td></td>
<td>Alabama</td>
</tr>
<tr>
<td>Guam</td>
<td>10 years ($10,000)</td>
<td></td>
<td></td>
<td>Alaska</td>
</tr>
<tr>
<td>Illinois</td>
<td>10 years ($10,000)</td>
<td></td>
<td></td>
<td>Arizona</td>
</tr>
<tr>
<td>Maine</td>
<td>10 years ($10,000)</td>
<td></td>
<td></td>
<td>California</td>
</tr>
<tr>
<td>Minnesota</td>
<td>10 years ($10,000)</td>
<td></td>
<td></td>
<td>Georgia</td>
</tr>
<tr>
<td>North Dakota</td>
<td>10 years ($10,000)</td>
<td></td>
<td></td>
<td>Puerto Rico</td>
</tr>
<tr>
<td>South Dakota</td>
<td>10 years ($10,000)</td>
<td></td>
<td></td>
<td>South Carolina</td>
</tr>
<tr>
<td>Washington</td>
<td>10 years ($10,000)</td>
<td></td>
<td></td>
<td>Tennessee</td>
</tr>
<tr>
<td>Kansas</td>
<td>5 years ($5,000)</td>
<td></td>
<td></td>
<td>West Virginia</td>
</tr>
<tr>
<td>Nevada</td>
<td>5 years ($5,000)</td>
<td></td>
<td></td>
<td>Wyoming</td>
</tr>
<tr>
<td>New Mexico</td>
<td>5 years ($5,000)</td>
<td></td>
<td></td>
<td>District of Columbia</td>
</tr>
<tr>
<td>Louisiana</td>
<td>5 years ($5,000)</td>
<td></td>
<td></td>
<td>Virgin Islands</td>
</tr>
<tr>
<td>Missouri</td>
<td>5 years ($1,000)</td>
<td></td>
<td></td>
<td>Nebraska</td>
</tr>
<tr>
<td>Vermont</td>
<td>5 years ($500)</td>
<td></td>
<td></td>
<td>New Jersey</td>
</tr>
<tr>
<td>North Carolina</td>
<td>7 years ($15,000)</td>
<td></td>
<td></td>
<td>New York</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>7 years ($2,000)</td>
<td></td>
<td></td>
<td>Delaware</td>
</tr>
<tr>
<td>Kentucky</td>
<td>5 years ($10,000)</td>
<td></td>
<td>Michigan ($2,500)</td>
<td>Missouri</td>
</tr>
<tr>
<td>Florida</td>
<td>5 years ($5,000)</td>
<td></td>
<td></td>
<td>Massachusetts</td>
</tr>
<tr>
<td>Michigan</td>
<td>5 years ($5,000)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ohio</td>
<td>5 years ($2,500)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oregon</td>
<td>5 years ($2,500)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iowa</td>
<td>5 years ($1,000)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mississippi</td>
<td>4 years ($1,000)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rhode Island</td>
<td>4 years ($1,000)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indiana</td>
<td>4 years ($10,000)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Massachusetts</td>
<td>2 years ($600)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oklahoma</td>
<td>1 year ($1,000)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Virginia</td>
<td>1 year ($1,000)</td>
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The greatest problem faced by the prosecution in establishing a prima facie case of larceny by false pretenses is the burden of proving intent to defraud. In Massachusetts, for example, the prosecution is hampered by inappropriate and unrealistic burdens imposed by a statute which was not originally enacted as a tool to protect consumers. For instance, if a consumer purchases a "lifetime" contract from a health spa which closes its doors shortly after selling the contract, or a consumer places a deposit on a trip which is cancelled and never receives his money back, the prosecutor must prove that there was an intent to defraud at the time the money was taken. Proof that the wrongful act occurred with evidence that the operator failed to disclose information which would have affected the consumer's judgment, or evidence of the operator's failure to correct a previous...

31.03 (1975); UTAH CODE ANN. §§ 76-3-203, 76-3-301, 76-6-412 (1975); VT. STAT. ANN. tit. 13 § 2501 (1972); VA. CODE ANN. § 18.2-95 (1975); REV. CODE WASH. ANN. §§ 9A.56.030, 9A.20.020 (1961); W. VA. CODE ANN. § 61-3-13 (1957); WIS. STAT. ANN. § 943.20 (1955); WYO. STAT. ANN. 61-3-13 (1957); D.C. CODE § 22-2201 (1953); GAM Penal CODE § 489 V.I. CODE tit. 14 § 1033 (1941). Note that these statutes apply to larceny or theft by a person. Some states impose a higher fine where the crime is committed by a corporation. See e.g. ORS. REV. STAT. tit. 16 § 161.655 (1971).

I. one of two possible alternatives
II. and/or double the gain from the theft
III. with or without hard labor at court's discretion
IV. fine in court's discretion
V. or double the gain from the theft, whichever is greater

33 MASS. GEN. LAWS ch. 266 § 33 (1932). To constitute the crime of larceny by false pretenses in Massachusetts, it must appear that there was a false statement of fact or present intention known or believed by the defendant to be false, made with the intent that the person to whom it was made should rely upon its truth, and that such person did rely upon it as true and parted with personal property as a result of such reliance. Commonwealth v. Green, 326 Mass. 344, 94 N.E.2d 260, 263 (1950); Commonwealth v. Louis Construction Co. Inc., 343 Mass. 600, 604 (1962). Note, however, MASS. GEN. LAWS ch. 175 § 176 (1932) establishes an evidentiary presumption which reduces the prosecutor's burden of proof in cases where insurance agents fail to pay premiums over to the Insurance Companies. Commonwealth v. Baker, 1975 Mass. ADV. SR. 1909-10, 830 N.E.2d 794, 808.


ly created or reinforced false impression, should be, but is not, sufficient to establish a prima facie case. 86

Another problem with traditional criminal laws concerns their applicability to corporate officers who attempt to insulate themselves from personal liability for their fraudulent practices within a protective corporate framework. Under existing Massachusetts law, for example, corporate officers and directors may be held personally liable for criminal acts only as narrowly provided by statute 87 or as provided by restrictive common law.88 The criminal liability of corporate officers and directors should be in accord with the recognized responsibility of corporate officers to be aware of their corporation's activities where they stand in a responsible relation to a public danger.89 Federal courts recently have held that criminal liability may attach to a corporate officer or director who has "deliberately closed his eyes to the obvious." 40

86 See American Law Institute, Model Penal Code § 223.3 (1962) [hereinafter Model Penal Code].
88 Massachusetts common law attaches criminal liability to an officer or director when he is actually present and an efficient actor in committing the offense, United States v. Winslow, 175 F. Supp. 578, 581 (D. Mass. 1959); or where the officer or director directed and assented to the unlawful act, Commonwealth v. Abbott Engineering, 351 Mass. 568, 580, 222 N.E.2d 862 (1967); or where the officer or director "participated in the act or countenanced it or otherwise approved it," Commonwealth v. Riley, 196 Mass. 60, 62, 81 N.E. 881, 882 (1907).
89 United States v. Park, 421 U.S. 658, 670-73 (1975) wherein the Supreme Court upheld the criminal conviction of an executive of a national retail food chain for violation by his company of a provision of the Federal Food Drug and Cosmetic Act despite his defense that he was not personally responsible for the action constituting the basis of the charge. The court noted that the purpose of the act was to protect people who were beyond self-protection and in the interest of the larger good the burden of awareness was placed on the person standing in a responsible relation to a public danger.
40 United States v. Natelli et al., 527 F.2d 511 (2d Cir. 1975) cert. den. 96 S.Ct. 1663 (1976). Federal cases have found the requisite criminal intent where the defendant: (1) made statements with reckless indifference or disregard as to whether they are true or false; (2) closed his eyes to what was plainly to be seen; (3) acted with a conscious purpose to avoid learning the truth; (4) failed to exercise due diligence to ascertain the truth; (5) acted with such gross carelessness and indifference to the truth of the representation contained in the statement as to warrant the conclusion that he acted fraudulently. Curnow, Economic Crime, A High Standard of Care 5 Fed. Bar J. 21, 23 (1976).
B. Model Penal Code: Deceptive Business Practice Act

The need to revise traditional larceny statutes has been recognized by many states. The American Law Institute has reported that as of April, 1976, twenty-nine states have revised their criminal code. Of those, at least five have revised their larceny statutes along the lines of the Model Penal Code. Under the Code, proof of facts other than intent to defraud carries the prosecution's burden of proof in numerous instances.

The Model Penal Code includes a Criminal Deceptive Business Practice Act. Under the act, proof that the specifically proscribed conduct occurred is sufficient to establish a prima facie case without any showing of intent to defraud. At least four states have enacted statutes modeled after this Act. However, constitutional standards limit the extent to which inferences may be established by statute.

At least sixteen of the twenty-nine states reported to have revised their criminal codes have adopted provisions similar to the Model Penal Code defining the personal liability of corporate officers in accordance with the recognized public

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See American Law Institute, ANNUAL REPORT OF THE 53RD ANNUAL MEETING (1976).

Cited statutes and definitions:
- Model Penal Code, supra note 36 at § 223.3.
- See also Wis. Stat. Ann. § 100.22. See also PROPOSED CRIMINAL CODE OF MASSACHUSETTS & 266 § 82 (1962) [hereinafter cited as FCCM].

A statutory inference is constitutional if the presumed fact is more likely than not to flow from the proved fact, and there is a rational connection between the proved fact and the presumed fact. Barnes v. United States, 412 U.S. 837, 842 (1973). Moreover, although intent is typically considered a fact peculiarly within the knowledge of the defendant, this does not justify shifting the burden to him. Unique hardship on the prosecution may, however, justify requiring the defendant to carry the burden of proving a fact critical to criminal culpability; e.g., presumption of sanity. Mullaney v. Williams, 95 S.Ct. 1881, 1891 (1975). In the interest of the public good the burden may be shifted to the defendant where he stands in a responsible relation to a public danger. United States v. Park, 421 U.S. 658, 670-73 (1975); see note 39, supra. Note however that in a criminal case the trier of facts is permitted, but not compelled, to draw from the basic fact the statutory inference. Commonwealth v. Pauley, 381 N.E.2d 901 (Mass. 1975).
responsibility of the business community. Under the Model Penal Code a corporate officer or director is liable for any conduct he performs or causes to be performed in the name of the organization or in its behalf to the same extent as if it were performed in his own name or behalf. Criminal liability is also imposed where the agent having primary responsibility for the discharge of a duty recklessly omits to perform the required act.

C. Criminal Sanctions for Violation of the Consumer Protection Act

Although a consumer protection act is a civil statute, it may also provide criminal sanctions. Presently, six states impose criminal sanctions for violations of their consumer protection act. Five of these states provide for a maximum sentence of one year in prison and/or fines ranging from a high of $10,000 in Alaska, to a low of $250 in Arkansas. Three of the states, Alaska, Maryland and New Hampshire, do not require any proof that the violation was knowing, willful or intentional.

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47 Model Penal Code, supra note 36 at § 2.07(6). See also PCCM, supra note 44 at ch. 263, § 23.


49 Note, however, that Alaska has not brought any criminal prosecutions under this act partly because of serious constitutional questions which would prevent successful prosecution. Letter from Stanley T. Fischer, Chief of the Consumer Protection Section of Alaska's Office of the Attorney General dated November 28, 1976. Partly for the same reason, New Hampshire is reluctant to use its statute and has brought only one prosecution, unsuccessfully, under the act. Telephone conversation with New Hampshire Assistant Attorney General John Funk on
Although the direct imposition of criminal sanctions for violations of the consumer protection act obviates the prosecutor's problems of tailoring specific conduct to existing larceny statutes or other economic crime statutes, it is not necessarily desirable or effective. Criminal sanctions may provide the operator with Fifth Amendment grounds of self-incrimination to avoid divulging otherwise discoverable matter in civil actions brought by consumers as well as the state. In addition, the obligation of the courts to strictly construe criminal statutes could force strict construction of the statute in civil actions as well. Furthermore, there may be serious constitutional questions of due process unless the statute is precisely drawn. These consid-

December 6, 1976. Maryland has brought criminal prosecutions under her act only recently and John N. Ruth, Jr., Chief of the Maryland Attorney General's Consumer Protection Division, has indicated the criminal provision is a troublesome section. Letter from John N. Ruth Jr. dated December 2, 1976.

Massachusetts prosecutors cannot grant immunity to the operator to compel testimony because MASS. GEN. LAWS c. 233 §§ 20C-20F do not apply to civil trials. See People v. Superior Court of Los Angeles, 525 Pa.2d 716 (Cal. 1974). In addition, Massachusetts, pursuant to induced a protective order under California's code of civil procedure to protect parties or witnesses from "annoyance, embarrassment or oppression" and further stated that no specific legislative authorization for judicial grants of immunity is required. See Mass. R. Civ. P. 26(c). In addition, the Fifth Amendment privilege provides limited protection: (1) the Fifth Amendment is designed to protect "evidence of a testimonial or communicative nature," not previously recorded tangible business records. See, Schmerber v. California, 384 U.S. 757, 761 (1966); (2) the right to be free from self-incrimination is a personal right applicable only to natural persons and cannot be exercised by a business entity. Hale v. Henkel, 201 U.S. 191, 197-198 (1906); U.S. v. Kordel, 397 U.S. 1, 7 (1970). Although an individual may not be compelled by subpoena to produce documents which would incriminate him, Fisher v. U.S., 19 Crim. Law Reporter 3183 (1976), documents seized by search warrant may be introduced as evidence, Andersen v. Maryland, 19 Crim. Law Reporter 3183 (1976). See infra note 66 and accompanying text.

Commonwealth by Creamer v. Monumental Properties, Inc., 314 A.2d 333, 337-38 (Pa. 1973); but see Turner v. Koscott Interplanetary, Inc., 191 N.W.2d 629 (Iowa 1971) wherein the court held that the act is to be interpreted liberally where a remedy is sought, and strictly when the action brought is criminal.

See note 49 infra, for indications to this effect from prosecutors in states which include criminal sanctions in their consumer protection act. Due process challenges that the statute is void for vagueness turn on the wording of the phrases challenged as unduly imprecise. As guides to make terms which are challenged as unconstitutionally vague more precise, courts have made reference to standard dictionaries, People v. Witzerman, 105 Cal. Rptr. 284, 291 (Cal. App. 1972); common sense and legislative intent, Kugler v. Market Development Corp., 306 A.2d 489, 492 (N.J. 1973); common law and federal trade law, State v. Readers Digest Association, Inc., 501 F.2d 290, 301 (Wash. 1972).

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orations argue against the desirability of criminal sanctions for violations of a consumer protection act.

D. Use of the Criminal Statutes

Although revisions of criminal statutes to distribute the burden of proof realistically in accordance with the interests of the public and the recognized responsibilities of the business community enhance the attractiveness of criminal prosecution as a tool to prevent unfair and deceptive trade practices, criminal prosecution is appropriate in only a limited number of situations. An overriding policy concern is whether the violation of law is severe enough to merit a criminal sanction. In this regard, the prosecutor must consider the need for strong deterrent measures to discourage others from the commission of like offenses as well as society's demand for discipline or punishment of the wrongdoer.

Even if criminal prosecution is deemed appropriate, there are problems generally associated with the prosecution of economic crimes which must be resolved. Because a criminal conviction requires a higher standard of proof than a civil action, more sophisticated investigations may be required to establish a prima facie case in a criminal trial than in a civil trial. For the same reason, criminal trials tend to be longer and more complicated than civil trials. In addition, because an injunction is unavailable in a criminal prosecution, the criminal defendant may continue operating with impunity right up to the time of trial.

Criminal convictions in economic crimes generally result in light sentences; and, even if a substantial penal sentence

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54 Because the court has no statutory authority to issue an injunction in a criminal prosecution it may be necessary to institute a civil action seeking injunctive relief. See infra note 54 and accompanying text.

55 ROBACHIO, supra note 28 at 636; EDELEBERT, supra note 53 at 58-59. Bernard Bergman, a central figure in the New York nursing home scandal, was sentenced
is imposed, criminal consumer fraud offenders rarely remain confined for more than the minimum term. Finally, a criminal prosecution does not necessarily provide restitution for the victims. However, restitution is commonly suggested by the defendant in negotiations with the prosecutor, in open court as a factor justifying a more lenient sentence, or may be considered by the judge as a condition of probation.

by United States District Court Judge Marvin Frankel to serve four months in Federal Correction Center. Mr. Bergman pleaded guilty to two counts of a federal indictment alleging Medicaid and tax fraud of 1.2 million dollars and to a state indictment charging the bribery of Albert H. Blumenthal, the majority leader of the New York assembly.

During the sentencing proceedings, Judge Frankel read from a long memorandum in which he discussed the theory of sentencing. He described the four-month sentence as stern. Judge Frankel acknowledged that the defendant’s actions had been blatant and unmitigated. He balanced these facts by observing that Mr. Bergman was an elderly man whose life was marked by illustrious public works. Judge Frankel stated: ‘The case calls for a sentence that is more than nominal. Given the other circumstances—including that this is a first offense by a man no longer young and not perfectly well, where danger of recidivism is not a concern—it verges on cruelty to think of confinement for a term of years.'

Charles J. Hynes, Special Prosecutor for Nursing Home Violations, stated that he was ‘extraordinarily disappointed’ by the sentence. He expressed a fear that the sentence would encourage public cynicism about special justice for the elderly and would also damage the continuing investigation into nursing home abuses. The special prosecutor said that Mr. Bergman had made a ‘palpably absurd’ offer to repay $367,000 defrauded from Medicaid; the state auditors had uncovered thefts totaling 2.5 million dollars. Mr. Hynes also stated the defendant had been less than forthcoming in cooperating with the special prosecutor’s office in the ongoing investigation into nursing home abuses in violation of the plea bargain agreement reached by attorneys for Mr. Bergman and federal and state prosecutors. Mr. Hynes also stated that he would consider reopening the prosecution of Mr. Bergman in state court. Reported in III ECONOMIC CRIME DIGEST 164:65 (National District Attorneys’ Assoc.).

See 18 U.S.C. § 3651 (1970) MASS. GEN. LAWS ch. 276 § 92 (1972); MEX. REV. STAT. ANN. tit. 17-A § 1204 (1976); N.M. STAT. ANN. § 40A-29-18 (1953); N.D. CENT. CODE § 12.1-32-07 MODEL PENAL CODE § 301.1 (1962); PCCM, supra note 54, at ch. 264, § 21 (these statutes make restitution a legislative guideline for probation). See also MD. ANN. CODE art. 27, § 340 (1976); NEB. REV. STAT. § 28-506 (1974); N.D. CENT. CODE § 12.1-32-08 (1978); S.C. CODE ANN. § 17.559 (1972) (these statutes compel restitution as part of the sentence). In the absence of appropriate criminal statutes or procedures the prosecutor must consider instituting a civil action to obtain restitution for defrauded consumers. See also UTAH CODE ANN. § 76-6-412 (1953), which allows the injured party to bring action for treble damages, costs and attorneys fees.
III. TACTICAL CONSIDERATIONS — THE INTEGRATION OF CIVIL AND CRIMINAL REMEDIES

The integration of civil and criminal remedies in one consumer protection program is essential to achieve the objectives of deterring fraudulent practices and compensating victims in a timely and efficient manner.\(^8\)

A. Considerations at the Investigative Stage

In a co-ordinated consumer protection program, the enforcing agency should make an initial determination at the investigative stage of whether to proceed civilly, criminally, or both. Such a determination should be based on criteria which the prosecutor, in his experience, has found significant, such as: (1) available resources; (2) target priorities to alleviate particular problems; (3) the need for immediate temporary relief; and, (4) the likelihood of success in a criminal prosecution.

State consumer protection acts typically contain authorization for the administering or enforcement official to conduct investigations through use of subpoenas.\(^9\) However, some states prohibit the use of information obtained thereby in a subsequent criminal proceeding.\(^9\) This limited form of subpoena is commonly referred to in Massachusetts as a Civil Investigative Demand (CID).

The CID gives the enforcing agency, prior to the filing of a complaint and without any showing of probable cause, the right to inspect and copy business records which may be relevant to an investigation. The CID may also compel the attendance of a person at a deposition under oath. It may be issued whenever the enforcing agency believes a violation of the Consumer Protection Act has occurred, or to assure the enforcing agency that the law is not being violated.\(^6\) In a criminal investigation, on the

\(^8\) See Edelhertz, supra note 5 at 38-44.
\(^9\) FTC Fact Sheet, supra note 2.
other hand, a warrant to search and seize is available only after there has been a showing to a neutral, detached magistrate that there is probable cause to believe that contraband, fruits, instrumentalities or evidence of a crime are present in the place to be searched. However, these and other considerations surrounding the choice of pre-litigation tools are obviated in states where the Attorney General has broad subpoena powers. Evidence obtained thereby may be admitted in either a civil or criminal proceeding.

B. Consideration at the Litigation Stage

After the investigative stage, a re-evaluation should take place to determine whether to file a civil suit, seek a criminal indictment, or both. In addition to considering the criteria relevant at the investigative stage, this second determination should be based on how best to deter the activity from recurring in the future and how best to rectify the present situation. In a civil action, for instance, a temporary restraining order and preliminary injunction are available to immediately halt unlawful practices. In certain situations, therefore, it might be advisable to initiate a civil action for the purpose of obtaining a restraining order and injunction, and subsequently seek a criminal indictment after the unlawful practices have been stopped.

There are numerous general factors which tend to support the pursuit of civil rather than criminal remedies. In a civil action:

1. The defendant may not have the right to a jury trial.
2. There is a less onerous burden of proof on the plaintiff.

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64 R.P. ALASKA STAT. § 45.50.495 (1976); ARK. STAT. ANN. § 70-909 (1964); COLO. REV. STAT. § 6-1-108 (1973); W. VA. CODE ANN. § 46A-7-104 (1976).
66 The Seventh Amendment does not control the actions of the states in abridging trial by jury but applies only to the courts and Congress of the United States. Minn. & St. Louis R.R. v. Bombolis, 241 U.S. 211, 217 (1916), Vallavanti v. Armour & Co., 264 Mass. 837, 342, 162 N.E. 689 (1929). Because injunctive relief and
3. The defendant’s Fifth Amendment rights against self-incrimination are more limited.66

4. There are tools of discovery that are not available to the state in a criminal action.

5. Restitution may be obtained by order of the court.67

6. The resolution of proceedings may be more rapid.

7. A suit may be maintained even against an out-of-state defendant,68 thus avoiding cumbersome extradition proceedings under a criminal indictment.69

8. The state may appeal an unfavorable decision, but is barred from doing so in a criminal prosecution on grounds of double jeopardy.70

9. The defendant has no constitutional right to be confronted by the witnesses against him.71

These considerations must be weighed against the known advantages of a criminal prosecution:

1. Successful criminal prosecution of several offenders acts as a significant deterrent to other prospective offenders.72

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66 See note 65, supra. Where there is a possibility that evidence obtained from an individual is to be used in a subsequent criminal proceeding against that individual, the invocation of Fifth Amendment privilege may be proper. U.S. v. Churchill, 483 F.2d 268, 272 (1973); U.S. v. Kordell, 397 U.S. 1, 7-8 (1969); however, the Fifth Amendment does not forbid adverse inferences to be drawn against parties to a civil action who choose to exercise this privilege. Baxter v. Palmigiano, 96 S.Ct. 1551, 1558 (1976). See also supra note 50.


71 Id.

72 See notes 28-31 supra and accompanying text.
2. The habitual consumer-fraud offender may be isolated from society for a period of time.\(^7\)

3. Criminal acquittal does not bar a subsequent civil action on the ground of double jeopardy.\(^8\)

In order to determine the most efficient and effective plan of action, each case must be evaluated on its own merits in terms of the competing considerations discussed above. Therefore, consumer problems should be referred to one centralized agency capable of implementing an integrated approach. An agency which is not versed in both civil and criminal consumer protection statutes will be handicapped in its efforts to discern and pursue the most appropriate available remedies.\(^9\)

IV. Conclusion

Effective consumer protection programs are dependent upon the coordination of both civil and criminal remedies which must provide for measurably strong sanctions if they are to be effective.\(^6\) The potential offender must be given notice that if he pursues a deceptive course of conduct, he will be severely penalized.\(^7\)

The private right of action alone is not adequate because many consumers do not know when they have been cheated,\(^8\) are ignorant of their rights,\(^9\) or are discouraged by the high cost of

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\(^7\) Rothchild, supra note 28, at 690.

\(^8\) Bowley, supra note 11, at 565.

\(^9\) E.g., the Maryland Attorney General has no criminal jurisdiction and must rely on local state's attorneys. Although several matters have been referred to local state's attorneys, criminal actions are rarely brought. Letter from John N. Ruth, supra N. 49. The Alaska Attorney General's Consumer Protection Section has no personal experience in criminal law and there is an apparent unwillingness on the part of the state's criminal prosecution staff to handle consumer fraud. Letter from Stanley T. Fischer supra N. 49.


\(^7\) See Rothchild, supra note 28 at 690-91, 693.

\(^8\) See Consumer Protection by Prosecutors, supra note 11 at 84.

\(^9\) State Programs for Consumer Protection 44 (National Association of Attorneys General, 1973)
litigation as compared to their individual loss. In addition, the response of federal enforcement agencies to the immediate needs of defrauded consumers is too limited. For these reasons, an aggressive state authority, capable of seeking sanctions of recognizable severity is necessary to deter unfair and deceptive trade practices.

An effective state legislative program should include, at a minimum, a consumer protection act with civil penalties for initial violations as well as criminal statutes appropriate for the prosecution of economic crimes. This may mean revising existing larceny statutes as well as enacting legislation directed specifically at problems of consumer fraud.

Legislation which protects consumers protects honest merchants as well. Whenever a consumer is defrauded, an honest merchant is injured, because he has lost a sale to a customer who has been induced to buy from the dishonest merchant offering "a better deal." Furthermore, when the consumer learns he has been unfairly treated he may be apprehensive when dealing with anyone in that business because he is not willing to assume the risk of loss attendant upon another unfair transaction. Aggressive enforcement of effective consumer legislation fosters an atmosphere in which the consumer develops greater confidence in the free market system since businesses are responsive to legitimate grievances. This increase in confidence influences consumer demand for goods and services to the benefit of the entire community, merchants as well as consumers.

80 Id., supra note 76 at 567-570.
81 FTC proceedings generally involve extensive delays. Cases can take about a year to reach the Commission in the first place for the issuance of a complaint. (See Comparative Fair Advertising Legislation, a Beginning (ADELAIDE L. E, 1971). Efforts to provide restitution through federal proceedings would be cumbersome considering the possible need to give the defendant a hearing in every jurisdiction where the alleged violation occurred and as to every consumer claimant, and federal budgets will never be sufficiently large nor federal personnel so numerous to protect the consumers in all states and localities. Letter from Gale P. Gutterball, FTC Counsel for Federal-State Cooperation, dated January 4, 1976.
Consumerism lives! ... and grows

by E. Patrick McGuire

Several years back a news magazine, examining the state of religion in America, asked on its cover "Is God Dead?" (He was not.) A few years later another magazine wondered, on its cover, whether consumerism was dead (It is not.)

It has been the belief among many senior executives, however, that consumerism, if not yet dead, is certainly moribund. And the 1977 defeat of the Consumer Protection Act seemed to support that point of view. Indeed, Edie Fraser, president of Fraser Associates, one of the country's top consumer consulting firms, advised her corporate clients that "Carter Administration hopes for legislative consumer initiatives in 1977 have gone up in smoke. No major piece of consumer legislation has been passed since the Magnuson-Moss Act and the Medical Device Act of 1976."

Despite the leadership of consumer grande dame Esther Peterson, all the consumer organizations could not muster forces to overcome major opposition by business and many Congressional leaders.

But a new picture, obtained from a Conference Board survey of nearly 100 consumer affairs and customer relations executives and interviews with the directors of a number of consumer advocate organizations, indicates that the movement remains remarkably healthy and influential. Consumerism, in fact, is here to stay.

How, then, have so many senior managements come to misjudge the situation? Consumer affairs managers believe it is because some business executives, despite all that has been written to the contrary, still view consumerism primarily as the expression of what is wanted by advocates not by consumers as a class — and that these wants are translated into new legislation and regulations.

Thus, in their minds, the legislative scorecard became all-important in assessing the strength of the movement. When the score declined — i.e., fewer laws, more emphasis on deregulation — they assumed that consumerism had spent its momentum.

Such a misperception betrays some consumer affairs specialists' Mary Gardner Jones, formerly an FTC commissioner, now a vice president of Western Union — says, "Some businessmen have never understood consumerism perhaps never will. They just can't seem to grasp the breadth of the movement." Consumer affairs executives, however, know the truth of the situation.

These executives are confronted by an increasing number of customer complaints. Their legal departments, they report, are "inundated with lawsuits" by consumer plaintiffs. According to the results of the Board's survey, consumer affairs executives, by two to one, believe that consumer advocates are having an increasing impact on the public and government.

And several major companies report that the number of customer complaints has jumped by more than 50 percent during the past two years.

Moreover, the number of Americans complaining to regulatory agencies has increased — in some cases, dramatically — over the past two or three years. Complaints to the Comptroller of the Currency about banking policies and practices have doubled in three years. Calls on the Consumer Product Safety Commission's hotline — a direct line for reporting or inquiring about unsafe products — have doubled in the last year. And the consumer complaint rate — complaints per population — has climbed notably at the Food and Drug Administration, Civil Aeronautics Board, Federal Trade Commission and other agencies.

Consumer advocates, because they are often among the first recipients of consumer complaints, are well aware that the tide of consumer dissatisfaction is still rising. But who are the consumer advocates, and what do they want? Organizations include a dozen or more umbrella-type...
groups—such as Ralph Nader's Public Citizen, The Consumer Federation of America, The Conference of Consumer Organizations, The National Consumer League—that tend to deal with a broad range of consumer issues, from financial services to truth in advertising. To a great extent, there is general agreement among these groups on various issues. On the other hand, there are many consumer groups that focus narrowly on specific issues, and their impact on business can be quite substantial.

GASP (Group Against Smoking and Pollution), for example, is concerned almost exclusively with smoking pollution and its reputed harm for nonsmokers. But this focus certainly affects many sectors of the economy other than cigarette manufacturers, particularly when government agencies decree that separate facilities must be provided for nonsmokers in planes, restaurants, trains. ACT (Action for Children's Television) concerns itself with advertisements aimed at young television watchers. But their efforts also reach the manufacturers of the products being advertised. And, the impact of these groups may be more serious than that of some of the broader range advocacy organizations.

Consumer affairs executives like to stay in touch with those groups that have an influence on these companies. Businesses and about half of those surveyed say they make regular contact with them. Identifying consumer advocate organizations, however, isn't always easy. And simply communicating on the traditional avenues isn't sufficient to fill the corporation's needs, since there is increasing evidence that organizations previously not thought of as consumer advocates are very much in the forefront of consumer issues.

Consider the American Association of Retired Persons (AARP), a group whose membership totals more than 12 million Americans over the age of 55. The AARP took on the issue of generic versus trade name drug prescriptions. Although the over 55 members of our population account for only 11 percent of the total population, they purchase 25 percent of all the prescription drugs sold—more than $2 billion worth each year. By not having the option of substituting generic drugs for brand name ones, they were paying more than they would have had they been able to buy generic drugs. Unable to effect a change at the national level, AARP lobbyists adopted a grassroots strategy and took their case to the state legislatures. The result? Since 1970 more than 40 states have adopted laws allowing... and in some states requiring... pharmacies to substitute generic drugs for brand names. Some companies, with a large investment in brand name drugs, have fought an unsuccessful guerrilla war against AARP lobbyists. In terms of media visibility, AARP was not ranked with some of the Nader organizations, but certainly it has been a force in the drug companies.

Now getting into the act are various health organizations—e.g., the American Heart Association, the Lung Association and the like. They may support the regulation—or even the abolition—of specific products or services, or urge government intervention on behalf of consumers in the sale and distribution of certain goods (such as artificial sweeteners). And any attempt to identify the most influential consumer advocates must take into account certain government officials who perform advocacy functions. In the insurance sector, for example, Herbert Dennenberg, former insurance commissioner for the state of Pennsylvania, is regarded as a pioneer in exposing insurance abuses and in drafting remedial action.

Or take California Gov. Jerry Brown, who joined such notables as Ralph Nader, Jane Fonda, Gray Panther founder Maggie Kuhn, and Dr. Benjamin Spock this past May in Washington, D.C., to participate in the anti-nuclear rally. The rally brought together an unlikely alliance of such groups as the Communist Party, the International Association of Machinists, the Union of Concerned Scientists, the Canned Milk Alliance, the Gay Liberation Movement, and many more. Among the groups was the Campaign for Economic Democracy (C.E.D.)

Despite the plethora of consumer advocate organizations, as well as corporate consumer affairs specialists, many dissatisfied consumers find that they must turn to the Federal government for assistance in resolving complaints. But the government's own studies show that the individual complainant is likely to receive short shrift from many, if not most, regulatory agencies.

Such was the finding of the Department of Health, Education and Welfare in a study of the handling of complaints by 22 federal agencies during a two-year period. The study revealed that most of the agencies treated consumer complaints as general public correspondence with no attempt made to analyze the data in order to use them to help formulate policy decisions. In 1978 consultants again visited the agencies and found that almost two thirds were attempting to segregate complaints and handle them more systematically. But Esther Peterson, President Carter's Consumer Affairs Adviser, in announcing the results of this study also pointed out that the survey revealed that the agencies did not really provide much assistance to individual complainants. Indeed, the study itself concluded: "The Federal agencies' general exhibited weaknesses in a number of complaint handling functions. Some of these weaknesses..."
are due to government-wide standard operating procedures and civil service regulations. Others are due to management's failure to understand the importance of performing these functions effectively. This lack of awareness has resulted in the allocation of insufficient resources for the performance of many complaint-handing functions.

Several consumer advocates, when interviewed, wondered whether there is, in reality, a need to coordinate the government's complaint processing functions if the agencies aren't really doing anything for the consumer by helping to resolve individual complaints. As one presidential aide explained, "In order to get a Federal agency involved in a complaint you have to be dealing with really big numbers. The agencies just don't want to have anything to do with an individual's complaint. They don't have the interest or the resources. They want to take on whole industries, to deal with basic economic inequities."

One result of this situation is that many of the consumer advocates have become disillusioned with government regulation as the business community has been. The picture that emerges from interviews with the advocates is that too many of the regulations are vague, arbitrary, even counterproductive. As a whole.

-- Ralph Nader who has had much to do with the "Federal policemen" in action (agencies such as the Consumer Product Safety Commission and the National Highway Traffic and Safety Administration), judges the regulators to be, often, more intractable foes than the companies he opposes. While it may come as a surprise to some of his adversaries, Nader continues to have considerable faith in a free and responsible enterprise system. It is his belief that a more rigorous enforcement of statutes that foster competition, such as antitrust laws, would go a long way toward correcting abuses that result from "product oligopolies"—dominance by a few suppliers.

Nader also subscribes to the theory that civil litigation, particularly the class action suit, is a powerful deterrent to corporate transgressions. Absence of individual consumers, he points out, often amounts to only a few dollars per customer. But millions of consumers may be involved. He would like to see the rules of procedure changed to make it easier for class action suits to be filed in the Federal courts on behalf of consumers. And he would oppose significant alterations in tort liability statutes, such as a statute of limitations on claims or the use of state of the art defenses that would result in reducing the consumer's access to product liability litigation.

Arlie W. Schardt, former executive director of the Environmental Defense Fund, agrees with Nader that the best way to get something done is through litigation. The targets of the Fund's suits, however, are the regulatory agencies themselves. The Fund has been involved in suits ranging from porpoise protection to Federal coal leasing. In suits aimed at getting Federal agencies to do what the law already empowers them to do. And the advocates point out that in some instances the agencies may actually welcome such suits. For a variety of reasons (including political considerations), regulations may be hesitant to enforce the letter of the law. But if an agency is sued and loses a court decision, it can evade the (political) responsibility of its activities by pointing out that their actions have been court mandated.

In the early days of Carter's Presidency he promised to "cure Nader" Nader; and he appointed several consumer advocates to government posts, including Carol Tucker Force, former director of the Consumer Federation of America, who accepted a position as an under secretary in the Agriculture Department, and Joan Claybrook, an auto safety specialist and a Nader associate at Congress Watch, who was named to head up the National Highway Traffic and Safety Administration (both of whom escaped the Carter staff purge). These and other well-publicized appointments created the impression that the Carter Administration was actively pursuing a campaign designed to give consumerism a voice in various government agencies. The reality, consumer advocates say, has been quite different.
Of the 50-plus sub-Cabinet positions appointed by Carter, fewer than a half-dozen could be said to have bona fide credentials as consumer advocates. Many more individuals from business or academia have received such posts. And the track record—and influence—of those consumer advocates who have moved into the regulatory agencies is mixed. Indeed, a 1977 study by Common Cause found that regulatory agency executives consult business lobbyists "ten times more often than they do consumer representatives." Belying consumer advocacy influence over regulatory decision making.

A recent study by the Committee for Economic Development ("Redefining Government's Role in the Market System," a statement by the Research and Policy Committee, July 1979) points out that "all too often the cost of regulation, evidence about the cost of specific regulations shows that the numbers are substantial." One of the conclusions drawn in the report is that many senior managements would support moves to improve the system. Some of the cost has been born by consumers and workers. The pursuit of unrealistic mandatory standards has therefore raised costs of production, reduced productivity, and contributed to inflation.

A majority of the consumer affairs executives surveyed believe that the actions of advocates have helped to make products safer and easier to use. "They have made us more critical of ourselves, of the products we make, of the services we provide," one appliance industry executive said. The advocates are seen as providing one very valuable contribution: a viewpoint not available from inside the corporation. "As hard as we try to market 'perfect' products," says Nell E. W. Stewart, director of customer relations at Whirlpool, "we cannot always determine all of the possible effects of them in day-to-day use."

Perhaps one of the most significant areas of service improvement, according to the service executives, is in complaint handling. "Consumer advocates don't solve complaints," points out R. H. Janssen, director of consumer affairs for Culligan U.S.A., "but they do force companies to take measures to solve individual problems.

In some cases, consumer advocates have more influence on senior management than do the companies' own consumer affairs executives. "I see complaints, understandably, as a force to be quashed on this point, but there are clear indications that outside pressure exerted by consumer activists has, at times, made the job of the consumer affairs executives an easier one to accomplish. "Management tends to procrastinate on some of my advice for improving service. But when an advocate or regulator gets interested in the area, management stops delaying and acts to correct the problem," says an airline customer service executive.

The concerns and opinions of consumer advocates can also help clarify consumers' views and be a valuable source of market intelligence. "While believing that advocates are occasionally "out of step with the consumer's interest," Coca-Cola vice president Diane McLaughlin points out that "they are sometimes in the forefront of identifying issues," and it is useful to listen to and sometimes to act on such subjects as a more comprehensive response to the consumer's right to know."

From the standpoint of both strategy and policy, com-
Many professionals in the consumer movement, including the corporate consumer affairs managers, the advocates, and the regulatory agency staff members, expect that the movement will gain further strength in the early 1980s. There are certain issues that a majority of those surveyed expect to be of primary concern in the years immediately ahead:

1. Public participation and intervention in regulatory decision making, including public funding for such participation
2. Renewed pressure for the establishment of a Federal agency for consumer advocacy
3. Standards for complaint processing and settlement, including mandatory use of third party arbitration
4. Measures to protect consumers against economic abuses such as utility cutoffs, invasion of privacy, credit discrimination, unfair debt collection, the continuing issue of unsafe products
5. More precise definition of the rights of consumers to sue for damages, with particular emphasis on easing the entry barriers to Federal class action suits
6. Deregulation of the trucking, communication, and insurance industries - an extension of the successful de-regulation efforts at the Civil Aeronautics Board
7. Reform of antitrust statutes to allow consumers to recover damages from antitrust violations, and new legislation to inhibit conglomerate mergers
8. Most of these issues can only be resolved at the Federal level. But some can be resolved by state or county governments. First priority will be given to those issues that will effect cost reductions (e.g., tax savings), and it will come as no surprise to find that consumers and business are once again at odds. But consumer advocate groups, beginning to realize that business is not a monolith, that it is often possible to find allies within the business community.

As for companies, some have already perceived certain trends in the consumer movement and are moving in the same direction. Dwight Johnson, corporate consumer affairs specialist for American Telephone and Telegraph, says, "Companies are going to have to decentralize their consumer relations efforts. They're going to be more and more dependent on consumer-conscious local management."

What happens to consumerism in a recession, is it put on hold? Looking back at previous recessions, one finds indications that consumer dissatisfaction rises as economic activity falls. That makes sense. When people have less money to spend, their expectations about products and the services they do purchase tend to rise. But reality falls short of expectations, as it inevitably must. "We're hip deep in complaints right now," one appliance company executive said, "but the really high water is yet to come".
DEBATE PROPOSITION ONE

RESOLVED THAT: THE FEDERAL GOVERNMENT SHOULD INITIATE AND ENFORCE
SAFETY GUARANTEES ON CONSUMER GOODS

In late 1972, Congress enacted one of the most comprehensive consumer measures in history—namely, the Consumer Product Safety Act. The Act provided for the establishment of an independent Consumer Product Safety Commission (CPSC) empowered to develop and enforce uniform safety standards for consumer products and to ban reasonably hazardous consumer products from the marketplace. Since its creation, the agency has come under wide-ranging criticism. Most of the critics feel that the Commission does not act quickly or efficiently, and that it does not try to compare benefits and costs in deciding where Government safety standards are necessary. A more general case is made by some that the CPSC experience is typical of well intentioned government intrusions into the market—costly, counterproductive, and inept. Proponents of government regulation for health and safety feel that it is one of government's most basic functions, namely, promoting the general welfare, and that the benefits derived far outweigh the cost of an agency such as CPSC.

The above proposition deals with the entire question of Government regulation, which involves more than the history of one particular Government agency. However, the scope of the CPSC and its actions to date illustrate much that the regulation question involves. The following articles provide background information on the CPSC, as well as other Government regulatory agencies, and look into the questions of safety, regulation, cost-effectiveness, and private enterprise.
The Consumer Product Safety Act—Its Impact on Manufacturers and on the Relationship between Seller and Consumer

By JAMES R. PATTON, JR.* and E. BRUCE BUTLER**
Washington, D.C.

ONE OF the most significant trends in the evolution of United States law with respect to the sale of goods has been the demise of a seller's power to limit his responsibilities to the purchaser or to subsequent purchasers for damage caused by the product sold.

A new phase in this evolution clearly has commenced, however, with respect to a limited, but nevertheless substantial, number of products. On October 27, 1972, the Consumer Product Safety Act became law.1 Significant new restrictions under the Act eventually will be placed upon production and distribution of a large number of consumer goods. This article will describe the new law and attempt a preliminary assessment of its implications.

I. Evolution of Buyer Protection

The doctrine of caveat emptor, which often protected a manufacturer from responsibility for damage caused by his product, has been undercut steadily over the past century. Tort liability long has been recognized for injury arising out of the negligent manufacture, first, of inherently dangerous goods,2 and then, of any product where a reasonable expectation of injury from such negligent manufacture existed.3 Further refinements to simplify the burden of proof of negligence, such as the doctrine of res ipsa loquitur, have assisted an injured consumer in securing recovery.4

Contract law long permitted recovery under a warranty theory in those limited situations where privity of contract existed between the manufacturer and the consumer.5 Contract warranty liability was extended a decade ago with the relaxation of the requirement of privity of contract.6 The recent doctrine of strict liability in tort has further increased the injured consumer's

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** Member of the Pennsylvania Bar.
2. See, Fruumer & Friedman, Products Liability § 3.02 (1971) and cases cited therein.
4. Fruumer & Friedman, supra note 2, at § 12.03.
5. Id. at § 5.01.

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ability to secure recovery from the manufacturer of a product causing injury. These developments all occurred at the state level. Each step was designed to compensate the injured consumer by increasing the consumer's ability to recover against the manufacturer of the product causing injury. At no time did the consumer have the right to restrain the marketing of hazardous products. Constitutional restrictions and limited resources restricted the extent to which states could regulate the distribution of hazardous products. By holding the manufacturer responsible for these injuries it was thought that the manufacturer would have a sufficient incentive to produce safer products.

The threat of adverse judgments and the supposed competitive disadvantage of unsafe products were not enough, however, to spur manufacturers to take the necessary preventive measures to avoid these injuries. In addition, all of these remedies under state law require resort to the judicial process, with the attendant delays and expense. When the economic loss is small, a consumer's opportunity to recover is, in practice, quite limited. Because of these weaknesses of state law in dealing with product liability loss, federal regulation became inevitable.

II. Legislative History of the Consumer Product Safety Act

Federal concern with product safety started in earnest during the mid-1960's, although federal involvement in the marketplace through the imposition of requirements on sellers in the interest of safety existed occasionally prior to this time. The Food and Drug Act became law in 1906, and the Flammable Fabrics Act was passed in 1953. Several other laws covering hazardous products had been enacted prior to 1965.

The present trend of federal involvement clearly began with the National Traffic and Motor Vehicles Safety Act of 1966. This Act required the Secretary of Transportation to establish motor vehicle safety standards applicable to motor vehicles and related equipment. Sale of non-conforming vehicles or equipment was prohibited. Remedies under the Act included civil penalties and injunctions. Manufacturers were required to notify purchasers if certain types of defects were discovered.

7 Greenman v. Yuba Power Products, Inc., 56 Cal. 2d 651, 388 P.2d 897 (1964), Restatement (Second) of Torts § 402A
8 The National Commission on Product Safety has observed: "Despite its humani- 

tation adaptations to meet the challenge of product caused injuries, the common law 
pus no reliable restraint upon product hazards." Final Report of the National 
9 21 U.S.C. § 301 et seq. The Act was later enlarged by cover conferences
10 15 U.S.C. §§ 1191 et seq. as amended
1159-50 (1965) for a complete review of legislation during this period
More than a half-dozen other laws followed in the succeeding five years, regulating poisonous packaging, the sale of products such as toys, boats, and household substances, as well as radiation emissions from electronic products.

In addition to this piecemeal approach to specific aspects of product safety, Congress created a National Commission on Product Safety in 1967 to study the problem in greater depth and to propose long-range solutions. The National Commission held hearings on various aspects of the problem from October, 1968, to March, 1970, and issued its final report June 30, 1970. The National Commission was quite critical of existing Federal legislation, characterizing it as "burdened by unnecessary procedural obstacles, circumscribed investigative powers, inadequate and ill-fitting sanctions, bureaucratic lassitude, timid administration, bargain basement budgets, distorted priorities, and misdirected technical resources." One recommendation of the National Commission was that an independent commission be created to establish standards for all hazardous consumer products. A consumer safety advocate on the staff of the standard-setting agency also was strongly recommended.

The Commission rejected reliance on voluntary industry standards as "legally unenforceable and patently inadequate." Because of the necessity of a consensus among manufacturers for a voluntary program, the Commission argued that the least responsible segment of an industry could retard progress in reducing safety hazards.

Legislation was first introduced late in the Ninety-first Congress, based upon a proposal prepared by the National Commission, to provide for an independent consumer product safety agency with authority to establish safety standards. No action on the bill was taken during that session, however. Efforts at passage of this legislation were renewed early in the Ninety-second Congress.

At the same time as the various bills regulating product safety were under...

18 Pub. L. No. 90-146, November 20, 1967
20 Id.
21 Id.
22 S 493 (June 1970).
23 S 983, introduced by Senator MODER (R-MO) ; S 1179, introduced on behalf of the Administration; and S 3419 reported by the Senate Commerce Committee as an original bill (April 1972).
consideration in the Ninty-second Congress, another piece of legislation had been introduced which would have created a consumer advocate, within the government.24 This latter bill to create a consumer advocate who would have had only generalized authority to intervene and no authority to regulate, created significant opposition which ultimately succeeded in killing the bill.

The product safety legislation, however, with specific provisions requiring extensive regulation of business, moved methodically through Congress and was passed by both houses in the closing days of the Ninty-second Congress. Although the bill contains much of the original National Commission proposal, significant changes were made in the House. The Act was signed by the President on October 27, 1972.

III. Provisions of the Consumer Product Safety Act

A. Structure

The Act establishes an independent commission, similar to the Federal Trade Commission or the Federal Communications Commission, which is charged with general responsibility for administering the Act. The National Commission's recommendation of an independent agency thus was adopted.25 No provision is included in the Act, however, for a consumer safety advocate on the Commission staff.

One of the compromises necessary to secure passage of the bill was the elimination of foods and drugs from the jurisdiction of this new agency and retention of this jurisdiction in the Food and Drug Administration. Other existing product safety legislation, however, is transferred to the Commission, to be administered according to the terms of these acts rather than under the new law.26

The Commission was to be established immediately after enactment. The Act generally came into force on December 26, 1972, although certain functions were not to be transferred to the Commission until March 26, 1973, at the earliest.

24 S. 3971 would have established a Consumer Protection Agency to represent consumers before federal, state, and local agencies. The Senate failed to limit debate on this bill three times during the closing weeks of the Ninty-second Congress by only eleven votes, and thus the bill died without consideration on the Senate floor.

25 Not only does the Consumer Product Safety Act (hereinafter CPSA) create an independent commission, but it grants the new commission autonomy from the executive branch generally, by providing (1) that the Commission's budgetary requests do not need Office of Management and Budget approval before submission to Congress and (2) that Commission testimony, recommendations or comments to Congress are not subject to prior executive branch approval. CPSA § 27(k)

26 CPSA § 10. The functions of HFW, FDA, Department of Commerce, and the FTC under the Federal Hazardous Substances Act, the Poison Prevention Packaging Act of 1970 and the Flammable Fabrics Act are transferred to the new Commission.
The Consumer Product Safety Act

B. Product Safety Standards

The new Consumer Product Safety Commission is required to develop product safety standards for those consumer products which it determines to present an unreasonable risk of injury to the public. The manufacture, distribution or importation of a product not in conformity with such a standard is prohibited. Standards promulgated under the Act can relate to the performance, composition, content, design, construction, finishing, or packaging of the product.

Under the procedure established by the Act, prior to the development of any product safety standard, the Commission is required to issue a notice indicating its determination that a safety standard is necessary to eliminate or reduce the risk of injury from a consumer product. The notice must contain information known to the Commission about existing standards and, in addition, must contain an invitation to persons interested in developing a standard for such product to submit to the Commission an offer to undertake such development.

The Senate version of the bill would have excluded manufacturers and other business interests from participating in the development of such standards. The conference committee deleted this amendment from the Act and thus persons with a direct business interest in the product to be regulated clearly are entitled to participate in the development of standards under the procedures set forth in the Act.

The Commission is precluded from promulgating a safety standard or from authorizing the development of an alternative standard after it has accepted one offer to develop a standard. The final version of the bill does permit the Commission to work concurrently on a standard, however, when the only person offering to develop such a standard is a manufacturer, distributor, or retailer of the product for which a standard is being developed. It is not

27. It should be noted that the Act applies only to consumer products, which are defined as an article or component part produced or distributed for sale to or personal use, consumption or enjoyment of a consumer in or around a household or residence, school or in recreation, (CPSA § 111a). Products intended for use primarily for industrial purposes are excluded, as are certain types of consumer products already subject to other regulatory legislation, such as tobacco, motor vehicles, economic poisons, boats, drugs, cosmetics and food.

28. 118 CONGO REC 9925 6 (daily ed June 21, 1972)
The Business Lawyer, April 1973

clear what the effect of Commission acceptance of an offer to develop a standard by a trade association representing these interests will be. From a policy standpoint, the Commission should be authorized to develop its own standard when the only offeror is a trade association, since this group's interest is identical to that of the manufacturers, distributors, or retailers acting individually.

The offeror is required to develop a standard pursuant to regulations and within a period of time set by the Commission. This period may not be more than 150 days after publication of the notice commencing the proceeding unless the Commission determines that there is good cause for this extension. The Commission may terminate development by an offeror if it determines that the offeror is unable or unwilling to complete its task within the period allotted. The Commission is required either to publish its proposed safety standard or withdraw its notice of proceeding within 210 days of publication of the notice of a need for such standard unless this period is extended by the Commission for good cause. Thus, if the Commission is dissatisfied with a standard developed pursuant to its acceptance of an offer, it could extend the time period and proceed to develop its own standard.

The Act requires the Commission to hold a rule-making proceeding, affording an opportunity for oral presentations, before it promulgates a standard. The Commission must consider a number of factors before it can promulgate the regulation, such as the degree and risk of injury, the need of society for the product, the effect of a standard on the utility, cost and availability of the product, the number of products which would be subject to the rule, and the means of achieving the public health and safety objective with minimum adverse effect on competition or the disruption or dislocation of manufacturing or other commercial practices. In addition, the Commission's determination to promulgate or withdraw a standard is subject to judicial review. Persons having standing to seek judicial review include anyone adversely affected by a rule, and specifically include a consumer or consumer organizations.

In addition, the Commission is empowered to seek a court order to have a product declared imminently hazardous even during the course of its standard-making procedure or despite the fact that a standard for the product exists. The Commission can request the court to order either temporary or permanent relief, which may entail seizure, public notice of the hazard, or recall, replacement, repair, or refund with respect to the product.

C. Effective Date of Standards

The effective date of any standard promulgated by the Commission may not be more than 180 days nor less than 30 days after the date of promulgation, unless the Commission determines that there is good cause for extending or reducing the period before the standard is to become effective. In no
The Consumer Product Safety Act

case, however, may the standard be made retroactive to a date prior to pro-
mulgation.

The Commission is authorized to prohibit stockpiling of a product between
the time of promulgation and the effective date of a standard. In order to
determine whether illegal stockpiling has occurred, the Commission is re-
quired to establish a base period for the product prior to promulgation of
the standard and to prohibit manufacture or import of a product at a rate
significantly greater than this base period.

D. Certification and Labeling

Every manufacturer of a product subject to safety standard is required to
certify that the product complies with such standard. Any certification given
must be based upon a reasonable testing program.

The Commission further is authorized to require labels setting forth in de-
tail a number of items about the product, including warnings regarding the
product and the date of manufacture. No product may be imported into
the United States unless it complies with applicable certification and labeling
requirements. Provision also is made for certification and labeling by private
labelers rather than the actual manufacturer. In this situation, the private
labeler assumes the responsibilities of the manufacturer under the Act.

E. Remedies

Any manufacturer, distributor, or retailer who determines that a product
fails to comply with an applicable consumer safety standard or that the pro-
duct contains a defect which could create a substantial risk of injury must re-
port this fact to the Commission.

The Commission, after an informal hearing, can require the manufacturer,
or any distributor or retailer, to give public notice of any defect creating
such a risk of injury or of failure to comply with an applicable standard and
to mail such notice to other manufacturers, distributors, retailers, or con-
sumers.

If the Commission determines that a substantial product hazard exists
because of the risk of injury or because of failure to comply with a standard,
it may compel the manufacturer, distributor, or retailer, at such business-
man's option, to repair, replace, or refund the purchase price for any par-
ticular product.

F. Inspection and Record-Keeping

The Act obligates manufacturers, distributors, and retailers to permit in-
spection of their facilities to determine compliance with the Act. In addition,
it requires manufacturers, private labelers, importers, and distributors to
maintain such records as the Commission shall require for purposes of de-
termining compliance. Retailers are specifically exempted from any record-
keeping requirements because of the burden which would be placed on them if records were required.

G. Preemption

The Act prohibits states or municipalities from establishing safety standards which are not identical to federal standards. Preemption thus exists only with respect to products subject to a federal standard.

States and political subdivisions are given the right to petition the Commission to exempt a local standard from the preemption clause if the state can show that the state standard imposes a higher level of performance than the federal standard; that this higher state standard is required by compelling local conditions; and that the state standard does not unduly burden interstate commerce.

H. Exports

Products destined for export, and which are so labeled, are not required to comply with federal standards.

I. Ban on Hazardous Products

The Commission is granted authority to ban further distribution of a product if it determines that the product presents an unreasonable risk of injury and that no feasible product safety standard would adequately protect the public.

J. Enforcement

Numerous methods of enforcement are provided under the Act. A knowing violation of the prohibitions contained in the Act subjects the person to civil penalties of up to $500,000. If the violation is willful as well, criminal penalties may be imposed. Injunctive relief against further distribution or seizure of goods already in commerce may be sought in U.S. district courts by the Commission (with the concurrence of the Attorney General) or by the U.S. Attorney General. Any interested person may seek injunctive relief to enforce safety standards and may recover a reasonable attorney's fee. A private right to damages for loss by reason of a knowing violation of a safety standard is created under the Act.

K. Miscellaneous

The Act provides for the creation of a Consumer Product Safety Advisory Council, which the Commission may consult, but is not required to consult, at any stage in its proceeding. The Advisory Council is to be composed of five governmental representatives, five industry representatives, and five con-

29 H R REP. NO 1153, 92d Cong., 2d Sess. 44 (1972); H.R. REP. No. 1593, 92d Cong., 2d Sess. 54 (1972).
The Consumer Product Safety Act

Consumer interest representatives. The Council is authorized to propose consumer product standards to the Commission.

In addition to the authorization for private petitions for injunctive relief against manufacturers violating an applicable product safety standard, private parties are permitted to petition the Commission to commence a proceeding leading to the issuance, amendment, or revocation of a consumer product safety standard. Judicial review is provided in the event of denial of such a petition, but only for petitions submitted after the Commission has been in operation for three years.

The Act also requires the Commission to maintain an injury information clearinghouse to coordinate the gathering and dissemination of information on injuries, to undertake studies and research, and to test products and develop testing methods and devices. The Commission can require that a manufacturer turn over to it technical data with respect to the performance and safety of a product and can require that the manufacturer disclose this information to consumers.

IV. The Significance of the Consumer Product Safety Act

The Act is one more step in the pervasive federal regulation of all aspects of industrial activity brought on by the increasing demands of society for governmental protection from those detrimental activities damaging the quality of life. The Occupational Safety and Health Act regulates in detail the manner in which industrial activity is to be carried on within the plant. The Clean Air Act of 1966 and the Water Pollution Act of 1972 regulate the manner of waste disposal from industrial activity. The Noise Control Act creates procedures for the establishment of permissible noise emission levels for all types of products.

The Consumer Product Safety Act now provides for regulation of the structure of a significant number of products manufactured or imported into the United States. Although the Act limits the Commission jurisdiction to consumer products which present a risk of death, personal injury, or serious or frequent illness, the number of products included still will be significant. The experience of manufacturers under other safety legislation, particularly the National Traffic and Motor Vehicle Safety Act, indicates that this regulation will create significant additional expenditures and could make the continued manufacture of some products difficult, if not impossible.

34 The National Commission on Product Safety listed 200 products which it believed to present serious risks of injury.
35 The Department of Transportation has issued numerous complex standards under the Traffic and Motor Vehicle Safety Act, 49 C.F.R. § 571.
In addition to these significant obligations with respect to the manufacture of a product, the Act imposes new and extensive obligations on the manner in which business must operate. The Act also adds a new dimension to the relationship of buyer and seller and will undoubtedly have some effect on product liability litigation. One other important aspect of this legislation is the extent to which both business and consumer groups are drawn into the regulatory process and are given an opportunity to shape safety regulations at all stages in the proceedings.

A. Impact on the Manufacturing Process

Clearly, the most dramatic impact of this new legislation will take place in the manufacturer's plant. The design of numerous products, in time, will be required to conform to new Federal standards. In some instances, these designs may not be feasible for certain manufacturers. Product lines may be required to be altered drastically and, in some extreme situations, even dropped. Other products will be banned totally as being too hazardous. No requirement exists that a standard be economically reasonable, although the procedure requiring acceptance of offers to develop standards will result in consideration of feasibility in all instances where manufacturers are participating in the development of the standards. The Commission is required to consider and make findings with respect to the impact of its action, but, nevertheless, is empowered to promulgate its proposed standard even if the economic effects will be significantly adverse. The only restriction on the Commission is that the standard be reasonably necessary to eliminate or reduce an unreasonable risk of injury. The House Commerce Committee indicated that it expected the Commission to balance the risk and gravity of harm against the utility, cost, or availability of a product in determining whether the hazard presents an unreasonable risk.

New products may take on increased importance and value if standards require their use. Since standard specification of the components to be used can create dangers and difficulties of governmental involvement in business planning, the Act requires the Commission, whenever feasible, to develop performance standards rather than product specifications. Performance standards clearly are desirable because they permit the manufacturer to achieve the required performance level by any competitive means, thus securing the desired protection without limiting the manufacturer's discretion in the method of achieving the desired result.

New labels and warnings may have to be added to products and new packaging developed. Conforming with these requirements will involve minor design problems. Labels which contain the date of manufacture can create production, distribution, and marketing problems because of consumer demand.

36. See, for example, § 6(c)(1) of the Noise Control Act of 1972, Pub. L. No. 92-574, where one of the criteria in establishing a standard is the cost of compliance.

The Consumer Product Safety Act

for products manufactured as near to the date of sale as possible. To avoid this "open-dating" problem, the Commission is authorized to permit manufacturers to code this information.38

The Act contemplates that most standards will become effective within a period of 30 to 180 days after their promulgation. Since goods on which manufacture is not completed prior to the effective date will be covered by a standard, manufacturers that need a long lead time to comply with the requirements of such standard either (1) will have to anticipate promulgation and make necessary changes while the standard is under development or consideration by the Commission, or (2) will have to seek extension of the period before the standard takes effect.39 This problem can be particularly acute for importers. Products manufactured before the effective date still may be exported to the United States unless the Commission, after a hearing, determines that the product contains a defect which creates a substantial risk of injury to the public. Products manufactured after the effective date of a standard and not in compliance with such standard may be imported under bond provided the products are brought into compliance before distribution in the United States.

One of the few clear benefits to manufacturers which may result from the Act is that the problems created by varying state product safety standards will be eliminated in many cases. The Act contains a strong preemption clause, which prohibits states from establishing safety standards which are not identical to those established at the federal level. The Act does not prohibit state activity, however, until federal standards have been established.

B. Impact on the Manner of Doing Business

The new legislation clearly will result in increased costs of doing business as the result of the new obligations imposed on manufacturers, distributors, and retailers. The Commission can require businessmen to keep extensive records showing compliance with the Act. The extent to which manufacturers and distributors will have to maintain lists of purchasers under the Act is not clear. It may be that manufacturers will fulfill this requirement simply by maintaining a list of warranty cards, although the percentage return of these cards in many industries is traditionally low. If the manufacturer does not have a suitable list of purchasers, however, the probability that it will be required to give a generalized public notice, with all the attendant adverse publicity, increases. The House Commerce Committee report indicates that if certification information is coded, the manufacturer's or private labeler's

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38. CPSA § 14(c).
39. Manufacturers may be forewarned of possible Commission action. The House Commerce Committee Report states that it expects the Commission to inform manufacturers about potential safety hazards as it develops information on products. The Committee indicates that it hopes that manufacturers will act to cure the problem without resort to the standard procedure, H.R. Rep. No. 1113, 92d Cong., 2d Sess. 30 (1972).
obligations to give adequate notice will be greater. The exemption of retailers from record-keeping requirements greatly increases the difficulty for manufacturers and distributors to establish their own lists of purchasers. Since the Commission is required to afford interested persons, including consumer groups, with an opportunity to comment on whether notice should be given, some adverse publicity will occur in any case where the issue either of a failure to comply with a standard or of the existence of a hazardous product defect is raised.

Additionally, manufacturers and consumer protection groups will have to maintain a concern for the progress of safety standard-development. Manufacturing groups may continue to develop voluntary standards, although such industry standards are subject to the antitrust laws. The Federal Trade Commission has published guidelines with respect to industry standards. Among these guidelines is the requirement that the public participate in the development of the standards.

Independent standards-making groups such as American National Standards Institute, which is a federation of the principal standards-making organizations in the United States, and private testing laboratories, such as Underwriters Laboratories, will play an increasingly significant role under the new legislation. Public participation in the proceedings of these groups also is required under the Act.

A manufacturer of a product which is subject to a safety standard, and thus is required to certify compliance with this standard, is also required to maintain a reasonable testing program upon which its certification is based. The Commission is granted authority to prescribe this testing program. Testing may be done by qualified independent third parties.

Manufacturers may be required to give notice to the Commission prior to the introduction of new products into the market. The Commission may not require pre-market clearance before these products can be distributed, however. The procedures for this pre-distribution notification will be established by the new Commission. The Commission also can require that products be marked with, or accompanied by, clear and adequate warnings or instructions, and can prescribe the form of this warning or instruction.

The Commission may require a manufacturer to maintain technical data related to the performance and safety of the product and can require that this information be given to consumers purchasing a product. The Commission also is empowered to require manufacturers to make reports to it and to secure other information through its own research. Manufacturers will have to be alert to Commission release of information and may have to file formal...
The Consumer Product Safety Act

The flow of information to the public with respect to a specific manufacturer or its products may be significant.

The Federal Trade Commission has issued three recent proposed complaints which relate to product safety labeling and the manner in which products may be advertised. The complaints in those cases allege that advertisements promoting the safety or hazard-free nature of the products are deceptive as proven by the warning labels on the product. In addition, the FTC alleges that the advertisements are unfair or deceptive because they detract from the effectiveness of warnings or instructions on the products.

C. The Manufacturer's Obligation to Consumers

Federal law is changing significantly the role of the warranty in establishing a manufacturer's obligations with respect to defective products. Doctrines such as strict liability in tort have developed at the state level to prevent limitation of a manufacturer's obligations after a defective product has caused injury. The new Act now increases the manufacturer's obligations to consumers before they have been injured.

If a product fails to comply with an applicable standard or creates a substantial risk of injury (even though no standard has been promulgated), a manufacturer, distributor, or retailer is required to notify the Commission of this failure to comply or risk of injury. A consumer also may bring the matter to the Commission's attention. In either case, the Commission must hold hearings before determining that a substantial hazard exists. This proceeding provides the manufacturer with an opportunity to present its case that the remedies set forth under the Act are not required. Once a determination is made that a substantial hazard exists, the Commission can require that the manufacturer give notice of the defect publicly or to each purchaser of whom it has knowledge. The House Report indicates that this notice must be actual notice and that a manufacturer will not be required to go through retailer records to develop a list of purchasers.

In addition to requiring this notice, the Commission also is empowered to require the manufacturer, at the manufacturer's option, to repair the product, to replace it, or to refund to the consumer the purchase price for the product, less a reasonable allowance for use if the product has been in the consumer's possession for more than a year after notice of the defects is made public or

44. See, FTC v. Sperry Hutchinson Co., 11 L. Ed. 2d 170 (1972) for a discussion of FTC authority to challenge unfair trade practices.
45. Additional legislation which would have reduced further the freedom of manufacturers in issuing warranties was introduced during the Ninety-second Congress, but did not pass, S. 986. This bill provided specific definitions for full and partial warranties and would require each warranty to be labeled as "full" or "partial."
acquired by the consumer. Similar requirements also can be imposed on distributors or retailers.

No charge is to be made to any consumer who avails himself of a remedy under this provision. In addition, the consumer is to be reimbursed for any reasonable and foreseeable expenses incurred in availing himself of the remedy. Thus, for example, any shipping costs incurred by the consumer in returning a defective product may have to be borne by the manufacturer, distributor, or retailer. The Commission also may order reimbursement by one manufacturer to other manufacturers, distributors, or retailers for their expenses incurred in carrying out a remedy required pursuant to this Act. The Commission can require that a plan for taking the required action be submitted to it for approval before it is implemented.

The Act requires that a new written warranty be given to consumers. This is a certification that the product complies with applicable product safety standards. Any consumer injured by reason of a knowing violation of a safety standard may sue in federal court. Such a litigant is entitled, in the discretion of the court, to recover reasonable attorney's fees. The Act specifically disavows any limitation on private litigation remedies. Thus, proof by a manufacturer that its product is in compliance with a federal standard may not be proof of due care. State law still may impose a higher duty of care on the manufacturer. Violation of a safety standard, however, may be held as negligence per se in many states.

The Act will have a further effect on private injury litigation because significantly greater amounts of data will be available to both parties to the litigation through the Injury Information Clearinghouse to be established within the Commission. Commission files presumably will include material as to the cause of various accidents, as well as test results with respect to products. Commission investigative reports on specific accidents will be available to the public. Public availability of information assembled by the Commission will be restricted only if the information contains trade secrets, confidential statistical data, or other matter entitled to confidential treatment. A procedure is established under the Act whereby a manufacturer is entitled to challenge the Commission's intended release of information before the actual release is made.

D. New Relationships in the Regulatory Process

The Act continues a trend developed in the forerunners to the present comprehensive consumer product legislation—the use of an advisory council composed of public, consumer, and industry members to consult with the Commission during the regulatory process. The role of the advisory council

may be significantly less important under the product safety act than has been true under other legislation because the Commission is not required to consult with the council but has complete discretion with respect to such consultation. These councils can be of significance in developing regulations because they afford both the consumer and business interests with an opportunity to assist in shaping regulations at an early enough stage in the proceedings so that changes can be made with relative ease and without delaying the regulatory process.48

The requirement that the Commission accept an offer to develop a standard if no existing standard is considered adequate insures that most standards will be developed outside the government. This lessens the budgetary impact of this new program, but is done at the expense of control over standards development. Since industry often already is working closely with those organizations most likely to submit an offer to develop a standard, industry input in establishing standards is assured. Because of the importance which these standards-making organizations are granted under the Act, consumer and public participation in these deliberations undoubtedly will increase. The Act requires that consumer groups be given notice and the opportunity to participate in the development of standards. The Commission may contribute to the costs of an offeror to assure public participation in the standard development process.

In addition, consumer interests are given the right of intervention to enforce existing safety standards. Any interested person, including consumers or consumer organizations, is permitted to petition for the issuance of a product safety standard. The Commission is required to act on this petition within 120 days. If such petition is denied, petitioners eventually will be able to seek judicial review in a de novo hearing on the question of whether the requisite risk of injury exists. Judicial review is not authorized for three years after establishment of the Commission in order to permit the new body to establish its priorities.

All proposed standards are subject to the informal rule-making procedures permitted under the Administrative Procedure Act,49 rather than the more formal hearing procedures, such as those utilized by the Food and Drug Administration, which require a written record and the opportunity for cross-examination of witnesses.50

V. Conclusions

This preliminary assessment of the Consumer Product Safety Act describes only the legislative framework for regulation of numerous products. The

48. See the Federal Advisory Committee Act of 1972, Pub. L. No. 92-141, § 10 (October 6, 1972) for procedures required of all federal advisory committees. These procedures generally are designed to insure that the proceedings of advisory committee deliberations are public information.

49. 5 U.S.C. § 553.

The Business Lawyer, April 1973

The manner in which the new Commission carries out its mandate will depend on numerous factors, including the vigorousness with which the new Commissioners move to regulate; the responsiveness of industry and consumer interest groups to the standard-making procedures; and the resources granted to the Commission for its staff and facilities. Regardless of the extent to which these factors vary, the existence of this Act, in itself, will have a significant impact on business operations.
Government policy toward consumer product safety has experienced major institutional changes in the United States over the past fifteen years. In particular, Congress has passed a number of laws imposing and strengthening federal regulatory controls on product safety across a broad spectrum of markets.

In the food and drug area, the 1962 Kefauver-Harris Amendments made the premarket approval process for new pharmaceuticals much more stringent and extended Food and Drug Administration (FDA) controls over the pharmaceutical research and development process. The 1968 Delaney Amendments required the FDA to ban any food additive from the marketplace found to be carcinogenic in animals, regardless of foregone benefits. The 1976 Medical Device Amendments extended FDA controls to all medical devices (for example, heart pacemakers, cardiographs, stethoscopes, etc.) and many classes of medical devices will now be subject to a premarket approval process similar to that for new drugs.

Beginning in the mid-1960's, Congress also has passed a succession of product safety laws dealing with specific products such as automobiles, toys, flammable fabrics, lead-based paints, and poisonous and toxic substances. Most of these responsibilities were eventually consolidated and put under the jurisdiction of the Consumer Product Safety Commission (CPSC), created in 1972. This new agency was given a broad mandate by Congress to set safety standards for all consumer products presenting undue risk of injury, except for those products already regulated by an established agency (for example, food, drugs, pesticides, and autos).

Thus Congress has extended federal product safety controls to virtually all areas of the marketplace. While it is too early to evaluate the impacts of this new regulation, it is possible to make some general observations about its emerging characteristics.

First, in drafting and funding new product safety legislation, Congress has strongly favored direct regulatory controls (for example, product standards, premarket approval, prohibitions of very risky products, etc.) compared to other policy instruments that might be employed to encourage greater product safety. In particular, two alteranatives often advocated in the academic literature—the generation and dissemination of better information about product safety hazards and the use of economic incentives (i.e., taxes or subsidies) have been given little attention.

Second, the decision-making process at the various agencies appears to embody a strong “safety imperative.” That is, there is strong resistance to the notion that the benefits of greater safety stemming from a particular policy must be weighed against the costs that might be entailed by that policy. To a considerable degree, the regulatory agencies are probably reflecting the desires of Congress in this regard. The product safety laws tend to be drawn with very specific and narrow mandates (for example, to protect consumers against unsafe products) and provide few incentives for agency decision makers to introduce cost considerations into their decisions. While it is true that these agencies are now required to calculate “economic impact” or benefit-cost analyses of their decisions, these generally take on an “after the fact” character. As we show in our analyses of the CPSC and the FDA below, the results of benefit-cost analyses apparently have little effect on regulatory decisions.
Under these conditions there is little effort to design regulatory policies to complement existing market and legal incentives regarding product safety. Presumably, the rationale for government regulation of product safety rests largely on the presence of market information imperfections and secondly on the fact that the tort liability system which makes producers liable for defects in their products provides weak incentives in many circum-
stances because of high transactions costs and uncertainties in legally determining fault. However, these market and legal incentives vary greatly across different product areas and industry categories. Therefore, setting priorities for regulatory action on agencies with broad discretion such as the CPSC should preferably concentrate on those areas where market and legal incentives for product safety are most deficient. In this way they can target their resources to the areas where potential benefits are greatest relative to costs.

Fourth, product safety standards and regulations can result in significant unintended side effects on the long-term competitive structure of an industry. Our own recent analysis of the pharmaceutical industry, for example, indicates that increased regulation since 1982 has resulted in a much greater concentration of innovation among the largest drug firms. Similarly, recent analyses of the CPSC and OSHA proposed standards in power lawnmowers indicate that implementation of these standards would eliminate several small producers and significantly increase industry concentration (see W. Blockett et al., 1983).

In the remainder of the paper we specifically analyze the behavior and performance of the two principal agencies engaged in product safety regulation—the CPSC and the FDA—and consider these points in more detail.

1. The Consumer Product Safety Commission

Congress passed the Consumer Product Safety Act in 1972 which created the CPSC and empowered it to protect the public against unreasonable risks of injury associated with consumer products (S. Rep. No. 93-833). It has been estimated that the CPSC has jurisdiction over some 20 thousand different products which account for about $250 billion in annual sales. Among the policy options which the Commission has to carry out its mandate are the dissemination of information, the development of minimum safety standards, and the outright ban or labeling of especially hazardous products.

To date the Commission has proposed or implemented safety standards for products such as bicycles, matches, books, power lawn mowers, swimming pool slides and public playground equipment. In establishing priorities on standards the Commission has relied heavily on its frequency severity index of product related injuries. This is based on the number and character of injuries from a particular product class recorded at hospital emergency rooms. This approach to establishing agency priorities has been strongly criticized in a recent study by Nina Cornell, Roger Noll, and Barry Weingast. In particular, they argue that while the products targeted for standards by the CPSC have above average injury rates, they are products involving risks which are well understood and voluntarily assumed by consumers. At the same time, the Commission has given little attention to more sophisticated products like microwave ovens, where the hazards are more subtle and less clearly defined and for which information on safety characteristics is more difficult for consumers to obtain. This type of product, of course, rarely shows up as the cause of emergency room injuries, but may pose significant long-run health hazards about which there is general consumer ignorance.

In our opinion, a major outstanding problem with the CPSC approach to product safety regulation is that it does not really try to compare benefits and costs in deciding where government safety standards are necessary. Rather, the Commission's decisions reflect a 'safety imperative' which tends to ignore the cost side of the equation.
almost completely. This is demonstrated by an analysis of the priority rankings for forty-six product classes which are considered in the CPSC Mid-Year Review (March 1977). This report suggests various factors and criteria in establishing Commission priorities including the frequency and severity of injuries, causes of injuries, costs and benefits of CPSC action, unforeseen nature and vulnerability of the population at risk, the probability of exposure to hazards, and other factors.

Table 1 presents the rankings and corresponding benefit-cost ratios for twenty-one product classes for which ratios were available. Although many of these benefit-cost ratios are based on very preliminary economic analyses, they are the numbers available to the staff and commissioners in establishing priorities. The priority rankings are not only for the Commission’s ordering of the twenty-one products in Table 1, but their rankings among all forty-six products that they evaluated. However, rankings 1-12 in the table were all accorded the status of “high priority” and are targeted for standards by the CPSC during the coming year.

It is clear from Table 1 that the CPSC does not accord great weight to benefit-cost analysis, either in the absolute sense of the desirability of pursuing the project at all or in the ranking of projects. Only five projects of the twenty-one have ratios exceeding unity. Furthermore, the number one priority ranking in the table: power mowers, was ranked second by the Commissioners out of forty-six and it has a benefit-cost ratio of only 40 (total benefits were estimated at $412 million compared to costs of $285 million).

In doctoral dissertation research currently underway, Larry Thomas is analyzing the CPSC decision-making process. His effort is directed at determining empirically the implicit weights for project attributes that the CPSC uses in establishing its choices among projects. Using a logit analysis, Thomas has found that estimated benefits (which are highly correlated with the estimated frequency and severity of injuries for each product class) dominate cost considerations in the setting of agency priorities. In particular, estimated coefficients on the benefit variable are ten to twenty times larger in absolute magnitude than those on the cost variable.

It should be noted that CPSC members and other product safety regulators have argued that there are very good reasons for not making their decisions depend directly on the outcomes of benefit-cost analysis. First, they suggest there is no generally accepted operational methodology among economists for valuing human lives. Second, they point out that the benefits and costs are not comparable. The benefits involve the saving of human lives and the reduction of bodily injuries and health hazards while the costs involve higher

<table>
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<tr>
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<th>Priority</th>
<th>Ratio</th>
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Source: Benefit-cost ratios were based directly from a CPSC Bureau of Economic Analysis staff memorandum or calculated from new or revised data supplied in the CPSC Mid-Year Review using the procedures of the CPSC Bureau of Economic Analysis. Priority rankings were obtained from a CPSC News Release.
product prices. Lower business profits and other economic effects.

While these arguments are apparently quite persuasive to many consumers and business advocates, others may argue against the use of a strict benefit-co
cost criterion or may argue that it is an approach that simply is not adequate to this issue. In any case, the large number of new drugs introduced after 1962 suggests that the benefits of increased regulation have been significant.

II. FDA Regulation of Pharmaceutica1s and Medical Devices

In contrast to the recent history of the FDA, government regulation of pharmaceuticals started in 1906 and has evolved over time into a very stringent system of premarket controls on new drug development and introduction. While early regulations were oriented at patent medicine abuses, the switch to synthetic drugs in 1928 led to passage of the Food Drug and Cosmetic Act, which required FDA approval of all new drugs, with full Health, Education, and Welfare Committee hearings before they could be marketed. Then in 1962, as the adverse effects of Thalidomide awakened new awareness, the Kefauver Harris Amendments were passed. This law expanded FDA controls to the clinical testing and development process for new drug compounds. In addition, manufacturers were required to demonstrate the therapeutic efficacy as well as safety of a new drug before FDA approval.

The fact that new drugs are the source of serious underrecognized adverse effects in addition to strong therapeutic benefits justifies these strong regulatory controls. In the minds of many individuals at the same time, FDA regulatory decisions have been characterized by an extreme form of safety imperative: As FDA Bureau of Drugs director Richard Crout has indicated, 'We emphasize very strongly that the Food and Drug Administration regulates health policy not economic matters. That is terribly important to understand. We do not pay any attention to the economic consequences of our decisions and the law does not ask us to.' (pp. 196-97)

Over the period since the 1962 Amendments were passed, a number of adverse trends have been observed, particularly with regard to the innovative performance of the pharmaceutical industry. In particular, average research and development costs for a new drug have increased more than an order of magnitude and now exceed $20 million per new drug. Development times and risks have also significantly increased. Most importantly, the annual rate of new drug introductions in the United States has fallen to less than one-third the rate which existed in the early 1960s. In a forthcoming paper, we consider various hypotheses for these adverse trends and, on the basis of international comparative analytic analysis, conclude that increased regulation has been a major factor underlying declining innovative performance in the drug industry.
the authors and Thomas). This is consistent with a number of other studies (see Martin Baily, Sari Peltzman, David Schwartzman).

There are clearly foregone health benefits to the public when beneficial drugs are left undeveloped or are substantially delayed because of FDA regulatory controls. William Wardell, a clinical pharmacologist and Louis Lavange documented many cases in which new drugs developed abroad and even many American drugs first introduced abroad generally took several additional years to gain FDA approval for use in the United States. Their findings are consistent with more recent analysis of the international diffusion of new drug therapies across four countries: the United States, United Kingdom, France, and Germany. Specifically, we found that a majority of all the new, therapeutically active drugs introduced into the United States over the period 1961-1986 were introduced in the United Kingdom, France, or Germany, and that most of these foreign entries appeared in these foreign countries eight to ten years earlier than the same set of drugs appeared in the United States. Thus, foregone health benefits to the public from such delayed products were high.

We have estimated that the entire period of the slowly evolving FDA regulatory approval process, including the time required for drugs to make it through the preclinical and clinical studies of the FDA, reduced the number of drugs reaching the US market by a factor of two. We have also estimated that new drugs submitted to the FDA are statistically less likely to receive approval than drugs submitted in earlier years. 

While the above analysis indicates that regulatory delays are a significant obstacle to the timely introduction of new drugs, the cost of these delays is not yet well understood. This is because the financial cost of new drug development is only a subset of the total costs. The costs also include the economic costs of delays in the development of new drugs, which include the opportunity costs of foregone sales of existing drugs, the costs of delays in the development of new products, and the costs of regulatory delays in the development of new drugs. These costs are difficult to quantify, but they are likely to be substantial.

In conclusion, the FDA's regulatory process has a significant impact on the development and approval of new drugs. The process is complex and often slow, and it can lead to the delays in the development and approval of new drugs. This is a serious problem, and it is necessary to take steps to address it.
Regulation: Asking the Right Questions

by Peter H. Schuck

Peter H. Schuck, a lawyer, was until recently Deputy Assistant Secretary for Planning and Evaluation at the Department of Health, Education, and Welfare. Prior to that, he was Director of Consumers Union's Washington office. Currently, a visiting scholar at the American Enterprise Institute, he will join the Yale Law School faculty in July.

In recent years a vast literature on regulation has emerged, literature to which many professional disciplines have contributed. Historians have chronicled the circumstances under which existing regulatory systems were established. Political scientists have described, often inappropriately, the political and institutional dynamics of regulation. Economists have analyzed the legal rules that govern the procedures and substantive policies of regulatory agencies. Economists have measured the economic performance of regulated industries and the costs and benefits associated with regulatory activity. And politicians, whose intellectual effusions fill countless volumes of nonprofessional journal (the Congressional Record), have debated the merits of regulation in general and of regulatory proposals in particular.

Very little of the analysis, however, has been upon the question that policymakers must next ask: How are regulatory programs likely to be implemented in the real world? To be sure, economic theory has analyzed market failure (i.e., market conditions such as external effects, inadequate consumer information, and free-rider problems) inadequately and remedy them, e.g., regulatory intervention on efficiency grounds and the efficiency and distributional consequences of particular regulatory programs (cost-benefit analysis). But the market failure and cost-benefit criteria are minimal, necessary but not sufficient to justify a regulatory intervention. Virtually all markets are imperfect to some degree because consumer markets in which among other things the factors influence consumer information possessed by consumers are often inadequate and the market works only imperfectly. The third parties affected by market failures (e.g., consumer purchasing a product may know little about its performance safety durability, etc.) and the policy is that the Consumer Product Safety Commission (CPSC) does not know what would have to be done in order to prescribe a safe standard that would maximize the welfare of millions of consumers while taking into account the dynamic economic and technical realities of hundreds of firms. Much the same is true of externalities. Market transactions in an unsafe product often have harm third parties (e.g., those injured in accidents or compelled to pay higher insurance premiums), but the potential for uncompensated unforeseen harm to consumers' workers, stockholders and consumers results from unforeseen economy-wide or industry-wide regulations may be far greater. Other aspects of what might be called regulatory failure— for example, protected legislative and expensive proceedings—can also contribute to the arbitrary nature of valuations of human life or health, the special difficulty of evaluating extremely low risk, but catastrophic events (e.g., malfunctions of a nuclear reactor) the problem of intertemporal and intergenerational comparisons of utility, and many others. These intertemporal and spatial cost-benefit analyses whether favorable or unfavorable should limit analyses of market failures constitute only part of the picture.

In brief, to address questions of regulatory implementation one must first possess a theory that is not only of how markets work but of how regulation—whether of markets per se, economic regulation, or of other market related phenomena such as pollution, patent, or social regulation) works. The theory of pollution and the factorial nature of human life or health, the special difficulty of evaluating extremely low risk, but catastrophic events (e.g., malfunctions of a nuclear reactor) the problem of intertemporal and intergenerational comparisons of utility, and many others. These intertemporal and spatial cost-benefit analyses whether favorable or unfavorable should limit analyses of market failures constitute only part of the picture.

Perhaps for that reason no such theory yet exists. And given the complexity, diversity, and value-laden nature of the phenomena to be explained, any such theory is not likely to be a rigorous one. Nevertheless, this article suggests some modest hypotheses as a starting point. First, the propositions that follow must be qualified by the condition that other things being equal, one...
POLICY FORUM

regulatory world of course the condition is never really met. Nevertheless such generalizations can help us to identify additional criteria or points of reference that can stimulate policy makers to think critically about the costs, effects of regulation in real world situations, and decide what form or forms the regulation might take. These criteria will be grouped into five general categories existing for the structure of the regulatory world: (1) the structure of the regulatory world, (2) the structure of the regulatory world, (3) the structure of the regulatory world, (4) the structure of the regulatory world, (5) the structure of the regulatory world.

THE STRUCTURE OF WHAT IS TO BE REGULATED

Uniformity and diversity between rule and discretion, between certainty and uncertainty and between the rough justice of broad categories and justice tailored to the equities of individual situations. Regulation almost invariably opts for the former of each of these dualities for several reasons limited resources the importance to economic enterprise of predictability the danger to collective regulation of delay and stale data and the sheer enormity of the regulatory task.

The experience of the Federal Power Commission provides a dramatic example of this phenomenon. When the FPC undertook regulation of producer rates for natural gas in 1954 it began by determining just very expensive rates for each of the more than 3,000 producers. In 1960 the sheer number of the rate-setting procedures had swamped the Commission. It was then decided to simplify the process by setting regulatory producer rates together into fewer regional areas. Each producer-regional area was accorded the same rate as a producer within the same area, plus a profit for the costs of the particular producer. The overall regional area rates were often difficult and cumbersome for the large number of area rates were then decreased in size by the elimination on the basis of area of like activity. Further, the complexity of the regulatory system for the price-volume regulation between commission regions, the Southern District the area was not altered by the Supreme Court until 1974 which a single rate was applicable to all the smallest producers. During those months the single rate had been changed by almost 20 percent and had been subject to inter-territorial, regulatory exceptions and other amendments.

Although OSHA devotes four-fifths of its staff to enforcement, its inspections during 1976 covered fewer than 2 per cent of the workplaces.

A new general method that the President proposes the Federal agency to be employed in the investigation about which is involved. It might be argued that in the economic world of the Federal Reserve's average American traveling to the Federal Reserve, that in other economic conditions in US. Congress was making an attempt to provide for in the different rate categories. Many similar rate cases were heard in the area of social regulation such as attempts to regulate as new numbers of over the area. But for safety, and efficiency could also be achieved.

When a rule is made it is necessary to be evaluated for its cost, benefits, and social context. Given the regulatory context, the specific task at hand, the resources available for regulation, the regulatory goals, and the political context the rule should be evaluated. An evaluation of a rule should consider the following:

1. The nature and purpose of the rule.
2. The expected costs and benefits of the rule.
3. The expected consequences of the rule.
4. The expected impact on the economy.
5. The expected impact on the environment.
6. The expected impact on public health and safety.
7. The expected impact on civil liberties.
8. The expected impact on national security.
9. The expected impact on international relations.
10. The expected impact on international trade.

Finally, the rule should be reviewed to ensure that it is consistent with the Constitution and other laws and regulations.
the "base year" concept in price regulation, for example, ensures that some firms will enjoy substantial pricing latitude while others will be severely constrained, depending upon how each firm happened to fare in the base year and how typical that year was for each. Similarly, the notion that the small firm is simply a large firm in miniature ignores the very real differences between them with respect to market conditions, scale economies, and other factors. Moreover, the notion that small firms are simply the base year and how typical that year was for each firm is violated whenever it happens that some firms will enjoy substantial pricing latitude while others will be severely constrained. An example ensures that some firms will enjoy substantial pricing latitude while others will be severely constrained.

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The dynamism of the particular market in which a firm operates is a major factor in determining the rate at which a firm will need to adjust its operations to changing conditions. For example, a firm that is a large firm in miniature may be able to maintain its competitive position by adjusting its operations relatively slowly, while a small firm may be forced to adjust its operations more quickly to remain competitive.

The existence of countervailing interests means that the interests of consumers are sometimes in conflict with those of regulated firms. For example, in the case of telephone companies, the interests of consumers may conflict with those of telephone companies. The interests of consumers may conflict with those of telephone companies in the case of telephone companies, for example, because telephone companies may want to charge consumers more than they would if consumers were the sole beneficiaries of the telephone service.

The nature of legal rules is also important in determining the rate at which a firm will need to adjust its operations. For example, the regulations governing the telephone industry may change in response to technological advances, but this does not necessarily mean that the telephone industry will adjust its operations as quickly as it would if the regulations were not in place.
Regulators ordinarily need a great deal of information in order to make sound regulatory decisions. Almost invariably, much of that information is in the exclusive possession of the regulated industry and some of that (e.g., cost data or trade secrets) may be legally protected against disclosure to the public.

The quality of information is, of course, critically important to the decision-making process by the National Labor Relations Board to examine systematically, well-defined, well-organized economic interests, management and labor against each other. This is sometimes true even when the regulated industry naturally generates some degree of information. For example, the International Trade Commission provides, in some cases, information on the basis of which it can assess, in some cases, the international trade industry and, in some cases, to an agency that cannot even obtain some of the information on which its regulatory decisions are based. For example, regulations that are based on data that are not legally protected against disclosure to the public.

The information needs of regulators

The availability and quality of information that is relevant and needed by regulators are critical to the effectiveness of their regulatory role. The information needs of regulators include the following:

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are highly concentrated and its benefits are widely dispersed than in those instances in which the reverse is true. Other things being equal, the quality of information available to the regulator as a result of these analyses is likely to be better than in their absence.

The Quantity of Information: Regulation through economic incentives tends to require far less information on the part of the regulator than regulation through command and control techniques. Better than all regulatory information of high quality is often difficult to come by, that is, to obtain. A regulator designing an efficient tax, for example, needs to know in detail the technology on the cost profiles of firms. He needs to know the extent of the adverse effects of his regulations on the environment and the economy. The ability to identify the extent of these effects depends upon information and procedures that are often not available to the regulatory body.

The Distinction between these types of regulatory objectives is not always clear-cut. Taxing, for example, typically eliminates feasible costs, whereas command and control techniques may limit feasible costs or increase them. Nevertheless, these value judgments are traded off against one another defining the regulatory objectives. Thus, economic incentives tend to require far less information than command and control techniques, but they may be more difficult to implement and may be more costly to society than regulating information and procedures. Therefore, the ability to identify the extent of the adverse effects of his regulations on the economy does not necessarily make the tax a better regulatory technique.

The Nature of the Regulatory Objective: The particular task that Congress sets for the regulatory agency is not necessarily control of future behavior for the agency is inevitably transformed over time into an instrument of legislative policy. Congress has the authority to define regulatory objectives, but it is not the task to do so. Instead, Congress sets regulatory objectives and agencies determine how to implement them. The most important differences relate to what Dahl and Lindblom have called the 'problem of calculation' and the 'problem of control.' The quantity and quality of data that the SEC needs to determine what kinds of information investors should have before the efficient functioning of the securities markets is the same as the problem of calculation, whereas the SEC needs to determine what is an appropriate level of dividends per share. Moreover, information generates costs and often changes important values and preferences. But it remains the case that what the SEC is trying to do is very different from what Congress is trying to do.

Most regulatory statutes are exceedingly ambiguous (and sometimes even contradictory) in defining the regulatory objectives. And particular regulatory objectives, such as occupational health and safety, are ordinarily mitigated by other regulatory objectives (such as feasibility) in the absence of any guidance given as to how these values should be traded off against one another. Nevertheless, the agency's formal objectives are important in establishing a regulatory model. They define the regulatory boundaries of the agency and other institutions. Congress, for example, sets the limits upon which the agency can act in determining its rules and regulations. Two dimensions are especially important to the regulatory agency: the substantive content of the objectives and the directness of the process. These two dimensions are illustrated below.

The Content of the Objective: Some regulatory objectives are more easily achieved than others. For example, the strengths and limitations of regulatory agencies correspond to the substantive content of the objectives. The effectiveness of a regulatory agency is like the law: if it is to be better at regulating prices, it must be better at regulating prices. The quality of information then at regulating market characteristics (e.g., the price quality and health and safety effects) which require, at the margin, a tradeoff between important economic and social values. That is, it is judged that the laws of standardization should not be too high or too low. Thus, the level of standards is often more easily achieved than others.

The Quality of the Information: The nature of the regulatory objective is also important. The economic incentives tend to require far less information on the part of the regulator than regulation through command and control techniques. Better than all regulatory information of high quality is often difficult to come by, that is, to obtain. A regulator designing an efficient tax, for example, needs to know in detail the technology on the cost profiles of firms. He needs to know the extent of the adverse effects of his regulations on the environment and the economy. The ability to identify the extent of these effects depends upon information and procedures that are often not available to the regulatory body. Moreover, the regulation of procedures and information generates costs and often changes important values and preferences. But it remains the case that what the SEC is trying to do is very different from what Congress is trying to do.

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POLICY FORUM

The ability to measure performance. The extent to which regulatory objectives are in fact achieved can be measured more directly with respect to some objectives than others. For example, 1974 there is a high correlation between the amount of effluent produced and the amount of allowable effluent, and when these are measured, the performance impact of the enforceability of regulations. The higher the correlation, the more likely that the regulatory objective will be achieved. This is especially true when the regulatory objective is to reduce the amount of effluent produced. When the correlation is low, the regulatory objective may not be achieved, even though the amount of effluent produced is reduced. This is because the regulatory objective is not being achieved.

The extent to which performance can be measured directly is often a matter of the specific standards used. As an example, the regulatory objective to reduce the amount of effluent produced can be measured directly if the effluent is measured. However, if the effluent is not measured, the regulatory objective cannot be measured directly.

In the case of occupational safety and health, the extent to which the objective of reducing accidents is achieved can be measured directly if the number of accidents is measured. However, if the number of accidents is not measured, the objective cannot be measured directly.

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In the case of occupational safety and health, the extent to which the objective of reducing accidents is achieved can be measured directly if the number of accidents is measured. However, if the number of accidents is not measured, the objective cannot be measured directly.
The political support for regulations is not simply a legal administrative and technical phenomenon. It is a highly visible and inescapable aspect of any large bureaucracy, whether it is a federal agency, a state department, or a local government. Once established, a regulatory agency must find sources of continuing support if it is to survive in a political system that values efficiency and effectiveness. One way in which such support is obtained is through the integrity of its regulatory programs. Another is by maintaining a strong and coherent policy position. The criteria that have been discussed do not exhaust the variety of factors that influence the success of regulatory programs. Other important considerations include the personal characteristics of the agency's leaders, the nature of the regulatory task, and the political environment in which the agency operates.

Our political system has come to be dominated by two views: that a public policy is to be justified less by its consequences than by the motivation animating its proponents, and that questions about implementation in the real world of regulations spawned by the political-bureaucratic world are haggling details that can safely be deferred until after the regulations have been signed.

CONCLUSION

Even the current mood of skepticism concerning regulation as manifested in the Administration's regulatory reform proposals has failed to accord much significance to these questions. Yet, the importance of these questions should be clear. It is important that we attempt to understand why this should be so. One answer is that it is in the interest of powerful political forces to keep our views focused on the consequences of regulations rather than on the motivation behind them. The criteria that have been discussed do not exhaust the variety of factors that influence the success of regulatory programs. Other important considerations include the personal characteristics of the agency's leaders, the nature of the regulatory task, and the political environment in which the agency operates.
The Mindless Pursuit

The pursuit of profit is the driving force behind many of the regulations we impose on businesses, particularly in the area of consumer protection. This pursuit is often driven by the desire to make a profit and the need to meet financial targets. However, the pursuit of profit can sometimes lead to negative consequences for consumers. For example, the pursuit of profit can lead to the creation of unsafe products, which can put the lives of consumers at risk. In some cases, the pursuit of profit can also lead to the creation of products that are not effective or that do not meet the needs of consumers.

To address these issues, regulatory agencies have been established to oversee the production and marketing of products. These agencies have the responsibility of ensuring that products are safe and effective and that they meet the needs of consumers. However, the effectiveness of these agencies can be limited by the pursuit of profit, which can drive the decisions they make.

For example, the Food and Drug Administration (FDA) is responsible for regulating the production and marketing of food and drug products. The FDA has the authority to inspect food and drug products and to require that they meet specific standards. However, the pursuit of profit can sometimes drive the decisions that the FDA makes, leading to the approval of products that are not safe or effective.

In addition to the pursuit of profit, the regulatory agencies are also influenced by the need to meet financial targets. This can lead to the creation of products that are not effective or that do not meet the needs of consumers. For example, the pursuit of profit can lead to the creation of products that are not effective or that do not meet the needs of consumers. This can happen when the regulatory agencies are under pressure to meet financial targets, which can lead to the approval of products that are not safe or effective.

To address these issues, it is important to ensure that the regulatory agencies are independent and that they are not influenced by the pursuit of profit or the need to meet financial targets. This can be achieved by providing the agencies with adequate funding and by ensuring that they have the authority to make decisions that are in the best interest of consumers.
of Safety

by WALTER GUZARD, JR

...although the manufacturers grumbled about the standards, at least they knew what they had to do. But today, while NHTSA is still writing standards, the agency seems to have lost its interest in them as a means of enforcing laws. NHTSA's standards have to be so minimal that they would not even have to be enforced. For example, the agency has found NHTSA to be very, very right for instance.

...a step at the Pritcham Arms. "Pritcham arms," part of the steering mechanisms, were failing in some 1976 Cadillac models when NHTSA began its investigation in 1973. The failure was coming only with very sharp turns made at very slow speeds—most often when a car was being parked. So no one could prove injuries as a result of the failure, and so the 43,400 cars of that model still left on the road had gone by 56 percent of their lives. C.A.M could not use the unreasonable risk that the court held that whenever steering or other vital components fail with warning that's unreasonable risk. But by the end, C.A.M had to fully study the stories of the errors and fix them, and in eighteen years old that they had a total. C.A.M made the repair with change.

...the door was at the point. A number of wheels on some 1976-80 C.A.M cars were collapsing when the load limits of the trucks were exceeded by overweight, curves C.A.M argued that the user should not go beyond the limits. But the court held that they were above all right, but it was impossible that weather caused this. But this is going to be found to be leading to unreasonable injuries. At least it took only 86 cases.

...to the Supreme Court. A.

Conflicts in recent years include:

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...and leading to these results

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all related by drink in. Instrumental factors, such as drunk driving have led to a surge in the number of accidents involving alcohol. The problem is particularly acute in young drivers, where the percentage of accidents involving alcohol is higher than in other age groups. To address this issue, the National Highway Traffic Safety Administration (NHTSA) has increased its efforts to raise public awareness about the dangers of drunk driving and promote safer driving practices.

The main factors contributing to the increase in drunk driving accidents include:

1. **Social Norms and Attitudes**: There is a growing acceptance of drinking and driving among young adults, which has led to a decrease in the perceived risk of drunk driving.
2. **Accessibility and Availability**: The availability of alcohol is widespread, and it is easily accessible to those who choose to consume it.
3. **Lack of Enforcement**: Lawson and her colleagues point out that the enforcement of drunk driving laws is often ineffective, as police resources are often spread too thin to adequately address the issue.
4. **Cultural Acceptance**: In some cultures, drinking and driving is seen as a symbol of prestige and status, which can encourage others to follow suit.

The NHTSA has implemented various measures to combat drunk driving, including:

- **Public Education Campaigns**: These campaigns aim to change public attitudes and behaviors by educating the public about the dangers of drunk driving.
- **Increased Law Enforcement**: The NHTSA has worked to enhance law enforcement efforts, including increased use of breathalyzers and blood alcohol concentration (BAC) testing.
- **Adoption of Safer Vehicles**: NHTSA has worked to improve vehicle safety features, such as electronic stability control (ESC) and seat belt usage, to reduce the impact of drunk driving accidents.

Despite these efforts, the problem of drunk driving remains a significant issue. Continued efforts are needed to further reduce the number of accidents related to alcohol use, particularly among young drivers. Public awareness campaigns, stricter enforcement, and advancements in vehicle technology are all critical components in the fight against drunk driving.
The most dangerous component is the consumer, and
there's really no way to recall him.
...to this simple fact: in the manufacturing and selling of products, the cost of production is the ultimate determinant of price. As the cost of production increases, the price of the product also increases. This is true whether the product is a piece of clothing, a piece of furniture, or a piece of machinery. The profit margin, or the difference between the cost of production and the price of the product, is what determines the manufacturer's profit.

In the end, the manufacturing and selling of products is a business. The manufacturer's goal is to make a profit, and the price of the product is determined by the cost of production and the profit margin. The manufacturing process is critical to the production of quality products, and it is the manufacturing process that determines the cost of production.

In order to reduce costs, manufacturers often look for ways to improve the manufacturing process. This can include the use of new materials, new processes, or new technologies. By improving the manufacturing process, manufacturers can reduce the cost of production and increase their profit margin.

In conclusion, the manufacturing process is a critical component of the production of quality products. Manufacturers must work to improve the manufacturing process in order to reduce costs and increase profits. By doing so, they can ensure that the products they produce are of high quality and are priced fairly. This is important for both the manufacturer and the consumer.
Crying Wolf

Joan Claybrook

For over a year, I have observed the rising corporate assault on government regulation, particularly regulation designed to spur business to advance health and safety. In widely circulated advertisements, in letters to shareholders, in pamphlets, speeches, testimony and trade association materials, the federal government is accused of creating unnecessary regulations—those that cause inflation, retard innovation, destroy jobs, and divert capital investment from “productive” pursuits. Readers will have noticed these corporate attacks on “Big Government,” “Bureaucratic Bungling,” “Overregulation” and, of course, “The Undermining of the Free Enterprise System.” But they will not have noticed much in the way of a response from the regulators. In my opinion, it is our duty as public servants to speak up—because these charges can generate unwarranted loss of respect for legitimate government action. They can demonize those who are trying to improve conditions within industries, and they can undermine efforts to develop the technological basis for life-preserving progress.

Here is the current corporate view as it appears to me:

If inflation rises, Washington is the cause, and Washington can provide the cure.

If there is unemployment, Washington is the taproot and the obstacle to its reduction.

If there is disease-producing pollution, it is necessary to produce a technological fix, and Washington has the power to curb it.

If there is serious related disease and injury laws that require investment to prevent such damage to society are not “productive”—as though improving the health of a nation does not add to its wealth.

If filthy, adulterated, and harmful additives are found in meat and poultry products, Washington is incompetent and the public’s health is at risk.

The solution is not to clean up the industry but to campaign against the Department of Agriculture and the Food and Drug Administration. If a company or industry is not doing well, it is Washington’s fault for not providing additional “incentives,” such as tax preferences or Treasury checks.

Corporations, in short, are engaged in a massive drive to blame the federal government for what really is the fault of their own business. At last reading, after all, the American economy was still overwhelmingly in the hands of the land that produces food, and the factories that manufacture the goods, to the office buildings that cause the capital and managerial resources. Not only is that true, but also the corporate economy plays a strong role in deciding how public revenues and resources are to be used. Yes, businesses regulate: government guilt frequently, and when it does seriously enough, it seeks certain kinds of “Big Government” goodies. In short, Uncle Sam’s fine when he plays Uncle Sugar. How many trucking or airline companies have been ready to shoulder the old-fashioned rigors of market pricing and entry by supporting proposals to put the regulations of these industries out of business? It is compellingly clear that many corporations welcome government when it is a subsidizer of last resort, lender of last resort, guarantor of last resort, insurer of last resort, and cartel-defender of last resort. But when Uncle Sugar becomes Uncle Sam, people protest. Of last resort, the corporate tiger bares his teeth and snarls.

In regulating for health and safety, government assumes what I believe to be one of its most basic functions, promoting the general welfare. Too many companies or industries refuse to recognize both the multiple hazards of their technology and the government’s legitimate interest in the public’s health and safety—despite extensive pesticide and other chemical plant tragedies, food-borne diseases, con
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certainly that, in the absence of the highly visible federal regulatory presence, a majority of the 65 million vehicles recalled since 1966 would be on the road with their defects unremedied.

In the area of fuel economy, the need for regulation is likewise evident. The oil shortage of 1973-74 taught us what could happen if this country continued to rely heavily on foreign sources for all motor vehicles account for about 40 percent of the nation's petroleum consumption. Consequently, there is an absolute necessity, given that alternative means of transportation for most individuals are still far in the future and that drastic changes in driving patterns seem unlikely. Regulating average vehicle fuel economy is the best present means to achieve this end.

We at NHTSA estimate the costs of all of our proposed regulations. However, since the standards are set in terms of performance, rather than hardware or design, individual manufacturers are generally free to choose from a number of options to meet a standard, which means that their costs may vary substantially according to the options they choose and the degree to which they may exceed the requirements of the standard. Nevertheless, it is the manufacturers themselves (who supply wholesale price information to the Bureau of Labor Statistics) who are the prime source of data on the costs of implementing our regulations. On the basis of their data and other available information, the Department of Transportation estimates the average cost to consumers of safety features contained in a model year 1979 automobile at about $270, approximately half the amount claimed by some auto makers and roughly 5 percent of the total vehicle price. Considering the payroll for the General Accounting Office, it is estimated in 1979 that vehicle safety standards had saved some 20,000 lives over the years from 1966 to 1974, safety requirements are one of the car buyer's best investments.

In a 1978 survey of automobile manufacturers, the NHTSA asked the following question: "Among the manufacturers' proposals was widespread use of the air bag. Manufacturers typically mention cost objections, but $50 yet of safety questions. How often does the manufacturer's air bag proposal raise objections in the minds of the consumers?" The manufacturers claim that the air bag is too expensive, and that consumers would not be willing to pay for it. Yet at the time, cost was never a question. Some manufacturers claimed our standards added $300 to a vehicle's price.

Auto industry executives have been particularly critical of regulations promulgated but not yet effective. These include an upgraded bumper standard, passive restraints, and fuel economy standards for passenger cars and for light trucks and vans. Yet the estimated additional cost to produce each car would be $100 more for a 1984 car than for a 1977 car. If that amount would save a consumer $100 over the life of the vehicle, indeed, because of the heavy travel by newer vehicles, the $100 could be recouped through decreased operating expenses within two years of a vehicle's purchase. And for trucks and vans, the fuel economy standards, in particular, will result in consumers' spending $50 cents to save a gallon of gasoline that would have cost them at least 35 cents (given our assumptions on vehicle use).

National opinion surveys show that the American public, by a wide margin, supports government health and safety standards. In a Harris poll of spring 1978, 78 percent of those polled stated that they approved of the new regulations on air bags, whereas 22 percent opposed them. This support provides a good climate for developing what has been labeled the socially responsible automobile.

But even if it did not—once the climate were truly poisoned by industry exaggerations of the permivable effects of government—the benefits of health and safety regulation and of fuel economy standards would still, in our view, outweigh the costs. And if the free enterprise system in this country is undermined when we force automotive manufacturers to do what the people want and what foreign companies are already doing, then perhaps our enterprise system is not worth saving because it is the system that has always worked. Perhaps our regulations are like the shepherd who stood by, because he grew tired of tending his sheep's own business. But this much is clear: if we do not act now, it may be too late.
The Costs and Benefits of Regulation—Who Knows How Great They Really Are?

Business complains that federal regulations cost more than $100 billion a year, but public interest groups disagree and argue that the benefits outweigh the costs.

BY TIMOTHY B. CLARK

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The Chase Manhattan Bank N A

When Weidenbaum produced his $100 billion estimate of the cost of federal regulation, he struck a chord that resonated through the business community. His figures, which he developed at the Center for the Study of American Business at Washington University in St. Louis, have been cited repeatedly.

A newspaper advertisement by Amway Corp. entitled "Regulatory Overkill." declared "The Center for the Study of American Business estimates government regulation costs a family of four more than $2,000 a year. That's more than 10 per cent of its income." The National Cotton Council, in an ad called "Regulation is a Cost," claimed that "Regulation could cost your family a fortune."" You're being eaten out of house and home by federal regulations. Many of them unreasonable. And all of them costing you money. As much as $130 billion a year or $2,000 per family," it said.

The Chase Manhattan Bank N A wrote an ad based on figures it said were developed by its own economists, that said regulation cost more than $100 billion a year. That drew a rebuttal from Peter J. Perucka, director of the Regulatory Council, which compiles the study of federal regulatory agencies and tracks the cost of their activities. In a letter to the Wall Street Journal, Perucka said, "Chase figures are exaggerated." He added, "Weidenbaum, on leave from Washington University this year at the American Enterprise Institute for Public Policy Research, more than three years to arrive at the magic figure of $100 billion in regulatory costs. His center at Washington University began in 1975 to study capital formation, taxation and labor policy. That year, Weidenbaum published a paper on 'Government-Mandated Price Increases' that said governments contributed to inflation not only through budget deficits and 'excessively easy monetary policy' but also through "less obvious and hence more insidious" way - regulation."

In that study, Weidenbaum did not attempt a guess at the total cost of regulation, but noted that the budgets of some 35 regulatory agencies had risen from $1.1 billion in fiscal 1973 to $2.2 billion in fiscal 1975. The study, boasted Weidenbaum in a recent interview, was "pioneering" and "widely read." In 1978, he and his associate, Robert DeFina, made what Weidenbaum characterized as a "careful" search of all public and private-sector estimates of the "indirect costs" of regulation and "home largely by industry. To estimate the costs imposed by the Occupational Safety and Health Administration, they relied on an annual survey taken by McGraw-Hill for The Council on Environmental Quality was the source of some of these estimates on the costs of environmental regulation. A large number of academic studies were cited as evidence for costs in other areas.

Weidenbaum contends that his cost estimates were conservative. When he could find no compliance cost estimates, for example, for the Consumer Product Safety Commission, the National Transportation Safety Board or the National Labor Relations Board, he omitted them from his total instead of attempting to guess at the costs they impose. When a range of estimates was

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THE MAGIC $100 BILLION

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A Look at Weidenbaum's Figures

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The study provoked a group's response from Weidenbaum's articles. Weidenbaum himself briefly examined the single-plant hearings by two interstate and foreign committees. Weidenbaum's response, saying, "The saddest aspect of the study group reports on the great emphasis on regulation, on the vastness of personal attacks on individuals with whom they disagree with his views."

A detailed critique of the study was made by the same committees. The targets of the study included the American Forest Institute and the author of numerous articles on regulation. Methods of evaluating the "benefits" of any project have been based on the "aggregate" of the total costs and benefits of the project.

DEFENSIVE MAKING

Though most of the debate has revolved around aggregate numbers, such as those produced by Weidenbaum and others, the issue is who should regulate the individual regulations. It is only if their benefits exceed their costs that we can justify, given the difficulties of quantifying benefits and their actual strengths and weaknesses. A 1978 report by the House Interstate and Foreign Commerce Committee on cost-benefit analysis was released last year. The most significant factor in evaluating any project is the study of the benefits of the project and the study of the costs of the project.

A detailed critique of the study was made by the Interstate and Foreign Commerce Committee. Methods of evaluating the "benefits" of any project have been based on the "aggregate" of the total costs and benefits of the project. In this case we have been talking about the benefits to the user of the benefits from the project, and the costs to the user of the benefits from the project. The study has been concerned with the methods of evaluating the dollar values to the benefits from the project. It is obvious that the project would have been more efficient if it had been included in the study. The study's primary concern was to prevent the exclusion of the "benefits" of the project from the study. The study has been concerned with the methods of evaluating the dollar values to the benefits from the project. It is obvious that the project would have been more efficient if it had been included in the study. The study's primary concern was to prevent the exclusion of the "benefits" of the project from the study. The study has been concerned with the methods of evaluating the dollar values to the benefits from the project. It is obvious that the project would have been more efficient if it had been included in the study. The study's primary concern was to prevent the exclusion of the "benefits" of the project from the study. The study has been concerned with the methods of evaluating the dollar values to the benefits from the project. It is obvious that the project would have been more efficient if it had been included in the study.
CONGRESS TO PUT THE 10-MILLION-TONNES-LIMITED styrene production scenario to a vote. The Senate's action on the Administration's proposal to require the styrene industry to reduce its production of styrene to 10 million tonnes per year is expected to be a key vote in the new Congress. The Senate has already voted to impose a 10-million-tonnes limit on styrene production, and the House has passed a similar measure.

The Senate's vote on the Administration's proposal is expected to be a key test of the new Congress's commitment to environmental regulation. The Administration has argued that the new limits are necessary to protect public health and the environment, and that they are supported by scientific evidence. However, some Senate members have expressed concerns that the limits could have adverse economic effects on the styrene industry and on the broader economy.

The Senate vote is expected to be closely watched, and it is likely to be the subject of intense lobbying by the styrene industry and its supporters. The industry has argued that the limits would have a significant impact on its operations and that they could lead to higher prices for consumers. The Administration has countered that the limits are necessary to protect public health and that they are supported by scientific evidence.

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Susan B. King, the commission's new head, believes in government regulation, and she is determined to improve her agency's reputation.

BY LINDA E. MAJOR

Don't let the outspoken Southern manner fool you. Susan B. King, the new chairman of the Consumer Product Safety Commission, talks with a "get down to business" toughness and determination that let you know she's going to try to create credibility in the agency and make it work up the law intended.

The job before her is a big one to transform the Commission, beset by external criticism and torn by internal strife. Since it was established in 1972, it has been a productive and efficient agency. No such were some of the problems that are now being faced. For the first time, the commission's structure was clearly defined in the Consumer Product Safety Act of 1972.

King, whom Carter named to the commission in January, said that he had the background to lead the agency into a new era. She said in a recent interview: "As a background to public administration and engineering, my career has been a strong influence on the commission." She found the stress of the job overwhelming at first, but she is determined to improve the agency's reputation.

The 56-year-old Georgian gained administrative experience as director of the Georgia State University and as an aide to the chairman of the Consumer Product Safety Commission. She is well known for her ability to work with the staff and bring them together.

"The agency is very large and complex," she said. "I have to be very careful about what I say and do. It is a very demanding job." She is determined to make the agency more efficient and effective.

A. A New Approach

The agency has faced a number of problems in recent years. One of the most serious is the lack of adequate personnel management. This has led to the hiring of inexperienced staff, which has caused delays and mistakes.

Another problem is the lack of adequate management procedures. This has led to a lack of coordination and communication within the agency. This has caused delays and mistakes.

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Dear lad

I've been a long time in coming. I know you'll be waiting for your
bottles. I'm afraid I've a job to do, and I'm not sure I can make it.

The problem is this: I don't want to be seen as the

person who

gets

their

way

by

some

sort

of

moral

manipulation.

So

I've

decided

to

try

an

alternative

to

the

usual

approach.

In

the

past,

I've

often

been

successful

by

using

a

combination

of

emotion

and

reason.

But

this

time,

I

think

I

should

try

something

different.

I

want

to

make

it

clear

that

I

am

not

interested

in

your

bottles,

but

in

the

future,

I

might

be

able
to

persuade

you

to

give

me

a

few

more.

Please

consider

this

request

as

a

favor,

not

a

demand.

Sincerely,

[Your Name]
PRODUCT SAFETY: DIMENSIONS FOR CONSUMER POLICY

Alvin S. Weinstein

Introduction

A sensitized society and the law of strict liability are social phenomena that have erupted as two peaks to be scaled by technology in reaching a societally acceptable policy for balancing risk and utility.

Where once society believed implicitly in technology's ability to solve all problems, the technological community is now held to be the inept midwife filling our lungs with pollutants, our stomachs with toxic chemicals and maiming us with unsafe products.

Regardless of how pervasive these charges are, it is clear that we are searching for guideposts which permit us to chart new directions in improving the quality of life.

There is no doubt that societal mores can be readily sensed by policy makers, yet they provide, at best, only vague guidelines for the decision-making functions. The legal thrust of strict products liability, however, offers a clearer picture of a desirable objective for social policy: products must not be unreasonably dangerous. We have literally made a legal about-face in the last two decades. From the historic rule of caveat emptor--let the buyer beware--the challenge is now caveat venditor--let the manufacturer beware! It is from this altered perspective that we begin to probe the directions for product-consumer equity.

The premise explored here postulates, quite simply, that the basic philosophy of the law of strict liability offers a matrix upon which to construct sound public policy for the interaction of technology and society. The law indicates appropriate questions to be answered and suggests the directions for efforts in resolving the difficult issues.

The Legal Premise

The California Supreme Court, in a 1963 decision, established strict products liability—a statement of social policy whose impact has traumatized the manufacturing community. The court stated, in part, in the decision rendered in Greenman v. Yuba Power Products:

A manufacturer is strictly liable...when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury.

The purpose of such liability is to insure that the costs of injuries resulting from such defective products are borne by the manufacturer that puts such products on the market rather than the injured persons who are powerless to protect themselves.

The social policy, enunciated with unmistakable clarity, which emerged from this opinion was, by 1969, delineated concisely as a new legal theory in section 402A of the Restatement of Torts (Second). It provides:

1. One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
   a. The seller is engaged in the business of selling such a product.
   b. It is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

2. The rule stated in subsection 1 applies, although
   a. The seller has exercised all possible care in the preparation and sale of his product
   b. The user has not bought the product from or entered into any contractual relation with the seller.
In the succeeding years, over 45 jurisdictions in the United States have adopted section 402A, either explicitly or in somewhat altered forms, still preserving the basic philosophy. The injured plaintiff need only establish that a flaw in the product created an unreasonably dangerous condition (a defect) and that this condition was the most probable cause of the injury.

The manufacturer's care either in the basic design of the product or in its production is of no importance in litigation. No longer is it necessary to demonstrate that a manufacturer did not act "reasonably," or was negligent, for a plaintiff to recover. He need only prove that the product was defective, that is, unreasonably dangerous and that the injury was a direct result of this condition of the product.

What is an unreasonably dangerous product? A product is after all an object, a thing. How does it become unreasonably dangerous? Perhaps it is important to stress the obvious at this juncture. In deciding whether or not a product is unreasonably dangerous we are focusing on the product and not on the conduct of the manufacturer. In order to develop the issue of unreasonable danger, it becomes crucial to understand not only the scope of consumer expectations but also the entire milieu of product use—the total environment in which the product finds itself.

When, through the litigation process, a jury is asked to conclude whether or not a product is unreasonable dangerous, the decision should have major social and societal significance. Since the legal focus is on the product within its environment of use, the test for unreasonable danger must derive from the elements of risk-utility balancing. It is this balancing process that is central to public policy determination, as well as to the legal forum. It is on the elements of this process that we direct our concerns.
A particularly appropriate view of these elements has been set forth by Dean Wade (Strict Liability of Manufacturers, 19 Sw. L. J. (1965)):

1) The usefulness and desirability of the product
2) The availability of other and safer products to meet the same need
3) The likelihood of injury and its probable seriousness
4) The obviousness of the danger
5) Common knowledge and normal public expectation of the danger (particularly for established products)
6) The avoidability of injury by care in use of the product (including the effect of instructions and warnings)
7) The ability to eliminate the danger without seriously impairing the usefulness of the product or making it unduly expensive.

It is the subjective amalgam of these seven elements, we submit, that can permit a jury to reach the conclusion of whether or not a product is unreasonably dangerous and hence establish "product liability." Consider the following example to illustrate the central issues which should be raised when the issue of unreasonable danger is addressed from the perspective of risk-utility premises, implied by the seven indicia.

There is no question that a kitchen knife is dangerous. It will slice a finger as easily as rib steak. But is a knife defective? That is, is it an unreasonably dangerous product? We approach the answer by considering the issues highlighted by the indicia.

There is no question of the overwhelming utility of a knife. It is a fundamental implement. While fingers may be a safer product, they hardly come close to meeting the same need.

The probability of injury is quite high, while the seriousness of those injuries, in general, can be classified as moderate to low. Even though knives are used by a large fraction of the public, ranging from youth to old age for both sexes, there is common knowledge, as well as expectation of a danger that is highly obvious.
In fact, because the danger is held to be widely recognized, knives do not contain warnings and the incidence of injury can be significantly lessened by care in the use of the product.

Finally, despite the wide recognition of the danger by the public and the moderate seriousness of injuries, we still ask if there is any way to design out the high risk of injury. Unfortunately, technology has yet to discover a cutting edge that can successfully distinguish between a side of beef and a finger.

Thus, in weighing all of these considerations, we would most likely conclude that, on balance, the utility of the knife exceeds the risk. That is, we are willing to subject ourselves to those risks in order to receive the benefit of the product. On balance then, while the knife is a dangerous product, it is not unreasonably dangerous.*

It is suggested that the issues described in this scenario are the same ones that should be raised by both sides in the courtroom.

The thrust of litigation, then, within the framework of strict liability should be, in each case, to distinguish between products which are reasonably safe and those which are unreasonably dangerous. Unless a manufacturer is able to demonstrate that the consumer either unforeseeably misused the product or knowingly assumed the risk of using an apparently defective product, he is liable to the injured party for having produced a defective product because it was unreasonably dangerous.

Given the trade-offs which are inherent in every design, it is suggested that the jury must really answer the question: Given the risk-utility or benefit-cost considerations, are we willing to live

*It should be noted that even if there were a technological breakthrough that might lessen the risk of knife injuries, we would still have to ask whether such a feature would lessen the utility of the product or substantially increase its cost. If the utility were lessened and the price increased, we might argue that we would prefer to leave the product as is.
with the product as is, with all of its attendant risks, or do we wish it to be marketed in an altered, less dangerous form?

Public Policy and the Reasonably Safe Product

If the question posed above is the critical one in the litigation setting for distinguishing between the reasonably safe product and the unreasonably dangerous one, isn't it also the same one that society must ask in formulating public policy for consumer product safety? Fundamentally, since no product can ever be completely safe, and since we have not yet decided on a policy of absolute liability, then our goal is to seek the methodology for deciding the risk level we can tolerate for each product.

This is the challenge which has resulted from the converging concerns of consumers and the enhanced perspective of the courts. The objectives are clear: to educate the consumer, realistically, in understanding the utility and the risks of products; to guide industry in order that products are designed and marketed anticipating real use and not intended use; and to aid the legal system in describing the appropriate considerations necessary for fair and reasonable adjudication of the issues brought before it. These objectives should become part of the province of public policy research.

It is suggested that an appropriate focus is to utilize, prospectively, during the product design process and in the formulation of product safety standards, the risk and utility indicia used by the courts retrospectively in determining the existence of an unreasonably dangerous product. If it is reasonable to assume that these indicia will form the basis for judging the interaction of technology and society in the courts, then it is obvious that these should be the same criteria to be used when products are designed and marketed and when standards or codes are devised for establishing guidelines of design and manufacture.
While deceptively simple to understand and while their intent and meaning cannot be ignored, these indicia, however, do not provide a firm basis for quantitative evaluation. Even if it were their task, the courts are not equipped to establish the groundrules for the important societal judgments that are implicit in testing any product against those indicia.

It does not necessarily follow that those responsible for design, manufacture and marketing are the only ones able to interpret the societal judgments implicit in the search for reasonably safe products. While there is no question that technology must exercise a conscious effort to enhance the decision-making process in design and manufacture, that process must enlist the perspectives and judgments of others to balance, counter, and expand the traditional constraints of industry.

Implicit in the indicia for reasonable safety is the fact that it is no longer the manufacturer's view of intended product use that will be tested in considering a product flaw and its danger, but rather it is the expectation of the consumer that underlies the judgment. The safety of a product must be measured as a balance of the probability of being harmed, the gravity of the harm if it occurs, and the burden of precaution against the harm. If, for a certain product, both the probability and gravity of the harm are low, while the burden of precaution is high (i.e., the cost of adding additional safety features or impairing the usefulness of the product if the harm is to be avoided), then society may decide that because of an inherently high utility in the product, the added cost produces insufficient benefits and hence the product is safe enough. On the other hand if the cost is relatively small to reduce a harm with high probability and gravity, then society would demand the safer product.

These kinds of judgments cannot be made as generalizations. They require serious consideration for each situation in order to make some type of quantitative cost-benefit analysis. The decisions will be difficult and will require the efforts of those whose research focuses on public policy. The implication in the balancing process between the

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196
existence of a harm and the precaution against it is that there is an acceptable risk level below which there need not be any precaution. While this is a valid generalization simply because nothing could ever be completely safe, decisions which permit residual risk of injury to be balanced against objective cost decisions are difficult to make in any event but especially so when they have to be made subject to public scrutiny.

When the reference point for probability and gravity of the harm has to be made, not from the manufacturer's point of view but rather from the consumer's perspective, the gathering of substantive data for decision-making becomes that much more difficult. Surveys that focus on the understanding of a product in the context of its actual environment of use are essential to insure meaningful feedback to govern design modifications.

There is a critical need for devising techniques that can warn, instruct and educate the consumer effectively for reducing the risk level in the use of a product. The techniques that permit decisions to be made between consumer education and design modifications to achieve that same reduction in risk level are not easy to quantify, but obviously must be developed.

There are other concerns as well. An essential dimension in achieving product safety are standards for design and manufacture. Both the voluntary groups and the regulatory agencies are seeking better methods for developing standards. The problems are not different from those in actual product design. How should the process be structured? What data and techniques should be used for hazard and risk identification? How can the concerns and abilities of the participants best be introduced and woven into the process? What are acceptable risk levels? Should the requirements be those of design and/or performance?

The legislatures of several states are now considering bills that would seriously limit or eliminate the basic social policy contained in the philosophy of strict liability. The enactment of this legislation
would be a serious error. While there may be legitimate concern over
the inconsistency of awards to injured plaintiffs as well as to current
litigation procedures, these are not symptomatic of fundamental problems
with the public policy articulated by the law. Rather, they suggest a
need for better understanding and implementation of methodologies for
establishing a reasonably safe environment for society. It is thus
argued that efforts to resist and counter these suggested legislative
changes must be undertaken as a public policy objective.

Underlying this discussion is the premise that appropriate risk
allocation is the fundamental determinant of public policy. Each
segment of society from the producer to the user, including the
government, must recognize the risks each is to assume and the risks to
be assumed by others.

What is being suggested is a modified and expanded set of
constraints that reflect directions for research. They are difficult to
quantify and may require enlisting or developing new skills, but they
must be undertaken, nevertheless. The government's response to
society's demands are patently evident and the legal system has a new
set of rules, in strict liability, that are still unfamiliar but place a
significantly greater burden on those who enter the market place. The
reaction to these stimuli must be positive, incisive and responsive to a
new era of understanding our technology in the context of its actual
environment and use.

It is suggested that the new directions for emerging technologies,
rather than being stifled by government or legal restrictions, will in
fact be more challenging because of them. The problems are undeniably
more difficult. The research efforts must therefore be more creative
and imaginative.

Our views must expand first to recognize that the additional
constraints of societal expectations and behavior should be a logical
and intimate part of our activities. We must also assume a
responsibility for educating the public, assisting the producers, and
counseling the legal system as we seek to understand the real
interaction of society with technology.
The benefits will be twofold: our products will be better understood by the producer as well as the consumer, and they will better utilized. At the same time, the governmental overseers, the industrial community, and the legal system will benefit by serious attempts to understand and design for society's use of its wares. The guidelines will be brought into sharper focus and the result will be coherent public policy.
The CPSC Experiment

Pitfalls of Hazard

BY THOMAS BICK and ROGER E. KAPPERSON

WHEN THE CONSUMER PRODUCT SAFETY COMMISSION opened its doors in 1973, it...
The Consumer Product Safety Act established four major goals for the agency: protecting the public against unreasonable risks of injury associated with consumer products, developing uniform safety standards for consumer products and minimizing conflicting state and local regulations, promoting research and investigating into the causes and prevention of product-related deaths, illnesses, and injuries.

To accomplish these objectives, Congress provided the CPSC with an unusually broad and potent set of regulatory tools. The agency can, for example, issue mandatory standards, require industry-financed testing procedures, ban or require the recall of products, direct the consumer to be notified of hazards, specify labeling requirements, and destroy hazardous goods. Manufacturers are required to provide performance data, and inform the public of the comparative safety of products within different categories. CPSC may enforce its rules and orders by seeking stiff civil or criminal penalties against those who fail to comply with its regulations.

The CPSC is headed by a Commission composed of five commissioners and a chairman. A majority vote of the commission is required for all major decisions; it is thus a "collegial" body. It is also a "matrix" organization in that it has both program and functional units. The Office of Program Management is divided into eight "program areas": fire and thermal burns, electric shock, acute chemical and environmental hazards, chronic chemical and environmental hazards, tools and household appliances, structural hazards, toys, and sports (with the latter four collectively designated as "mechanical hazards"). The functional units are organized into five direct service and support organizations.

Management

The management is responsible for the overall direction and control of the agency. It is headed by a Commission composed of five commissioners and a chairman. The Commission is responsible for setting the overall direction and goals of the agency and for ensuring that the agency is operating in accordance with the law. The Commission is also responsible for approving the agency's budget and for ensuring that the agency is operating within its budget constraints.
Managing the Hazards

Hazard management by the Commission involves a number of steps (Figure 1). First the CPSC identifies the product-related injuries and determines their causes. This is done primarily through the National Electronic Injury Surveillance System (NEISS) or a mesh of telecommunications terminals located in the emergency rooms of 129 statistically representative hospitals across the country. In-depth investigations of injuries (over 4,000 in a 5,000 investigations yearly) and screening of death certificates, consumer complaints, consumer laboratories, and data from other agencies supplement this information. In addition, any interested person or group reviewing a product hazard may petition the Commission to institute a hazard control action.

Next the Commission (as of 1977) assigns product hazards into priority groups. Once priorities have been established, strategies for managing the high-priority hazards must be formulated. The hazard is assigned to one of the eight program areas. The program manager, in developing a management strategy, utilizes technical expertise from the various CPSC directorates. When all the information and analysis has been assembled and assessed, the program manager prepares a "briefing package" summarizing the information and preparing one or more management strategies, listing the pros and cons of each. The Commission reviews the briefing package; chooses a particular strategy, or returns the package for further work. Not uncommonly, a briefing package appears before the Commission for several times before it makes a final strategy decision. If the decision is to promulgate a safety rule or ban, it initiates rulemaking procedure. However, a public education strategy can be chosen, the staff prepares an information and education plan.

After a strategy is implemented, the Commission evaluates its effectiveness. The Directorate of Hazard Identification and Analysis monitors the agency's injury reporting system to gauge the injury-reducing impact of the managerial strategy. Meanwhile, the Directorate of Compliance and Enforcement determines the extent of industry compliance.

Public Participation

The CPSC has two important public participation features: the "offeror" and the citizen petition process.

The "offeror" process is unique to the CPSC. Section 7 of the Act requires the Commission, when it decides to issue a product safety standard, to announce this intention publicly and to invite any interested person to submit an existing standard for adoption by the CPSC or to offer to develop a standard. The CPSC must accept one or several of these offers if the "offeror" is technically competent, capable of developing an appropriate standard, or if the only acceptable offeror represents the industry to be regulated. The Commission then reviews the proposed standard prepared by the offeror and, after analyzing its estimated economic and environmental impacts and its hazard-reducing potential, either adopts, amends, or rejects it. If there are no qualified offerors or if the only acceptable offeror represents the industry to be regulated, the Commission may develop its own proposed standard. Once a standard is adopted, any person may request judicial review of the standard within sixty days.

October 1978
208
In addition, the Act ptuvIdes for
early public participation In Its &Melon

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ESTIMATED SAFETY CONTRIBUTION OF OCPEC REGULATIONS.

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nil, of injury" and the denial "unreason.

ably cermet the petitioner or other con
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honer, however, may challenge such a
dental in court.

CPSC Performance
Despite us broad regulatory powers
and the early enthusiasm of Ito spOnsurs
and stall, the Commission has developed
a reputation m a poorly run, unaggres-

sive, and largely Ineffectual burcauc
my. A 197b llOUS7 oversight committee
report spoke for many of the agency's
critics when it concluded that, after
three years, the Commission had nut
utilized its broad regulatory powers,
had been slow to develop safety stem
duds. and hod "yet to demonstrate its
capacity to plan, to premnbe adminisnative rules and guidelines, and to set
clear priorities." Hearings held to the
House and Senate in 1977 and 1978
further highlighted the failures and de
ficiencies of the agency. In 1978 the
Preeident's Office of Management and
Budget (OMB) indicated Its intention
of seeking to have the Commission
abolished. To what extent does the
record support the negative assessments
of so many of the CPSC's observers.

It is important to note at the outset
that the Commission is nut without Its

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nave also been successful. In Its first
two and a half yeah, the Commission
processed 350 notillietions from menu.

lecturers, resultingin the correction
(largely through Informal negotiation)
of four million defective consumer
products. The product standards and
bans Issued as of January 1, 1978,

though criticized by many as too few
and too weak, could ultimately prevem
an estimated 553,600 annual consumer
injuries (Table I) and thousands of

positive achievements. Most observers
would agree that the agency's open door

deaths.

policy has made It a model of a publicly
accessible bureaucracy. Most of its meet.
Inge have been open to the public and,
unlike the situation in mom other fed
era' agencies, Commission policy has
made disclosure of its records the rule
rather than the exception. Even many
of the Commission's meat vocal codes
agree that its system of injury surveil.
lance is among the best hazard identifi
cation systems in the country. Most,
also agree that the actions the Commis
lion has taken in requiring industry to
notify It of substantial product hazards

federal regulation has undoubtedly led
industry to impose safety product stars.
dards of Its own, although the actual
extent of such action is, of course, not
known. The consumer product Indus
try is also well aware that a growing
number of private attorneys are using

Finally, the continuing threat of

the C01111711111011% Injury data to help

win product hability suits. This is an

unpublicized but important contribu
tion of the hazard identification sys
tern and may well prove one of the
Commission's most significant impacts
on product safety.

EliVf011OrnItal, Vol. 20, No. 11

20

As significant as these achievements
are, they are more than matched by
the agency's many deficiencies. The
Commission has in the past consistently
backed away from forceful regulation.
Thus far it has enacted only eleven
standeldi and bans!The first safety
standard did not become effective tin.
td some three and onehalf years after
the Commission opened its doors for
business:even worse, the standard was
for swimming pool slides -hardly a
product at the top of the average coin
sinner's "most hazardous" list. To add
insult to injury, a federal appeals coot
recently invalidated most of the stam
clod on the basis that it was unsup
ported by the evidence available to the
Commission' The Commission has re .
peatedly opted for less controversial.
labeling requirements whenever its staff
has proposed standards or bans. It has
ahnost totally neglected one of its most

important responsibilities-to provide
consumers with comparative in fomution
on the safety of specific products. De.
spite explicit authorization in the act,
the Commission has failed to promulgate


orders requiring annual reports to keep prices within limits, in order to preserve the health of the economy.

So far, the agency has restricted its involvement to the most important issues, right to be discussed under Section 12(c) of the statute. Instead, the Commission has focused on the more significant problems, especially those affecting children. In 1975, the Commission held a long hearing on asbestos, for example, which led to the ban on its use in children's pajamas. In 1976, the Commission conducted a major investigation into the safety of children's cribs, resulting in new standards for cribs.

The Commission has also been involved in other areas, such as the safety of toys and household products. In 1975, the Commission issued a report on the dangers of children's toys, which led to the development of new safety standards. In 1976, the Commission issued a report on the dangers of household chemicals, which led to the development of new labeling requirements.

Table 2: Funding of the CPSC

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Amount Authorized</th>
<th>CPSC Request</th>
<th>OMB Request</th>
<th>Amount Appropriated</th>
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<tbody>
<tr>
<td>1974</td>
<td>180</td>
<td>280</td>
<td>230</td>
<td>240</td>
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<tr>
<td>1975</td>
<td>180</td>
<td>280</td>
<td>230</td>
<td>240</td>
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<tr>
<td>1976</td>
<td>180</td>
<td>280</td>
<td>230</td>
<td>240</td>
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</tbody>
</table>

The Commission's budget has increased significantly over the years, reflecting its expanding responsibilities. In 1975, the Commission's budget was $20 million, which increased to $30 million in 1976. The budget for 1977 is projected to be $40 million, and for 1978, it is projected to be $50 million.

In conclusion, the Consumer Product Safety Commission has played a crucial role in protecting the public from hazardous products. Its ability to perform this essential task has been influenced by a variety of factors, including its statutory mandate, the nature of the products it regulates, and the political environment in which it operates. However, the Commission has been able to achieve significant results despite these challenges, and its role in safeguarding the public's health and safety continues to be critical.
The Pitfalls of Innovation

Hundreds of billions are siphoned away from a host of federal agencies. In a context of not surprising that many observers of the agency's evaluation, one does not need to be an expert to see that the current innovation in the workplace has been laced with those sources of employee behavior. But one must not be surprised by the 2001. The agency's evaluation, or to state the research, must be conducted on the agenda of the newly formed agency 1111Zald ability to establish a framework of ornrunier prod

Imi,erse ..1 diverse hatards within the oil 01 the attempt to regulate a broad hattrd manager and its rulentalting proceedings be

It has been determined to those sources of the CPSC's failures which stem from its experimental nature as a hazard manager and as a new kind of regulator. Two of the CPSC's early shortcomings are the absence of the agency's ability to regulate a broad universe of diverse hazards within the first half of the 1990's and the paucity of computer products. These two are both failures to regulate hazards effectively and the in ability to manage hazards

The small size of resources has been largely a result of the agency's inability to establish priorities. As an age of an economically ruined hazard domain, the newly formed agency must understand that the hazard problem is only a portion of violent death and injury. Former Chairman John Byington ordered the preparation of the "Product Hazards" report after taking office. Preparation of these profiles cost 9500,000 yet proved to be of no little value that the project was discontinued.

In 1975 the Commission warned that a type of large aluminum frame presented an electrocution hazard and brought complaints against five manufacturers of the product. After obtaining agreements from five of the companies to discontinue making the frames, the Commission decided the product was actually a toy and should have been disclosed under a different law. The earlier agreements were rescinded and no new ban has yet been issued.

Despite this declaration of intent and despite the availability of an effective hazard identification system (see Figure 1), the Commission failed to publish priorities until well into its tenth year. As a result, it became noted as an agency with an indefinite span of a report, the agency's evaluation, or to state the research, must be conducted on the agenda of the newly formed agency 1111Zald ability to establish a framework of ornrunier prod

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such a broad-based consumer. Table 4 shows the annual injury, fatality, and property damage costs for each of the 29 high priority hazards finally recognized by the Commission.

These data, when compared with the results of CPS regulations enacted as of January 1, 1979 (Table 1), suggest the extent to which misplaced efforts have been possible in the absence of clear priorities. While two of the agency's safety rules that address sharp glass and breakable bottles should have an estimated 250 to 300 deaths averted a year, other rules that have much lower injury reduction potentials that the Commission has used its limited resources on higher priority hazards (i.e., it could have provided much greater protection for the American consumer). As an example, the Commission estimates that a safety standard for power lawn mowers could save up to 200,000 annual injuries, fatality, and $1 billion annually. As Table 4 shows, the annual saving potential for 35 hazards is over $1 billion.

Table 6
THE HIGH PRIORITY HAZARDS OF THE CPS

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<td></td>
<td>1978</td>
<td>1978</td>
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<td>1979</td>
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<tr>
<td>Family</td>
<td>25</td>
<td>25</td>
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<tr>
<td>Injury in Utah</td>
<td>2</td>
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<tr>
<td>Death in Texas</td>
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<tr>
<td>Accident</td>
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<td>Injury in Ohio</td>
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<td>Injury in Nevada</td>
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<td>Injury in Alaska</td>
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<td>Injury in North Carolina</td>
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<td>Injury in South Carolina</td>
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<td>Injury in West Virginia</td>
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Table 6 shows the annual injury, fatality, and property damage costs for each of the 29 high priority hazards finally recognized by the Commission.

October 1979
The Power mower standeed was the sole EPS standard developed by a consumer organization.
In creating the CEA, Congress set out to establish a model of regulatory reform. It included in the Consumer Product Safety Act provisions that justified the agency's creation and its authority to promulgate and enforce regulations to ensure the safety of consumer products.

A number of regulatory provisions were included in the act. The provisions included restrictions on the sale of certain hazardous consumer products. The agency was to be responsible for promulgating and enforcing regulations to ensure the safety of consumer products. The agency was also to be responsible for investigating and prosecuting violations of the law.

The President was responsible for the management and budget of the agency. The President was to appoint the director of the agency and the other members of the agency. The President was also responsible for the budget of the agency. The President was to provide the agency with the funds necessary to carry out its functions.

The CEA was to be subject to review by the Congress. The Congress was to review the agency's budget and performance. The Congress was also to review the agency's regulations and policies. The Congress was to have the power to veto the agency's regulations and policies.

The CEA was to be subject to review by the President. The President was to have the power to veto the agency's regulations and policies. The President was also to have the power to dissolve the agency at any time.

The CEA was to be subject to review by the courts. The courts were to have the power to review the agency's regulations and policies. The courts were also to have the power to review the agency's budget and performance.

The CEA was to be subject to review by the public. The public was to have the power to review the agency's regulations and policies. The public was also to have the power to review the agency's budget and performance.

The CEA was to be subject to review by the media. The media was to have the power to review the agency's regulations and policies. The media was also to have the power to review the agency's budget and performance.

The CEA was to be subject to review by the international community. The international community was to have the power to review the agency's regulations and policies. The international community was also to have the power to review the agency's budget and performance.

The CEA was to be subject to review by the public and the media. The public and the media were to have the power to review the agency's regulations and policies. The public and the media were also to have the power to review the agency's budget and performance.

The CEA was to be subject to review by the courts and the international community. The courts and the international community were to have the power to review the agency's regulations and policies. The courts and the international community were also to have the power to review the agency's budget and performance.

The CEA was to be subject to review by the President and the Congress. The President and the Congress were to have the power to review the agency's regulations and policies. The President and the Congress were also to have the power to review the agency's budget and performance.

The CEA was to be subject to review by the media and the public. The media and the public were to have the power to review the agency's regulations and policies. The media and the public were also to have the power to review the agency's budget and performance.

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positions detailed in Table 2, were the result. Substantial third- and fourth-year funding increases, confidently anticipated by CPSC planners, were never forthcoming.

In sum, the effort to establish the CPSC as a politically independent hazard manager within the federal government was a failure, a fact that attests to the inadequacy of the provisions in the act designed to counter that authority and to the inadequacy of the decisions of the Commission in the face of political pressure on the agency whenever affected industries tried to have their standards modified or set aside.

Public Participation

Many would agree that the CPSC has become one of Washington's most accessible and open agencies but fail to look beyond the shortcomings of the CPSC in hazard management to the CPSC as an instrument of public participation. It is assumed that, in a well-ordered world, these two roles must be somehow compatible, indeed reinforcing.

The CPSC's "officer" process requires the Commission to accept the offer of one or more qualified persons or groups to develop a needed safety standard. The intent was that both industry and consumer groups would become directly involved in the Commission's most important rule-making activity. In the issuance of product safety standards. In fact, however, industry has all but totally dominated the process. Indeed, not only has the power structure been developed by a consumer group to consumer, CPSC staff and the CPSC, but the nominating provisions have been frustrated by a host of industry consumer group offers.

In retrospect, it is also apparent that the CPSC's congressional sponsors hardly understood the time and money needed to draft comprehensive safety standards. Some offers, and others participating in the process, have spent millions of dollars, and four to five years, working to draft acceptable standards. Consumer Union found its four-year involvement with the power mower standard so costly that it stated in a letter to the Commission that it would probably never again serve as an officer. Although consumer representation, by law, is added to all standards development committees, they usually lack the technical expertise and funding to compete effectively with well-heeled industry groups. The Commission, for its part, has failed to provide the consumer groups needed for effective consumer participation (though it ideally has the power to do so). The other measure intended to assure public involvement in CPSC rulemaking, the citizen petition process presents the agency with the dilemma of how to reconcile the need for effective citizen participation with the need for efficient hazard management. Recently the CPSC has moved toward a policy of summarily denying petitions not related to high-visibility hazards. Such a policy not only potentially weakens the "regulatory values" portion of the CPSC's mission but also may undermine the petition substantive value of the petition process in its ability to alert the Commission to the occasional hazard that is unidentified or underestimated by normal agency processes. An even larger issue, however, is involved in determining the long-term effectiveness of the CPSC. Facing a regulatory domain occupied by powerful industry groups, the Commission...
Since she became chairman of the CPSC in July, Susan Bennett King has-embarked on a bold and controversial course of action, aiming to make the agency more effective in protecting consumers. She has proposed a series of measures designed to enhance the CPSC's role and increase its influence in the marketplace. These initiatives, if adopted, could significantly change the landscape of consumer protection in the United States.

The Problem

The CPSC has faced numerous challenges in recent years, including a lack of funding, the need for more research and data, and the difficulty of enforcing regulations in a rapidly changing market. King has identified a number of specific issues that need to be addressed, including the need for more aggressive enforcement, improved communication with consumers, and a stronger focus on preventing hazards before they occur.

Some Suggested Solutions

To improve the CPSC, King has recommended the following four specific changes:

1. Increase Congressional approval and funding: The CPSC should be given more resources and autonomy to carry out its mission effectively.
2. Strengthen enforcement: The agency should be given more power to enforce regulations and take action against companies that violate them.
3. Improve communication with consumers: The CPSC should develop better ways to inform consumers about potential hazards and encourage them to take action to protect themselves.
4. Enhance research and data collection: The agency should invest more in research to better understand consumer behavior and the risks associated with different products.

Conclusion

King's proposals are a significant step forward in the effort to make the CPSC a more effective and powerful advocate for consumer safety. If adopted, these changes could help to create a safer and more informed marketplace for consumers.
Congress should reconsider the appropriateness of the Commission's domain of hazard responsibility. It should either remove the Commission's responsibilities for chronic hazards and vest in a new central governmental institution or, alternatively, mandate uniform national chronic hazard policies and procedures which would apply to all federal regulatory agencies.

Congress should provide more guidance on the criteria for setting priorities and should specifically outline how the Commission's resources should be allocated in relation to those priorities. Congress should also specify procedures for demonstrating achievement in creating a safer environment and about American households.

The Commission should immediately undertake an ambitious program, adequately funded and staffed, to determine the relative safety of various products within different classes of products. It should then mount a vigorous campaign to inform the public, so that this information can be used by consumers in making decisions about their purchases.

The Commission should take effective action to counter those political influences in its regulatory process which are clearly harmful to the protection of the American public from the dangers of consumer products. Specifically, the current process should be altered to reduce industry dominance, substantially increased funding should be provided to support expanded consumer participation in the agency, and the creation of a full-time "consumer advocate" within the agency should be reconsidered.

The Larger Lessons

An examination of the difficulties which have plagued the CPSC experiment suggests that there is a pressing need for the classification of hazards (hazard assessment and a defensible assignment of priorities. Ad hoc, case-by-case response is the quicksand of modern hazard management.

A second lesson can be learned from the CPSC's mixed record as an experiment in regulatory reform. The experiment indicates how little is known about how to give the public an effective voice in bureaucratic decisions, and suggests that even less is known about how to design institutions that contribute to rather than detract from the substantive work of an agency.

Finally, given the fact that some benefits to society must usually be foregone in order to reduce hazards, a regulatory agency can travel down the road of hazard control only so far without a "safety constituency." Long-term success in creating safer households, workplaces, and other environments depends upon an unambiguous public resolve both to demand protection and to pay the price, together with a Congressional commitment to implement change even in the face of an unhelpful economy.

The first version of swimming pool slides by the CPSC, June 1975, with a label that there is a pressing need for the classification of hazards (hazard assessment and a defensible assignment of priorities. Adhoc, case-by-case response is the quicksand of modern hazard management.

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ACKNOWLEDGEMENTS

The authors wish to express their appreciation to their colleagues Christoph Hohenemser, Joanne Kaufman, and Robert Kates, all of the Clark University Hazards Assessment Group, for helpful comments and suggestions. The research was supported by the National Science Foundation under grant number ENV 77-15331. Any opinions, findings, conclusions or recommendations expressed herein are those of the authors and do not necessarily reflect the view of the National Science Foundation.

All pictures for this article were provided by the Consumer Product Safety Commission.

NOTES


2. U.S. House of Representatives, Committee on Interstate and Foreign Commerce, Subcommittee on Oversight and Investigations, Federal Regulation and Regulatory Reform, 94th Cong., 2nd Session, Washington, 1976, p. 197. The Commission may regulate any product that is used in or around a residence or school for the personal, comfort, or enjoyment of a consumer. Specifically excluded from CPSC's jurisdiction are motor vehicles, fuels, nuclear materials, pesticides, aircraft, boats, food and drugs, medical devices, cosmetics, tobacco products, firearms and ammunition, all of which are regulated to some degree by other federal agencies.


4. Almost all successful challenges to the Commission's rules have been based not on the substance of the rules but on failure of the Commission to follow proper rulemaking procedures.

5. Section 10 (e) of the Consumer Product Safety Act.


7. See Federal Regulation and Regulatory Reform referred to in note 3 above, p. 195.

8. This claim should be viewed in light of the fact that some 2.5 million firms sell 10,000 consumer products annually. Only 250 notifications may indicate the failure of some firms to report such hazards. Ibid., p. 211.


11. A report submitted by President Nixon in 1971 (known as the "Achille Report"), for example, thoroughly criticized collegial decision making. Former CPSC Chairman Simpson has also criticized collegial decision making. In a response to questions submitted by Representative John E. Moss, I had referred to collegial decision making as "an unworkable alternative for effective and productive leadership of an organization."


15. See note 11 above, p. 15.


17. The first "phase" of the CPSC's chronic hazard policy—the classification of potentially dangerous household chemicals—has recently been challenged in the courts on procedural grounds by Dow Chemical Co.

18. This 1976 Amendment to the Act grew out of a dispute between the CPSC and the Civil Service Commission resulting from the CPSC's refusal to approve the hiring of CPSC employees who had not received political clearance from the White House. This amendment clarified CPSC's authority to hire personnel at the White House when hiring new personnel.

19. While the sponsors of the CPSA intended the transfer of some personnel, they hardly contemplated that 10 percent of the CPSC's original manpower would be under going government programs. This influx of personnel, who had operated under the policies and practices of their former organizations, contributed significantly to the CPSC's start-up problems.

20. According to Rhoda H. Karpatkin, Executive Director of Consumers Union, the lumberwork industry has lobbied Congress extensively regarding power mower standards.

21. Letter from Rhoda H. Karpatkin to Bede Dunn, Secretary of the CPSC, dated January 9, 1976, reprinted in Note 14 above, p. 864. As a result of this letter, the Commission reimbursed Consumers Union for most of its out-of-pocket expenses. The CPSC in 1978 is in its fifth year of work on power-mower safety standards, and it has already spent over $1,000,000 on CPSC resources, and $86,000 provided to Consumers Union. The $8.2 million lawnmower industry, for its part, estimates that it has spent $4 million in research and response. Meanwhile, Combined Insurance Co. of America last year sold 100,000 policies and several deaths this year from power mowers Sturbridge, Mass., May 24, 1978.

22. See Note 8 above, p. 231. The Commission now has before it a rulemaking petition seeking a regulation providing for funding of consumer participants.

23. See Tables III-1 and VI-9, Louis Harris and Associates, Inc. and Marketing Science Institute, Consumerism at the Crossroads (N.Y., 1977), pp. 28 and 89 respectively.Rhode Karpatkin of Consumers Union comments that she believes there is increasing public demand for product safety and consumer protection and considers the results of the Harris poll "heartening" and an indication of the dual desire for better, safer products and an end to inflation.

Last winter, in living rooms across the country, more than a million people warmed themselves in front of fires fed by artificial fireplace logs. Most of them did not realize that these artificial logs and ashes were emanating small particles of asbestos that floated slowly through the air and into their lungs, where the deadly fibers became permanently embedded.

When asbestos fibers are absorbed into the lungs, they cause a fatal disease that scientists first diagnosed in the late 1920s. They found that many asbestos workers were dying from a disease they called asbestosis. Tiny asbestos fibers accumulated in their lungs and were soon covered by scar tissue that made breathing increasingly difficult. The scar tissue would thicken, even after the workers were no longer being exposed to asbestos, and the strain on their pulmonary systems became so great that they often died of heart failure before their lungs could give out.

The growing asbestos industry, however, chose not to heed the alarming studies that were published in this country beginning in 1930. By 1935, asbestos was found to cause lung cancer, and later it was linked to cancer of the stomach, intestine, and rectum. Asbestos was also found to cause mesothelioma, a particularly painful form of cancer that eats away at the lining of the lung or abdominal cavity and generally kills its victims within one year after its first symptoms appear. Because the asbestos manufacturers deliberately ignored the mounting evidence, at least 400,000 workers—or four out of ten in the industry—are now expected to die from asbestos diseases. It was not until the early 1970s that strict limits on the amount of asbestos to which workers could be exposed were imposed on the industry by federal law.

And today, millions of American consumers are unwittingly being exposed to this same deadly asbestos. Those artificial fireplace logs and ashes are just one of the more than 3,000 consumer products that, although most of the public doesn't know it, contain asbestos.

Such hidden dangers in the marketplace are the reason that Congress decided five years ago to create the

Consumer Product Safety Commission. But the commission, which is supposed to ban products that injure or kill people, has not acted against this hazard with any greater sense of urgency than federal officials displayed when workplace hazards were exposed in the 1930s.

The commission has been such an abysmal failure that it is at least as responsible as any other government agency for the plummeting popularity of consumer protection. It's no secret that people have become increasingly fed up with meddlesome government bureaucrats issuing annoying minor regulations on such matters as interlocking seat belts and child-proof aspirin bottles. But even the consumer protection movement's most ardent critics would have to concede that the government has a basic responsibility to stop companies from foisting dangerous products on an unsuspecting public. Asbestos, after all, is no borderline case about which reasonable people can disagree, and the most conscientious citizen has little way of knowing of the hidden ingredient in artificial fireplace logs and ashes.

Instead of cracking down on dangers like asbestos, however, the CPSC has been so ineffective that even its most enthusiastic supporters have become disillusioned. Since its inception it has issued safety standards for only one product, swimming pool slides, and even that took two years. The commission is so stricken with bureaucratic paralysis that it has not acted on a backlog of over 150 questionable products.

The CPSC was first asked to ban artificial fireplace logs and ashes that contain free-floating asbestos in November 1975, in a petition from environmental writer Rachel Scott. In July 1976, the Natural Resources Defense Council, an environmental group, asked the commission to ban asbestos patching compounds, which are widely used to repair crumbling ceilings, walls, and floors. “Even very brief exposure to asbestos fibers such as those experienced by consumers of patching compounds have been shown to substantially increase the risk of cancer,” the group warned.

The commission’s own scientists readily agreed. The following month, Robert Hehir, director of CPSC’s Bureau of Biomedical Science, warned in a memo: “Data demonstrating the adverse effects of asbestos in humans, as well as in experimental animal studies, is clear and irrefutable.... Exposure to consumer products containing [free-floating asbestos] poses an unnecessary, unreasonable and completely avoidable potential risk to consumers that cannot be adequately controlled by warning labels.”

Despite this unequivocal warning, the commission did absolutely nothing for another year. One possible reason for the delay is suggested in another internal memo: “The longer it takes to promulgate a ban and/or repurchase [of asbestos], the smaller the economic effect on the industry will be.” Most of the commissioners are Republicans appointed during the Nixon-Ford years, and they often appear concerned more about the impact of their actions on corporate profits than their effect on public health. Several of them have voted to ban products only reluctantly and under the greatest public pressure.

“They laughed at our first petition,” recalls Barry Castleman, the National Resources Defense Council lawyer who wrote it. “It made the case for them, but they spent a year quibbling with us. They had no sense of the consequences.” One CPSC staff member agrees: “We dragged our feet interminably. The staff still hasn’t looked at many products that contain asbestos. Nobody told us it was a high priority.”

Finally, the commission voted last April to ban patching compounds and fireplace logs and ashes that contain asbestos. But although two million people a year are being exposed to these products, the CPSC didn’t order an immediate halt to sales and a recall of existing inventories. Instead, it is
allowing sales to continue while it draws up regulations banning future use. This has been dragging on for months and may not be completed for months more. "What this means," complains Castleman, "is that stores can have special sales on asbestos patching compounds, and a few more people will get cancer."

The CPSC's voluble chairman, S. John Byington, concedes that his agency wasn't as aggressive as it might have been. "Oh sure, we could have moved faster," he says. But Byington claims he never received the scientific memo that detailed the risks of asbestos. "What happened after it was written, God only knows," he says. "We never saw that memo." Nevertheless, it has been known since a landmark study in 1964 by Dr. Irving Selikoff of New York's Mt. Sinai School of Medicine, the country's leading asbestos researcher, showed that people can get lung disease from brief exposure to free-floating asbestos fibers that break free from finished products.

'Cosmetic Changes'

Byington, a handsome young Republican from Grand Rapids, Michigan, who was appointed last year by President Ford, believes the commission's shortcomings can be corrected through better management techniques. He insists that he will cope more effectively with CPSC's massive backlog of health and safety hazards now that he has reorganized the agency's structure. To the second highest paid agency staff in Washington—about 200 of its 900 employees earn over $28,000—he has added five "supergrade" managers, who report directly to him. But one CPSC member, R. David Pittle, told Byington in a private memo: "Except for a few cosmetic changes, you have not really reorganized the agency at all. You have simply added a layer of unneeded supergrade Associate Executive Directors over the technical bureaus."

While Byington has been fiddling with organizational charts, his commission has done very little research on other dangerous asbestos products. For example, asbestos remains a hidden ingredient in such innocuous products as children's modeling clay and papier-mache. Dr. Selikoff discovered last year that thousands of pounds of modeling clay ordered by New York schools contained as much as 50 percent asbestos. Asbestos is not a necessary component of these products, but manufacturers prefer it because it is much cheaper than its substitutes.

Hundreds of thousands of tons of asbestos also are used in textured paints, cement powders, brake linings, stove panels, wallboards, and floor tiles. Manufacturers are now rushing to obtain patents for dozens of new uses for asbestos, apparently secure in the knowledge that the CPSC is unlikely to act against them soon.

Byington, meanwhile, has been far more energetic in pursuing his own career than dangerous products. The talkative chairman, who is said to have political aspirations in Michigan, flew at taxpayer expense to Hong Kong, Taiwan, Tokyo, Brussels, Geneva, Bonn, Hamburg, Puerto Rico, and the Virgin Islands during his first ten months in office. Byington's avowed mission—explaining U.S. safety standards to foreign officials—could have been accomplished just as well by long-distance phone calls. But as one CPSC official puts it, "John likes the spotlight, the travel, the glorification."

Another example of Byington's passion for public relations over product safety is the $425,000 he paid an Atlanta advertising firm last year to promote the commission's work—a strategy that, naturally, entailed more traveling and speeches for its chairman. He also spent $45,000 to make television commercials featuring a character named "Safety Sadie," who offers friendly tips on matters like fireworks and bicycles. Then he decided he didn't like the actress who played Sadie, threw the commercials...
in the trash can, and led the search for a new Sadie, eventually settling on the wife of comedian Dom DeLuise.

'Meaningless Mush'

Such incidents have demoralized many of the commission's workers; one survey shows that 43 per cent of them don't think their agency is doing a good job. They were further aggravated by Byington's expenditure of $500,000 on product profiles that turned out to be worthless. An angry letter from CPSC employees to Senator Wendell Ford, one of Byington's harshest critics, explained: "At the direction of management the profiles were re-written numerous times ... each time with additional facts and figures incorporated. Finally, senior staffers took the profiles and manipulated them into meaningless mush so that they would be innocuous enough to release under Freedom of Information."

To put it bluntly, the CPSC has failed to reduce deaths and injuries to consumers because Byington and his colleagues have not been aggressive enough in banning the products that cause them. Part of the reason for this is that the commission sees manufacturers, rather than their customers, as its most important constituency. The economic impact on business, Byington admitted, was a factor in his decision not to push for an immediate recall of asbestos products.

The manufacturers of these products have known for years that asbestos can hurt people, just as they knew 50 years ago that they were destroying the lungs of their workers. In the pursuit of profit, the companies have been willing not only to peddle harmful products, but to create a market for them through aggressive and sometimes misleading advertising that glosses over their dangers and defects. They took a calculated risk that the hapless bureaucrats in Washington would not take their products off the market in the near future. So far, that risk has paid off.

The Washington Monthly/December 1977
Issues of the Day
Product Safety

Howard E. Brehm

"Industry must include in its research and engineering activities a thorough and coordinated approach to product safety so that it receives as much attention as performance, appearance, producibility, and cost."

Five years ago, the Consumer Product Safety Act emerged from Congress. This act established a five member Consumer Product Safety Commission whose objective is to reduce injuries to consumers using consumer products. It defined a consumer product as an article for use by consumers in or around the home, at school or in recreation or otherwise and provided certain remedies for dealing with hazardous products which include such acts as banning the product and seizure of the product.

Additional actions provided for in the act could be voluntary standards and educational programs. These include: establish an information gathering requirement for hazards and accidents and have the authority to inspect company records dealing with complaints, injuries and similar subjects; establish the requirement that all manufacturers, distributors and retailers report to the Commission any product which fails to comply with an applicable consumer product safety rule or which contains a defect which creates a substantial risk of injury to the public; establish inspection and record-keeping requirements and the requirement to make reports as the Commission may deem necessary to demonstrate compliance with the Act, establish that imported products must comply with the Act, but that exported products need not; and establish civil and criminal penalties for violation of the Act.

The Consumer Product Safety Commission began operations in 1973 and now has over 700 employees located in two buildings in Washington and thirteen field offices across the United States. They have a budget of about $30 million dollars per year. A variety of internal offices and associate executive directors have been established to cover communications, congressional relations, public participation, strategic planning, hazard identification and analysis, engineering and sciences, and compliance and enforcement, all to carry out the responsibilities established by the Act.

The Consumer Product Safety Commission administers a total of five laws. I have already mentioned the Consumer Product Safety Act. The others are the Flammable Fabrics Act, which deals with the flammability of children's sleepwear, carpeting, and other fabrics; the Federal Hazardous Substances Act, which relates to the control and labeling of household chemicals; the Poison Prevention Packaging Act, which was responsible for the childproof packaging on medicines; and the Refrigerator Safety Act, which limits the force required to open a refrigerator door to a maximum of 15 lbs. One of the most powerful provisions of the Consumer Product Safety Act is section 15(b) which reads: "Every manufacturer of a consumer product distributed in commerce and every distributor and retailer of such product who obtains information which reasonably supports the conclusion that such product 1) fails to comply with an applicable consumer product safety rule; or 2) contains a de-

*Director, Corporate Product Safety, Whirlpool Corporation. Article is condensed from paper given at I.R.I. Fall Meeting.

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fect which could create a substantial hazard described in subsection (a) (2), shall immediately inform the commission of such failure to comply or of such defect unless such manufacturer, distributor or retailer has actual knowledge that the commission has been adequately informed of such defect or failure to comply."

To recall situations, products may be returned to the factory for rebuilding, or reworked in the field using prepared repair kits. In either case, the product must be located before the repairs can be accomplished. The location process is extremely difficult and very expensive. It involves many people throughout the country who are attempting to locate product under severe time pressures. The longer the product has been in the field, the more difficult it is to locate. Anyone who has conducted a product recall will attest to the fact that product recalls are upsetting to the organization and expensive to conduct.

Fines under the civil penalties provisions for reporting potential substantial hazards too late can be expensive. Two cases recently have involved fines of one hundred and twenty-five thousand dollars and three hundred and twenty-five thousand dollars for alleged violation of the reporting rule.

Another provision of the Consumer Product Safety Act relates to the preparation of product standards. These may be generated by the voluntary standards system and adopted by the Commission, or they may be developed by a manufacturer under standards offeror program. They also may be prepared directly by the Commission staff.

Impact on R & D

With this background, let's turn to the impact of the Consumer Product Safety Commission on industrial research and engineering. What does it all mean? What can we do to cope with it? And what will be the results in terms of research and engineering projects, the utilization of time, talent, money and facilities?

First, industry must include in its research and engineering activities a thorough and coordinated approach to product safety so that it receives as much attention as performance, appearance, producibility, and cost. To accomplish this, product safety should be formulated and centralized in the technical division under the guidance of someone whose function is to know, understand, and communicate what is going on in the product safety arena, and provide the means by which research and engineering can adequately develop and control the safety of the product. The motivation for this action is easily found both in the requirements of specific product safety laws and in the common law relating to product liability.

The product safety specialist should be qualified product engineer, familiar with the products and operations of his company and his industry. He must know, and be capable of working with, all levels of responsibility in the company, and he must be willing and able to preach the gospel of product safety both to those who agree with him and support him — and to those who disagree with him and resist him. He is the organizer of the product safety function. He is a communicator, a listener, an evaluator, and a promoter. Above all, he is the focal point of the product safety program.

The effort of this person can quickly reflect on the bottom line of the operating statement, as he eliminates product safety problems in products both before they leave the factory and after they move into the field. His efforts can also reflect positively on the company image as its concern for the customer and for the safety of its products become apparent.

To put teeth into any company product safety program, the product safety specialist must be supported by a policy detailing the company's product safety posture and his responsibilities. The policy and the responsibilities must be communicated throughout the company by top management so there is both understanding and acceptance of what the product safety specialist is doing.

The burden of product safety has landed squarely on the technical function, because it is engineers, whether research, design, production, or quality control, who create and manufacture the products, and who, therefore, are the people with the training, experience and opportunity to directly influence product safety. True, there are countervailing forces to be considered. Inherent product limitations, market requirements, government regulations, and the like make the task of building safer products more challenging and difficult, but no less essential.

Technical Considerations

Now, what are some of the major technical considerations in designing and producing safer products? The most important item is knowing the product — what it will do, and what it will not do, under various conditions of normal use, misuse, and abuse.

There are a number of tools which can be used in evaluating a product for potential hazards. Some of these are gross hazards analysis, classification of hazards, frequency severity analysis, failure modes and effects analysis, hazard priority ranking, fault tree analysis, energy transfer analysis, catastrophe analysis, human error analysis, transportation hazard analysis, and maintenance hazard analysis. The purpose of most of these techniques is self-explanatory, and most are well described in the literature. They should be employed on a selective basis at various levels in the life of the product from concept to disposal.
The results of all of these evaluations can be combined into an all inclusive evaluation, generally called a product safety audit. Such audits are conducted regularly on an established schedule by the technical department. The product safety audit should be the final look at the total product, and the mechanism which determines final acceptance or rejection prior to release for manufacture.

This audit procedure simply addresses the basic question, will the product perform safely the job for which it was designed? To determine this, the research and engineering departments that have the technical expertise and or the design control of the product must become involved in a number of ways. Some of these are: 1) Knowing the product and what it will do under situations of misuse and abuse, and how it will interact with people, whether they are expert or not in its operation. 2) Investigating how the customer will relate to the product and how owners will use, misuse or abuse the product, and then allowing for such treatment in the design. 3) Designing fail safe systems, particularly where they involve some energy source. 4) Designing systems to identify how variations in power supplies will affect the product, and allowing for them. 5) Designing products so they can be produced with a high degree of reliability, product after product, and developing manufacturing controls which will assure this reliability. 6) Using materials which are not readily combustible. 7) Eliminating sharp edges and corners and openings that can pinch. 8) Designing products that can withstand misuse and severe transportation conditions. 9) Developing packaging which will both protect the product and keep children out of it. 10) Developing instructions, warnings, cautions which adequately communicate the presence of any potential hazards. 11) Developing techniques for product investigation and evaluation which provide the basis for adequate defense in product liability litigation. 12) And finally, participation in the development of rules and regulations relating to your product, and speaking up, if you don't like them, through your standards and trade associations.

Whether we may like it or not, the technical function must carry the prime responsibility for product safety. A systems effort, properly applied, can be a cost effective management tool with which to reduce potential hazards, accidents and damage; to reduce costly product recalls or field modifications, and to provide for early identification and control of potentially hazardous product in the field.
Today's business climate demands that industry reassess its priorities. These are two important aspects that require top management attention, since failure to provide emphasis and support here could be disastrous.

"THE AMERICAN Consumer in a democratic society is a lot like the end result of crossing a tiger with a parrot—you may not like what the creature says, but when it talks you had better listen." The consumer has spoken and continues to speak. The end result is new legislation which broadens and enforces an irreversible trend—new ground rules and new burdens of regulations for businesses that deal in the marketplace.

The new federal agency established in 1972, the Consumer Product Safety Commission, is an important and sometimes overlooked adjunct to an impressive array of governmental agencies affecting businesses in the marketplace. This agency has broad powers and has been referred to by many as having more far-reaching implications on businesses than does any other agency established to date. Its powers encompass imposition of an outright ban on the sale of a product, a product recall, repair or replacement by the manufacturer, and the creation of mandatory standards for product conformance. One of the Commission members has been quoted as saying, "When it involves a product that is unsafe, I don't care how much it costs the company to correct the problem."

Product recalls, replacement, or repair are almost commonplace in today's headlines due to alleged defective or unsafe products in the market. When injuries occur, product liability suits may result; and the decisions being handed down by the courts are sizable and in some instances can literally bankrupt a company. A recent study by A.T. Kearney, Inc., states that product liability claims increased from $500,000 in 1965 to $1.5 billion in 1972 and are projected to increase to $50 billion in 1975. Alert businessmen are aware also that consumers now constitute what A.T. Kearney terms "The New Silent Majority." A study by Nielsen revealed that only 2% of the dissatisfied consumers write to the manufacturer; but by their refusal to buy that brand again, 34% impose a penalty far more severe than complaining.

The implications of the foregoing are such that successful businesses must reassess their priorities. For many years, service, and quality have been of prime importance, but now an additional emphasis in the areas of quality and product safety is added. Perhaps the primary action for any company today is to evaluate the awareness of its management, and all pertinent groups, to the
It is good to remember that in the event of legal action all records and files concerning the matter in litigation may be subpoenaed by the plaintiff's attorney.

Research Institute, and many other trade associations and groups. Excellent literature is available, and it is being disseminated to various levels of management. The Defense Research Institute, the Newark, New Jersey College of Engineering Product Liability, Prevention Proceedings, the Research Institute of America, and the Liability Insurance Congress are among those who have publications that can be put to good use. Several visual presentations employing slides and commentary also are available. The Aluminum Association in New York City and the Liberty Mutual Insurance Company of Boston, Massachusetts have such available.

The need for development of management philosophy, on quality and product safety, is important. Even more important is the recognition that this philosophy results in a written policy statement indicating to persons of damage to property, as well as consumers, what might result from the product's use.

In instances in which a product's hazardous qualities may not be observed or commonly understood, precautions are being built into in-house testing programs covering a variety of possible environments in which the product may be exposed. Feedback on product performance during the in-house test is being successfully employed to determine design improvement.

Component analysis is vital during the in-house testing. Economic considerations are also evaluated. It is at this time that decisions regarding purchase of outside components should be made and specifications for such prepared.

This should be followed by written analyses and reports. Specifications once written should be incorporated in the purchase orders and the stipulations made that the supplier is to make no changes in the product without written authorization. All changes are reviewed and approved. Determination of audits to be applied is made. When the testing requirements have been satisfied, the decision to market is usually made.

Production Quality Control

Once the decision to produce is made, the quality for market test. Appropriate production quality control measures are established. It is good to remember that the test design can be carried out in production. To establish the parameters for adequate production quality control, the following are recommended and should be prepared:

1. Minimum qualifications for inspection and quality control personnel should be set. These qualifications should be written and encompass not only the degree of technical knowledge and competence required, but also the physical requirements involved. Above all, all personnel should be given an eye examination and color blindness tests to make certain their vision meets satisfactory levels.

2. Detailed instructions for inspection should be prepared. These instructions should be written in clear, concise language so that each inspector can clearly understand its duties and what is involved in performing his job satisfactorily. This is extremely helpful in training new inspection personnel. A checked list of inspection personnel.

3. Procedures for removal of obsolete drawings should be implemented. This involves setting up a system to make certain that all concerned have the latest revision of any drawing or specification. It also includes making certain that all drawings and specifications that have been superseded are removed. A central location to maintain a complete file on all changes for historical and record purposes should be designated. Failure to provide such a system could lead to errors.

4. Calibration of inspection equipment and instruments for calibration should be set, Recognized standards.
The job of labeling is becoming increasingly difficult, and the words which are used must be carefully chosen.

Instructions, Labeling, Packing

Perhaps one of the most important areas in concerned with product use instructions, labeling, and warnings. Whether a product is for industrial or consumer use, proper labeling is important. However, the job of labeling is becoming increasingly difficult, and the words which are used must be carefully chosen. All labeling should be reviewed by legal counsel, especially for those products about which there may be a legal duty to inform the user. Naturally,
legal counsel should be asked to check compliance with federal, state, and local laws and regulations. It even may be necessary to incorporate warnings as to how the product is not to be used. Many industry associations have valuable information available concerning labels, and it may be good to keep advised of the industry associations' assistance in this regard.

All instructions, whether they are on the carton, packing case, or in the form of instruction manuals, must be evaluated. Important questions to be covered are:

1. Do the instructions advise of dangers inherent in the use of the product?
2. Does the instruction manual adequately describe safe methods of assembling and performing repairs by purchaser?
3. Are the instructions clear, concise, and easily understood by the persons most likely to need them?
4. If maintenance or service instructions are included, are users alerted to potential dangers in using unauthorized parts when repairs are necessary?

One area of utmost importance here is to make certain that sales personnel are properly instructed and do not make exaggerated or unauthorized claims, either oral or written, regarding product performance which could lead to unexpected liability.

Perhaps of equal importance is evaluation of the packing and packaging procedures. Packaging standardization assists greatly in making certain that all applicable components, as well as instruction manuals, and so on, are included in each package.

Advertising

All advertising, sales and promotional material, and publicity releases should be evaluated by technical and legal personnel, and procedures must be established for review by them. Legal review of advertisements and sales literature for undeclared product claims or inferences can eliminate potential legal booby traps. Technical personnel also can be used to deter overenthusiastic marketing or advertising personnel from making statements or claims that cannot be technically substantiated. One of the most important accomplishments from this kind of review and evaluation is to prevent the use in sales literature of photographs which portray potentially hazardous uses of the product.

Warranties, Guaranties, Disclaimers

On January 4, 1975, the 93rd Congress enacted a new federal law governing warranty practices. The new law, Title I of The Magnuson-Moss Warranty-Federal Trade Commission Improvement Act, set forth minimum federal standards for written warranties. It also requires that each warranty be designated "full" or "limited," limits disclaimers of implied warranties, and sets procedures for the Federal Trade Commission pertaining to warranties. It further suggests procedures for settling warranty disputes.

This Act has caused great activity among manufacturers and retailers to review their warranty policies and practices, and knowledge of the basic provisions of this Act by management is vitally important. It is critical that legal counsel approve all warranties and disclaimers before they are issued, as well as when they are revised for any product. It is important that counsel have the best advice of the appropriate technical personnel. In addition, marketing and advertising should ensure that any claims made in advertising do not exceed those contained in the written product warranty.

The responsibility every business has to its customers and the public today is great. Uppermost in mind at all times must be the thought to make quality products that can be safely marketed and used. New dimensions for quality and product safety are demanded if business is to minimize large economic losses.

1. Alexander M. Schmidt, Commissioner of the Food and Drug Administration, before the National Canners Association board meeting, Spring 1975.
CONSUMER PRODUCT SAFETY:
THE CURRENT RECORD OF ADMINISTRATIVE
INTERPRETATION

By Judy Feinberg

Congress created the Consumer Product Safety Commission (hereafter, CPSC, or the commission) on October 27, 1972, as an independent regulatory agency, headed by five commissioners, to protect consumers against unreasonable risks of injury or death caused by substantially hazardous products used in or about the home.1

CPSC was established as a direct result of the recommendations and findings of the National Commission on Product Safety.2 This commission reported that 20 million Americans are injured each year in incidents involving consumer products. Of the victims, 30,000 are killed; 110,000 are permanently disabled. Based upon this evidence, Congress empowered CPSC with the legal machinery to regulate manufacturers, distributors, retailers, private labelers, importers, and others affected. This article discusses the current state of administrative implementation of consumer product safety legislation during the past five years.

The commission exercises its safety function under five statutes.3 To assure that the products covered by the law are safe, CPSC has the authority to set safety standards, ban hazardous products, require bookkeeping, examining records, call for reports, inspect business premises, impose labeling and warning requirements, and demand safety certification.

Enforcement is effected by court injunctions,4 seizure of hazardous products,5 and criminal proceedings.6


PRODUCT SAFETY

products, criminal sanctions, and administratively by imposition of civil penalties.

Remedial devices imposed to correct product violations vary under the different acts. The Federal Hazardous Substances Act (FHSA), Poison Prevention Packaging Act (PPPA), and Consumer Product Safety Act (CPSA), provide for a "refund" remedy. Under FHSA and PPPA, the manufacturer, distributor, or dealer must repurchase any product sold which has been banned as a hazardous substance and reimburse the consumer for any necessary transportation expense. Under CPSA, a manufacturer, distributor, or retailer who has sold a hazardous product may elect to offer a refund of the purchase price, less a reasonable allowance for use, if the consumer has had the product for at least one year; to repair; or replace the product so it will conform to safety requirements. The notice and repurchase provisions of Section 15 of CPSA are more flexible than those of FHSA and may be enforced through civil penalties.

Under the Flammable Fabrics Act (FFA) the commission has the authority to issue a cease and desist order for articles of wearing apparel and fabrics moving in commerce which are so highly flammable as to constitute an unreasonable risk of the occurrence of fire leading to death, personal injury, or significant property damage. In contrast to FHSA, PPPA, and CPSA, the Flammable Fabrics Act does not explicitly provide for a refund to consumers. Whether or not the commission, as successor to the Federal Trade Commission (FTC), has the power to recall flammable fabrics from the consumer is presently under consideration. The power to recall flammable carpet from distributors and retailers has been asserted and is presently on appeal in the Ninth Circuit.

\[\text{CPSA} \text{ } \S \text{202(b), 15 U.S.C. } \S \text{2071(b) (Supp. V 1975); FFA } \S \text{6(h), 15 U.S.C. } \S \text{1195(b) (1970); FHSA } \S \text{6, 15 U.S.C. } \S \text{1263 (1970). These sections basically regulate the commission's seizure power, governed by the rules of maritime admiralty. CPSC investigators do not have the authority to seize the goods themselves. They may, however, initiate a proceeding by process of libel for the seizure and condemnation of hazardous products in any district court of the United States when the goods are seized. The clerk of the U.S. District Court, without a judicial hearing, issues a warrant authorizing a United States marshal to seize the goods. The United States marshal must publish notice of seizure on rods and in local newspapers. The claimant then may seek a judicial determination on the issue of seizure. If no claim is asserted the goods are destroyed.}\]

\[\text{CPSA } \S \text{20, 15 U.S.C. } \S \text{1269 (Supp. V 1975); FFA } \S \text{7, 15 U.S.C. } \S \text{1196 (1970); FHSA } \S \text{5, 3, 15 U.S.C. } \S \text{1264 (1970). Although } \S \text{20 of CPSA does not expressly confer jurisdiction on civil penalties upon either the federal district courts or the commission, the latter has recently initiated a civil penalty procedure whereby the agency will in an expedited proceeding assess the amount for violations according to formal APA requirements. See Atlas Roofing Co. v. OSHRC, U.S.L.W. (No. 75-746), where the Supreme Court also in deciding Grey v. OSHRC, (No. 73-748) unanimously affirmed the lower courts' rulings that upheld the administrative assessment of penalties before an administrative law judge without a jury trial. See 29 U.S.C. } \S \text{654(f).}\]

\[\text{FHSA } \S \text{15, 15 U.S.C. } \S \text{1274 (1970); CPSA } \S \text{11(a)(2)(c), 15 U.S.C. } \S \text{1264(b)(1)(c)(2)(c) (Supp. V 1975).}\]

\[\text{FFA } \S \text{5(b), 15 U.S.C. } \S \text{1194(b) (1970), incorporates the enforcement powers of the FTC Act, 15 U.S.C. } \S \text{45 (Supp. V 1975).} \]

\[^{2}\text{Two cases were orally argued before the commission on March 14, 1977, on appeal from an administrative law judge's ruling that, absent a CPSA } \S \text{30(1) finding (discussed infra at note 33), the commission does not possess authority under FEA or the FTC Act to order a recall, repair, or refund of carpets actually installed on the consumers' floor. See Barrett Carpet Mills, Inc., CPSC Docket No. 75-5, Initial Decision of Administrative Law Judge Paul N. Pfeiffer, (July 8, 1976); Northwick Carpet Mills, Inc., CPSC Docket No. 76-6, Initial Decision of Administrative Law Judge Paul N. Pfeiffer (Sep. 7, 1976) (order granting partial summary judgment Nov. 9, 1976); Westland Carpet Mills, Inc., CPSC Docket No. 75-21. Initial Decision of Administrative Law Judge Paul N. Pfeiffer (Sep. 7, 1976) was withdrawn from oral argument before the commissioners but was submitted for decision based upon the record and briefs.}\]

\[^{3}\text{In re Complanix Industries Inc., FTC Docket No. 8806, (1974); appeal pending No. 75-3512 (9th Cir. Feb. 18, 1976).} \]
The rules, regulations, standards, and test methods authorized under these five acts are enforced by a voluntary corrective action plan (CAP), a consent order, or administrative litigation. After a formal hearing before an administrative law judge, a litigant can appeal to the commission whose decision is subject to judicial review in the appropriate federal circuit court of appeals.

I. THE CONSUMER PRODUCT SAFETY ACT

The purposes of CPSA are to protect the public against unreasonable hazards associated with consumer products, to assist consumers in evaluating product safety, to develop uniform consumer product standards, and to promote product safety research. Congress recognized the need for a comprehensive federal consumer product safety program to balance the equities between the consumer and the manufacturer, finding that the competitive marketplace forces were not strong enough to promote industry self-regulation as the consumer’s appetite for technologically advanced products increased. Thus, the commission was established as a safety agency with the objective of identifying and removing unsafe products from commerce.

The commission regulates substantial product hazards under section 15 of CPSA, the tattletale provision. This section requires manufacturers, distributors and retailers to notify the commission when a product fails to comply with an applicable consumer product safety rule or contains a defect which could create a substantial product hazard.

Government and industry are at odds over the obligation under this provision. Manufacturers are loosely construing their duty to report. Many times manufacturers are not negligent in notifying the commission, but rather
fail to do so only because they do not think their product creates a substantial hazard. Manufacturers believe the initial judgment rests with them. In contrast, under the new proposed regulations, government imposes a duty on manufacturers to report whenever the possibility exists that a product could create a substantial hazard.

In most instances, once a manufacturer, distributor, or retailer either notifies the commission or receives notification from it that his product may involve defects posing substantial product hazards, he agrees to a voluntary corrective action plan to recall the noncomplying product and to offer repair, replacement, or refund to the consumer less a reasonable allowance for use.

If a manufacturer refuses to undertake voluntary corrective action, a prehearing conference is scheduled to dispose of the matter. A consent agreement has a similar effect as a voluntary corrective action plan except that a commission order is imposed. Since consent agreements are signed and accepted by the commission, a cease and desist order is usually issued concurrently. A civil penalty can be imposed for a violation of that order.

If neither a voluntary corrective action plan nor a consent agreement has been reached, then the parties go to hearing under section 15(c) of CPSA. The matter of criminal penalties has been reserved by the statute for court action. Civil penalties may be imposed after an expedited administrative hearing procedure.

The commission's most effective enforcement efforts have been in section 15 cases. During 1976, the commission processed by consent order 140 possible substantial product hazard cases: 59 were initiated by the staff and 81 were voluntarily reported by manufacturers, distributors, and retailers. This method of enforcement reaches the objective of removing an unsafe product without expense of litigation. The litigated cases under CPSA are few in comparison to the number of voluntary corrective action plans and consent orders. Manufacturers fearing the impact of government regulation by public hearing, often with slight chance of success, have been willing to comply in lieu of litigating. In all of the cases, whether litigated or (with the exception of the case of White Consolidated Industries, Inc.), the result has been the same: the manufacturer, distributor, or retailer has either repaired or replaced the offending product or refunded the purchase price.

The commission initiated a proceeding in 1975 against White Consolidated Industries, Inc., alleging that approximately 336,000 Kelvinator...
refrigerators manufactured between 1970 and 1974 presented a substantial product hazard within section 15(a)(2) of CPSA, due to an alleged design defect in the refrigerator defrosting system which could cause fire and resultant injury.

The presiding officer found that the design was defective, but did not find a high probability of substantial hazard existing in any given Kelvinator refrigerator since none of the field incidents involved a serious fire resulting in injury. No appeal was filed by the staff from the initial decision, and the case was dismissed by the full commission.

The second litigated case reviewed by the commission was In re Relco, Inc., affirming the administrative law judge’s interim initial decision which held that WelDex electric arc welders presented a substantial product hazard in terms of potential electric shock, burns, and fire due to certain design and performance defects. The administrative law judge’s initial decision ordered respondents to stop the manufacture and distribution of the product, to give public notice of the dangers presented, and to offer replacement welders or refunds. Further proceedings were held on the question of the proper amount of refund where the consumer possessed the welder for more or less than one year.

On appeal, the Commission modified the order on two counts:

1. The commission provided that tender of the welder or its vital parts should be mandatory for all persons seeking a refund regardless of how long it has been possessed.
2. The commission required that an affidavit of disposal for safety reasons be tendered by all claimants prior to refund.

In addition, the commission required proof of purchase to be submitted with the affidavit and required that detailed and illustrated instructions for dismantling the welder be included in the recall letter sent to consumers.

The commission’s third litigated section 15 case under CPSA was In re Francis Alonso, Jr., d/b/a Mylar Star Kites. The administrative law judge found that the aluminized polyester film kites with long, aluminum-coated tails though not per se dangerous, presented an electric shock hazard to the
PRODUCT SAFETY

The administrative law judge concluded that labeling and warning literature was insufficient to eliminate the risk and ordered respondents (1) to give public notice of the hazard; (2) to cease and desist from further manufacture of kites made of conductive material; and (3) to elect to replace any metallized polyester film kites with tails returned to them by their customers with a nonmetallized kite or refund the purchase price. Repair was conceded to be impracticable. On appeal, the commission concurred with the administrative law judge’s findings as to the hazardous nature of the aluminized kites. However, the commission dismissed the case for lack of jurisdiction. The majority held that since aluminized kites are articles intended for use by children, the action should have been brought under FHSA. Moreover, respondent will be free to manufacture and sell aluminized kites until a rule regarding all aluminized kites under FHSA can be undertaken. Commissioner Kusher pointed out in his dissent “that the respondent has been allowed to avoid an order which has been applied to other respondents, who are no more or less guilty of having manufactured a product judged to be a substantial hazard.”

The “toy debate” is a perfect illustration of the problem associated with the interrelationship of CPSA and FHSA. At the time of this proceeding, Section 30(d) of CPSA required the commission to proceed under FHSA rather than CPSA if the risk of injury could be remedied under FHSA. Today, the commission has greater flexibility under the amended Section 30(d) to regulate the risks of injury associated with consumer products under the various acts through CPSC procedures and remedies, if it finds by rule that such is in the public interest. Thus, the commission had the option to proceed under the more flexible repurchase provision of section 15 of CPSA. Thus the jurisdictional gap between CPSA and FHSA can be greatly reduced.

The amendment provides:

A risk of injury which is associated with a consumer product and which could be eliminated or reduced to a sufficient extent by action under the Federal Hazardous Substances Act [15 USCS § 1261 et seq.], the Poison Prevention Packaging Act of 1970 [15 USCS §§ 1471 et seq.], or the Flammable Fabrics Act [15 USCS §§ 1191 et seq.] may be regulated under this Act only if the Commission by rule finds that it is in the public interest to regulate such risk of injury under this Act. Such a rule shall identify the risk of injury associated with the product and shall be promulgated in accordance with section 553 of title 5, United States Code [5 USCS § 553]; except that the period to be provided by the Commission pursuant to subsection (c) of such section [15 USCS § 553(c)] for the submission of data, views, and arguments respecting the rule shall not exceed thirty days from the date of publication pursuant to subsection (b) of such section [15 USCS § 553(b)] of a notice respecting the rule. 15 U.S.C. § 2079(d), as amended by Act of May 11, 1976, Pub. L. No. 94-224, §§ 307, 10, 90 Stat. 304, 310.
The purpose of FHSA is to protect the public health and safety by requiring labelling of hazardous products for use by children or adults in or about the household, or, notwithstanding the cautionary labelling, to ban the hazardous substances by keeping them out of commerce due to the degree or nature of the hazards involved. Certain products, however, are exempt under this act since they are covered by other regulatory legislation.

Under FHSA, once an article or substance is deemed a banned or misbranded hazardous substance, the commission notifies the manufacturer, distributor, or dealer of the statutory or standard violation. The commission also advises these parties to apply the correct labelling, to recall the hazardous product, or bring the product into compliance. Section 15 of FHSA requires the manufacturer, distributor, or retailer to repurchase the banned hazardous substance from the consumer and to refund the purchase price paid for the article or substance plus reasonable and necessary transportation expenses. Under the repurchase provision, signs are required to be posted in stores carrying the banned hazardous substance in order to notify consumers that they are entitled to a refund. Since the commission has no authority to issue an administrative order to recall, if the manufacturer, distributor, or dealer does not voluntarily repurchase the item, then the commission can obtain a court order to seize the products or subject the manufacturer, distributor, or dealer to a penalty for introducing into commerce a banned or misbranded hazardous product.

U.S.C. § 1261(p)(1)(2) (1970) states that a hazardous substance will be “misbranded hazardous substance” unless a label bears the following information:

(1) which states conspicuously: (A) the name and place of business of the manufacturer, packer, distributor or seller; (B) the common or usual name or the chemical name (if there be no common or usual name) of the hazardous substance or of each component which contributes substantially to its hazard, unless the Secretary by regulation permits or requires the use of a recognized generic name; (C) the signal word “DANGER” on substances which are extremely flammable, corrosive, or highly toxic; (D) the signal word “WARNING” or “CAUTION” on all other hazardous substances; (E) an affirmative statement of the principal hazard or hazards such as “Flammable,” “Combustible,” “Vapor Hazard,” “Causes Burns,” “Absorbs Through Skin,” or similar wording descriptive of the hazard; (F) precautionary measures describing the action to be followed or avoided, except when modified by regulation of the Secretary pursuant to Section 3; (G) instructions for handling and storage of packages which require special care in handling or storage; and (H) the word “Poison” for any hazardous substance which is defined as “highly toxic” by this section; (I) adequate directions for the protection of children from and the hazard; and

(2) On which any statements required under subparagraph (1) of this paragraph are located prominently and are in the English language in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the label.

The Commission may also establish by regulation reasonable variations of additional labelling requirements, if the minimum cautionary labelling is not adequate for the protection of the public health and safety in view of the special hazard presented by any particular substance. 15 U.S.C. § 1262(a)(1)(1970).

Under 15 U.S.C. § 1261(1)(2)(D) (1970), certain items exempt from the definition of a “hazardous substance” include: (a) poisons within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act; foods, drugs and cosmetics subject to the Federal Food, Drug, and Cosmetic Act; substances intended for use as fuels when stored in containers and used in the heating, cooking, or refrigeration system of a house; any source material, special nuclear material or byproduct as defined in the Atomic Energy Act of 1954 as amended, and regulations issued pursuant thereto by the Atomic Energy Commission.

230
PRODUCT SAFETY

This alternative places a heavy economic burden upon the noncomplying manufacturer, distributor, or dealer. The justification, however, lies in the fact that the parties in the chain of distribution placed an unsafe product into commerce and realized a profit.

Banned Products

From May 14, 1973 through March 10, 1977, 202 manufacturers have recalled the following banned hazardous products:

<table>
<thead>
<tr>
<th>Product</th>
<th>Number of Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toys</td>
<td>138</td>
</tr>
<tr>
<td>Record player</td>
<td>2</td>
</tr>
<tr>
<td>Rock polisher</td>
<td>1</td>
</tr>
<tr>
<td>Train set</td>
<td>1</td>
</tr>
<tr>
<td>Cribs</td>
<td>2</td>
</tr>
<tr>
<td>Vinyl chloride</td>
<td>11</td>
</tr>
<tr>
<td>Lead paint</td>
<td>44</td>
</tr>
<tr>
<td>Silver solder with cyanide</td>
<td>1</td>
</tr>
<tr>
<td>Carbon tetrachloride</td>
<td>1</td>
</tr>
<tr>
<td>Benzene in plastic balloons</td>
<td>1</td>
</tr>
</tbody>
</table>

*Samalik, Bureau of Compliance Report (1976), Bethesda, Maryland.

"Under § 201(d) of the act, any toy or other article intended for use by children which the commission by regulation determines, in accordance with § 3(c) of the act presents an electrical, mechanical, or thermal hazard is deemed to be a banned hazardous substance and is subject to § 15 repurchase. Under the regulations the commission has determined which types of toys or other articles intended for use by children present a mechanical hazard within the meaning of § 201(d) of the act because in normal use, or when subjected to reasonably foreseeable damage or abuse, the design or manufacturer presents an unreasonable risk of personal injury or illness. These types of banned toys and other banned articles intended for use by children have been subject to recall. FHSA § 201(d)(3)(D), 15 U.S.C. § 1261 (4)(1)(D)(1970). See also 16 C.F.R. § 1500.18(a) (1976).

"The record players, rock polisher and train set were recalled for failure to meet the requirements for electrically operated toys or other electrically operated articles intended for use by children. 16 C.F.R. § 1500.18(a) (1976).

"A full size baby crib which is defined in 16 C.F.R. § 1508.1 (1976) as a bed (1) that is designed to provide sleeping accommodations for an infant, (2) that is intended for use in the home, and (3) that is within a range of ±1 centimeters (±.2 inches) of the interior length or width dimensions specified for full size baby cribs in § 1508.3 and does not meet the requirements of § 1508 is deemed to be a toy presenting a mechanical hazard. 16 C.F.R. § 1500.18 (a)(13) (1976).

"The commission classified all self-pressurized household products containing vinyl chloride monomer as a banned hazardous substance. Most manufacturers have agreed to recall such products. However, Pantry Industries, Inc., appealed the commission's ruling to the Ninth Circuit which set aside the rule holding that a formal hearing is required as part of the rule-making procedure where a controversial issue is involved. Pantry Industries, Inc. v. Consumer Product Safety Commission, Nos. 74-2902, 74-3168 (9th Cir. May 2, 1977).

"The commission has determined that items intended for use by children or packaged in a form suitable for use in or around the household and containing paints with more than 0.5% lead content are subject to banning procedures of repurchase. 16 C.F.R. § 1500.17(a)(b)(c)(R) (1976).

"Silver solder containing a concentration of cyanide greater than 25 parts per million are deemed to be a banned hazardous substance and are subject to repurchase. This excludes unavoidable manufacturing residues of cyanide salts in other chemicals that under reasonable and foreseeable conditions of use will not result in a concentration of cyanide greater than 25 parts per million. 16 C.F.R. § 1500.17 (a)(5) (1976).

"Atmospheric concentration of carbon tetrachloride and mixtures containing it in fire extinguishers greater than 10 parts per million are banned hazardous substances and are subject to repurchase. This excludes unavoidable manufacturing residues of carbon tetrachloride in other chemicals that under reasonably foreseeable conditions of use do not result in an atmospheric concentration of carbon tetrachloride greater than 10 parts per million. 16 C.F.R. § 1500.17(a)(2) (1976).

"CPSC recalled plastic balloon toys deemed to be a hazardous substance. Due to an error by the manufacturer, the product contained benzene which, over an extended period of time, could cause a type of blood disorder known as aplastic. The distributor voluntarily agreed to offer a full refund to purchasers upon tender of the hazardous item. 16 C.F.R. § 1500.14(a)(3) (1976).
Labelling

Hazardous substances intended for use in the household or by children are subject to the labelling requirements of Section 2(p) of the act. If the labelling requirement has not been met, then the hazardous substance is termed a "misbranded hazardous substance."¹⁰

From May 14, 1973 through March 10, 1977, 41 manufacturers have recalled misbranded hazardous substances for improper labelling.¹⁰ A misbranded hazardous substance is not subject to section 15 repurchase. Most manufacturers will either recall the misbranded hazardous substance or utilize the required label. The following includes a breakdown of the misbranded hazardous substances which have been recalled due to improper labelling:

<table>
<thead>
<tr>
<th>Product</th>
<th>Number of Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spray adhesives</td>
<td>5</td>
</tr>
<tr>
<td>Drinking birds</td>
<td>4</td>
</tr>
<tr>
<td>Cyanocrilite glues</td>
<td>5</td>
</tr>
<tr>
<td>Jequirity beans</td>
<td>4</td>
</tr>
<tr>
<td>Petroleum distillates—including thiners, removers, cleaners, etc.</td>
<td>17</td>
</tr>
<tr>
<td>Dry masonry paint</td>
<td>1</td>
</tr>
<tr>
<td>Dry masonry cleaner (HC1)</td>
<td>1</td>
</tr>
<tr>
<td>Self-pressurized container</td>
<td>1</td>
</tr>
<tr>
<td>Adhesives/glues</td>
<td>2</td>
</tr>
<tr>
<td>Microscope set</td>
<td>1</td>
</tr>
</tbody>
</table>

Rule-Making Proceedings

In contrast to the other acts, the commission is required to hold a formal hearing prior to promulgating a regulation banning a substance as hazardous if reasonable grounds exist.¹¹ To date, the commission has published final banning and safety regulations for fireworks devices, baby pacifiers, and a ban on children's garments and fabrics containing the flame-retardant chemical Tris.

The first formal rule-making proceeding involved proposed regulations governing labelling, performance standards, and banning of certain Class C fireworks.¹² The proceeding ultimately evolved into two major issues: the first included proposals to strengthen the regulation by banning all

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¹¹ See note 40, supra.
PRODUCT SAFETY

firecrackers and/or tightening the labelling and performance requirements, and the second included proposals to weaken the regulation by elimination of the ban on firecrackers, clarification of the requirements relating to color and/or configuration of toy smoke and flitter devices, and a proposed grace period to dispose of noncomplying fireworks inventory.

In his initial decision the administrative law judge concluded that the degree and nature of the hazard involved in using fireworks, primarily malfunction, did not warrant a total ban to protect the public health and safety. Instead the administrative law judge recommended a restriction limiting the powder content of Class C firecrackers to 1.2 grains of flashpowder or up to 2 grains of nitrate and aluminum flashpowder or nitrate and carbon powder. Improved visual and timed fusing, labelling, and packaging requirements to prevent fuse damage in transit were made applicable to all Class C firecrackers. The administrative law judge also concluded that no age limitation for use by children should be implemented but suggested that adults insure proper supervision of children in the use of fireworks.

On June 7, 1976, the commission in a tentative 3-2 decision issued its final regulation. It lowered the permissible explosive charge in firecrackers...
instead of banning them as originally proposed and established performance standards and labelling requirements for other fireworks devices sold or distributed for consumer use. The commission found that firecrackers and other fireworks devices are "hazardous substances" within the meaning of 2(f)(1) of FHSA. The commission determined that firecrackers containing more than 50 milligrams of pyrotechnic composition could not be remedied through cautionary labelling and thus are banned hazardous substances. Firecrackers under 50 milligrams were permitted upon a finding that the public health and safety would be protected by adequate labelling.

The regulation became final by a 2-2 vote, the chairman, who had not won reappointment, having resigned.

On June 23, 1977, the Court of Appeals for the District of Columbia circuit remanded the case to the commission for further clarification. The court had technical difficulties with the commission's ban. The court held the commission could not adopt a 2-2 vote as a final decision what it previously adopted as a tentative 3-2 majority vote. Therefore, there had never been a legal vote elevating the decision to a final order. The court also sought clarification concerning the basis for overturning the administrative law judge's finding that hazards associated with firecrackers containing 1.2 grains or less of explosives may be remedied by labelling rather than imposing a ban.

On a remand the commission formally adopted their 2-2 decision as final by a vote of 3-2 and buttressed their reversal of the administrative law judge's conclusion concerning firecrackers with further reasoning.

Recently the commission, in one of its more highly publicized decisions, banned the sale of any children's clothing containing the flame-retardant chemical TRIS. The commission acted in response to petitions filed in federal district court by the Environmental Defense Fund (EDF). Alleging that the flame-retardant chemical TRIS was carcinogenic, EDF sought a total ban on the sale of TRIS-treated wearing apparel.
PRODUCT SAFETY

The commission, based on its own laboratory testing, found that TRIS could be absorbed by children through the skin or by "mouthing" TRIS-treated children's clothing. After a closed session between the staff and the commission, a ban on the sale of all TRIS-treated garments with an authorization for a consumer refund was published in the Federal Register.67 No representatives of the manufacturing, wholesaling, or retailing industry were afforded their procedural safeguards such as advance notice, right to file objections, or right to a public hearing. A federal district judge in South Carolina found that the commission violated the textile industry's right to due process and enjoined the commission from enforcing the ban.68

In a separate action the American Apparel Manufacturers Association sought an injunction against the commission's repurchase order requiring apparel manufacturers to bear the entire economic burden of the TRIS ban.69 On May 3, 1977, Judge Hart gave the commission 10 days to amend the definition of banned hazardous substances to include fabric, yarns, and fiber in cut or uncut form. Thus, fabric and TRIS manufacturers were ordered to share the economic burden of repurchase. The commission voted unanimously to extend the ban.70 Industry-wide regulatory ban on TRIS-treated children's sleepwear is presently in a state of limbo. The commission is attempting to impose individual bans upon retail sales of TRIS-treated sleepwear by petitions for injunctive relief in separate enforcement actions against retailers in numerous federal district courts.71

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67 42 Fed Reg 111,810 (1977)
70 42 Fed Reg. 22878 (1977)
71 *The following injunctions against retailers have been brought by the Commission to enjoin the continued sales of TRIS-treated articles of children's wearing apparel*

1 United States v. P. W. Woolworth Co.
CA 77 Civ. 2437 (S.D. N.Y.)
Final Consent Order entered May 17, 1977

2 United States v. A. W. Myers, Inc.
CA 77 Civ. 1356 (S.D. Ind.)
Final Consent Order entered June 1, 1977

3 United States v. R. H. Macy & Co.
CA 77 Civ. 4124 (S.D. N.Y.)
Final Consent Order entered November 4, 1977

4 United States v. Zayo Corporation
CA C-77-213-3 (D. Mass.)
Preliminary Injunction issued December 11, 1977

5 United States v. Allied Stores Corp.
CA 77 Civ. 4214 (LWP) (S.D. N.Y.)
Final Consent Order entered November 29, 1977

6 United States v. Lamonts Apparel, Inc.
CA C-77-436-M (W.D. Wash.)
Final Consent Order entered August 30, 1977

7 United States v. Federated Department Stores
CA C-77-457 (S.D. Ohio)
Final Consent Order entered August 31, 1977

8 United States v. E. B. Most Co., Inc.
CA 3-77-194-F (N.D. Tex.)
Complaint filed September 2, 1977
The TRIS controversy is still an enigma to the commission. On February 6, 1978, the commission modified the flammability standard for children's sleepwear. If the commission makes a finding that a substance represents an imminent hazard to the public health, it may by order published in the Federal Register give notice of such finding, and thereupon such substance will be deemed to be a "banned hazardous substance" pending completion of a section 701(e) formal rule-making proceeding to determine whether the ban should be made permanent or be dissolved. In the interim a preliminary finding of imminent hazard can be made after the commission holds an oral, adversary-type hearing with an opportunity for the presentation of written submissions. This procedure would at least afford all interested parties an opportunity to be heard by the commission before a proposed temporary ban is promulgated.

More recently, the commission, feeling the heat over the TRIS controversy, decided to issue a public interest finding under section 30(d) of CPSA with respect to free-floating asbestos fiber, contact adhesives, and toys and furniture containing lead paint. The commission chose to regulate these products under section 8 and 9 of CPSA rather than under FHSA, thus opting for informal rule making over formal rule making. In addition, the commission favored enforcement of civil penalties under CPSA.

III. THE POISON PREVENTION PACKAGING ACT

Under PPPA, the commission is authorized to develop special packaging standards for household substances in order to protect children from serious personal injury or illness resulting from handling, using, or ingesting such substances.
PRODUCT SAFETY

To date there have been no litigated cases under PPPA for failure to incorporate safety closures on bottles or containers involving potentially poisonous household substances. Since violation of PPPA is a violation of FHSA, enforcement under PPPA is similar to that under FHSA. Under PPPA, the commission uses a procedure similar to that incorporated in FHSA by sending a warning letter to the manufacturer when a violation of PPPA is found. Most of the letters advise the manufacturer to recall the product and to notify retailers not to sell until the violation is corrected. However, under PPPA, there is no repurchase provision covering banned hazardous substances as is mandated under section 15 of FHSA. Nevertheless, at the request of the commission, manufacturers have voluntarily recalled the following products:

<table>
<thead>
<tr>
<th>Products</th>
<th>Number of Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>aspirin</td>
<td>5</td>
</tr>
<tr>
<td>furniture polish</td>
<td>5</td>
</tr>
<tr>
<td>sodium and/or potassium hydroxide</td>
<td>5</td>
</tr>
<tr>
<td>turpentine</td>
<td>3</td>
</tr>
<tr>
<td>kindling and/or illuminating</td>
<td>3</td>
</tr>
<tr>
<td>methyl alcohol</td>
<td>13</td>
</tr>
<tr>
<td>sulfuric acid</td>
<td>4</td>
</tr>
<tr>
<td>prescription drugs</td>
<td>1</td>
</tr>
</tbody>
</table>

IV. THE ADMINISTRATION OF THE FLAMMABLE FABRICS ACT

FFA prohibits the introduction or movement in commerce of any product, fabric, or related material which is so highly flammable as to constitute an unreasonable risk of the occurrence of fire leading to death, personal injury, or significant property damage. Enforcement of FFA is lodged in CPSC utilizing section 5 of the FTC Act.

Although FFA is a public safety statute, neither it nor the FTC Act provides express authority to require notification, recall, and repurchase of items that do not conform to standards issued under FFA. Those provisions of the FTC Act that are incorporated into FFA provide only for the issuance of cease and desist orders upon a violation of the act.

By contrast, CPSA explicitly contains authority to require the manufacturer to either repair, replace, or refund the purchase price less an allowance for use in the case of substantial product hazards.

Thus, the Commission is presently considering on appeal whether it possesses the legal power to recall products from consumers which fail to

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meet an applicable standard. The Bureau of Compliance has mainly enforced flammability standards for four products: carpets, mattresses, wearing apparel, and children's sleepwear.

The first fully contested litigation involving the enforcement of FFA occurred in In re Congoleum Industries, Inc., which was commenced by FTC before CPSC was established. The FTC's administrative law judge's decision, which this commission affirmed, directed recall of carpet from distributors and retailers for testing but not recall "from the floor" of a consumer. The administrative law judge found that implied authority to recall from distributors and retailers was necessary in order to protect consumers from injury, death, or substantial property damage by fire. However, the administrative law judge held that recall of carpet which had been installed in a consumer's home was impracticable because of the legal and practical problems presented by any order contemplating the taking up of installed carpet.

The commission's decision of July 14, 1975 has been on appeal to the Ninth Circuit. The extent of delay inherent in appellate review is illustrated by the fact that the appeal was finally set down for oral argument on February 9, 1978.

A proposed extension of the Congoleum doctrine to include recall of failing carpet from the consumer's floor is now pending in three CSC cases. The matter arose on appeal from an administrative law judge's ruling that the commission, absent a Section 30(d) CPSA finding, does not possess authority under FFA or the FTC Act to order a recall, repair, or refund of carpet actually installed on the consumer's floor. In his opinion, the administrative law judge noted that FTC failed to obtain authority from Congress to effect consumer recall; that FTC never invoked administrative recall authority on its own initiative in a contested case; and that under the recent FTC Improvement Act, Congress, instead of granting administrative recall authority to FTC, authorized the agency to apply to a federal district court to obtain recall and refund remedies.

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1 See discussion in note 10, supra.
2 The Standard for Surface Flammability of Carpet and Rugs, FF 1-70, 40 Fed. Reg. 59951 (1975), 16 C.F.R. 1630 (1976), is commonly referred to as the "pill test." The test method requires eight replicate 9" x 9" carpet specimens. The specimens are dried in an oven and placed in a draft free environment. A flattening frame with a hole four inches in radius is placed on the specimen. A small methenamine tablet is then placed in the center of the hole and ignited. If the flame front burns within one inch of the flattening frame, a specimen fails. If two specimens of the eight tested fail, the sample is considered as failing.
7 See note 10, supra.
8 See note 16, supra.
10 In the only case where the FTC attempted to issue a consumer refund order involving the fraudulent procurement of a contract, the Ninth Circuit Court of Appeals reversed and the Commission did not seek certiorari. Hoover v. FTC, 503 F.2d 321 (9th Cir. 1974).
PRODUCT SAFETY

The administrative law judge's conclusion that this commission does not possess the legal power to order recall from the consumer's floor has merit. When Section 3(a) of FFA and Section 5(b) of the FTC Act are read together, they merely provide for the remedy of a cease and desist order against engaging in an unfair method of competition or an unfair or deceptive act or practice. A regulatory agency cannot validly transform language authorizing a cease and desist order into a recall order requiring restitution on the grounds of implicit power to protect consumers.

Additionally, in 1971 the Senate Commerce Committee, reporting on a proposed amendment to the FTC Act to empower the Commission to order refunds, stated: "At the present time, cease and desist orders have prospective application only and afford no specific redress to consumers already injured."

In 1975, Congress did grant broad recall powers in Section 206(a) of the FTC Improvement Act to the federal district courts. A condition precedent to obtaining a recall order from the federal district court is the issuance of a prior cease and desist order authorized by Section 5(b) of the FTC Act.

The FTC Improvement Act does not apply prospectively to CPSC. Under the transferred functions provision of Section 30 of C P S C , the commission was subrogated to the position of FTC in enforcing FFA. Any rules, regulations and procedures subsequent to the transfer were to be determined by CPSC rather than FTC. Thus, there appears to be a gap between the commission's regulatory and enforcement powers without the legal power to recall from the consumer.

The commission's only alternative to a congressional amendment is to make the necessary 30(d) finding under CPSA that "it is in the public interest to regulate such risk of injury under this Act." Then the respondent would be subject to the repair, replacement or refund elective remedies provided under CPSA.

The majority of alleged violations of the flammable fabric standard have been settled by consent order in which some manufacturers, apparently not interested in litigating the commission's recall power under FFA, agreed to recall all noncomplying products from distributors, retailers, and consumers. When the recalled product is returned to the manufacturer, the latter can either bring it into compliance with the flammability regulations or destroy it.

Even though it takes both parties to agree upon a remedial action, CPSC appears to be in a superior bargaining position. By urging the manu-
facturer to enter into a consent agreement in lieu of litigation, violative products are being recalled from the consumer under questionable statutory authority. The manufacturer might, in this instance, be forced to recall violative products when the commission's power to recall is still an unsettled question.

The commission has dealt with other cases not involving the recall issue. In three cases the commission dismissed the notices of enforcement due to voluntary action by respondent in immediately withdrawing the dangerously flammable fabric from sale, improper flammability testing, and bankruptcy of respondent. In two other cases, the administrative law judge issued a cease and desist order and recalled cardigan sweatshirts, nylon scarves, and untested mattresses for failing to meet the flammability standard.

All products regulated under FFA are subject to an applicable standard which may prove to be a per se limitation. The question remains open whether the existing standards and testing procedures accurately regulate the hazards involved.

In an enforcement case against Ups 'N Downs, Inc., a retailer of cotton tops, the administrative law judge concluded that statistical projections of failure are not enough to prove a flammability case. The staff tested 89 items from various retail outlets and found 26 of them failed the flammability test. None of the samples collected from Ups 'N Downs failed the standard when tested, thereby raising a substantial issue as to whether this retailer did in fact sell any failing playtops. The staff's case largely rested upon a statistical presentation, which indicated that between 13 and 23% of the samples obtained from all of the retail outlets of the importer which were tested failed and, therefore, that it was probable that some percentage of the playtops sold by Ups 'N Downs, Inc., were failing garments. No correlation between the statistical projections of failures and the actual cause of the failures was ever proved. Thus, the administrative law judge refused to issue a cease and desist and recall order since there was insufficient proof that respondents actually sold a flammable garment.

Since violation cases are the easiest to litigate, respondents many times are unnecessarily harrassed. For instance, complaint counsel has brought actions against respondents for failing to prototype test their mattresses and

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Footnotes:
6. The Bureau of Compliance compliance council is responsible for prosecuting violations under the Act.
PRODUCT SAFETY

maintain records as required by the standard. They argue that the failure to test mattresses and keep records of test results creates a presumption that the mattresses produced and marketed in violation of the flammability standard present an unreasonable risk to consumers so as to require the manufacturer to cease and desist from manufacturing and recall the mattresses (offering replacement or refunds).

Failure to properly conduct flammability tests, frequently results from the confusion in the mattress industry as to the exact meaning of such terms as "mattress prototype" and "mattress type." In the National Mattress Company case, the administrative law judge rebuked the commission's staff for failing to promote voluntary compliance in lieu of an expensive and broad cease order prohibiting the firm from violating not only the testing provisions of the mattress standard charged in the complaint, but any possible violation of FFAI in the future, which violation could result in substantial civil penalties. In an innovative decision the administrative law judge issued a limited cease and desist order prohibiting the precise future sampling, prototype, and product testing violations alleged in the complaint and supported by the evidence of record. Once again, enforcement counsel had proposed a remedy of a broad cease and desist order which is far more severe than the hazard which it sought to prevent—a classic case of overkill.

V. ARTICLE III COURTS REACTION TO CPSC ENFORCEMENT ACTIONS

Enforcement counsel has the option under section 12 of CPSA to resort to Article III courts rather than "in-house" administrative hearings. The commission has authorized enforcement counsel to seek court injunctions in numerous cases as a short-cut in lieu of an administrative hearing.

However, the commission has not fared well in the courts. In the TRIS controversy, the District Court for the District of Columbia found that the commission did not go far enough in properly distributing the economic burden among fabric, garment, and TRIS manufacturers. The federal district court in South Carolina enjoined the TRIS ban for lack of procedural safeguards and the judge in the Central District of California refused to issue an injunction because of insufficient proof of carcinogenicity. In the case of vinyl chloride the Court of Appeals for the Ninth Circuit found that

102In re Fag D, Associates, CPSC Docket No. 76-4, settlement (July 9, 1976). In re Castro (Bay Area Mattress Co., and Kent Mattress Co.), CPSC Docket No. 75-2. The Commission on January 29, 1976 affirmed the administrative law judge's issuance of a cease and desist order prohibiting the manufacture of untested mattresses in the future. No recall order was issued since there was no evidence that any of the mattresses in the hands of purchasers had failed the mattress standard. In re Slumber King Mfg. Corp., CPSC Docket No. 73-24, Cease and Desist and Recall Order, (January 27, 1977).


the commission failed to hold the necessary formal rule making proceeding on the record before promulgating a regulation under FHSA. While the commission was debating whether to commence a section 15 CPSA proceeding involving allegedly hazardous aluminum wire, a federal district court enjoined the commission on jurisdictional grounds, holding that aluminum wire is not a consumer product for use in or about the household but instead a part of the home which is regulated by local ordinances and building codes. On the other hand, the District Court for the District of Columbia found that the commission did have jurisdiction. Both decisions are currently on review in the Third and District of Columbia circuits.

Recently, a federal district court judge invoked the doctrine of exhaustion of administrative remedies where respondent in an FTC action to regulate the official airline guide under the antitrust laws challenged FTC jurisdiction. The judge concluded that the plaintiff failed to show that the statutory mechanism for ultimate appellate review of the challenged agency action is inadequate to protect his rights before he may seek a district court injunction.

This illustrates the reluctance of federal district court judges to hear administrative cases ab initio. Why should the court clog their calendars unnecessarily when the agency's own administrative law judge has probably more expertise to handle it and when the administrative process has already begun? If for example, TRIS or aluminum wire had initially been commenced "in-house" before an administrative law judge instead of resorting to the federal district courts or waiting to be challenged in the district courts, a final administrative decision coupled with the right of appellate review could run its natural course. By circumventing its own administrative process, the commission has prodded different localities into diverse opinions. Thus, the short-cut has become a long-cut.

**CONCLUSION**

Consumer interest in product safety is of recent vintage. Thus, critics are closely scrutinizing the workings of the commission to see whether it is functioning as Congress intended. Consumer groups are stressing the need for more and better standards, arguing that the commission is not going far enough in regulating unsafe products. Industry takes the opposite view. Manufacturers, distributors, and retailers believe the commission is going too far in regulating and in placing such a heavy economic burden on them. Others contend that the commission is of no purposeful use since there are not many truly hazardous products in the marketplace and that the Com-
PRODUCT SAFETY

mission's approximately 40 million dollar annual budget does not justify policing a few hazardous products.

A major criticism directed against the commission is undue delay. Complaint counsel is bringing actions today for violations which occurred three or four years ago. The litigated cases have in many instances raised spurious issues requiring dismissal or minor remedies. Where recall has been ordered, the time lapse between investigation and final decision has been such as to minimize the remedial effects. Only about 15% of products ordered to be recalled have in fact been tendered by consumers. Hopefully, the notice requirements incorporated in the cease and desist orders have adequately warned consumers and prevented a substantial number of injuries and deaths. Until the issue of recall from consumers in FFA enforcement actions is resolved by the commission and ultimately by the courts, litigation under this act appears to be at a standstill.

The Commission is moving rapidly toward the promulgation of rules of practice in expedited proceedings to process administrative civil liability cases including a number involving failure to timely report the existence of a substantial product hazard. This would be a step toward remedying delay.

Another weak link in the commission's performance is the lack of a sufficient number of standards. A fabric, related material, or product not subject to an applicable standard may go unregulated under FFA. The consumer's only redress then is to petition the commission to institute an investigation and research the development of a new standard. This has proved to be extremely time-consuming and costly. In contrast, even though a product may not be subject to an applicable standard under CPSA, complaint counsel may bring a section 15 administrative action if a substantial product hazard exists. The commission, instead of promulgating safety standards has the burden of proving, based upon the substantial evidence of the record taken as a whole, that a substantial product hazard exists. Thus, a consumer receives greater immediate protection under CPSA than FFA if an unsafe product has not been subjected to a standard.

The legislative mandate to protect public health and safety would most certainly be enhanced by combining the various remedial powers under the five acts. The commission cannot afford to dismiss a case after two years and a full administrative hearing upon a finding that it was issued under the wrong law. CPSA and transferred acts are not mutually exclusive. Like all new agencies, the commission is experiencing growing pains. As a safety regulator the commission could best serve the needs of industry and consumer alike by promulgating regulations and taking administrative enforcement action under the most modern CPSA. The courts primarily serve the review function and were not intended to supersede the large and expert-staffed regulatory agency in the initial adjudicatory stage.

113See note 10, supra.
116CPSC Docket No. 75-18, Appeal from Initial Decision (July 20, 1976).
A RECORD YEAR
FOR RECALLS

The government is getting tougher on product safety, and liability suit awards are soaring. One expert sees the number of product recalls growing at a 10%-to-15% annual clip.

At the recent Financial Foliotier, an annual black-tie sports of business put on by the New York Financial Women's Association, the opening number depicted Charter- man Henry Ford of Ford Motor Co. and Richard A. Riley of Firestone Tire & Rubber Co. singing (no tune of Kool) "Recall! They're buggin' us with recalls..."

It is nothing for businessmen to sing about, for as Jimmy Durante might phrase it, industry ain't seen nothing yet.

Last year, a record total of more than 72 million products—from foods, drugs, and prescription cosmetics to auto, appliances and lighters—died by their manufacturer. Consumer complaints and pressure from one of the four major government agencies empowered to police the marketplace for dangerously defective products, (Products that are not defective but which manufacturers believe might be dangerous are not recalled.) And the prospect is for an even bigger number this year in 1979. One expert predicts that over the next five years the number of recalls will not only grow at an annual rate of 10%-to-15%, but that all manufacturers and perhaps half the manufacturers of TV sets and electric appliances will recall at least some of their products.

Management Migraine

As we go to press, recall is probably the most spoken-about word in executive suites nowadays. The Conference Board reports that a significant number of the 45,000 information requests it receives from business every month now deal with recalls, though some companies euphemistically call them "distribution interruptions" or "strategic withdrawals." By any name, the complexity and vast process of bringing defective products back to the marketplace for repair or replacement is now a thriving, multimillion-dollar industry from which no industry can see any relief. How bad is it? Says E. Patrick McGuire, a project director at The Conference Board: "If you're a major manufacturer, you know you're going to get a recall..."

The company that receives a dreaded recall notice from a government agency also knows that it is bad news. For the procedure, which costs the consumer nothing and is the cost of shipping, can be forbiddingly expensive for the manufacturer. Depending upon the product, how widely it is distributed and the extent of the correction, the bill can run from thousands of dollars into the tens of millions.

Tales from the pollution-control systems on 27,000 of us 1978-model cars, American Motors Corp. figures it will spend around $5 million—including close to $4.000 just for first-class postage to notify the owners. For Firestone, the cost of replacing 7.5 million steel-belted radial tires in its notorious recall case, in which 41 deaths and 63 injuries were allegedly connected with the tires, may run upward of $135 million after taxes—more than the company's net income in fiscal 1977. It could be worse, however. When the presence of benzene showed up in a Bonneville muscle car several years ago, the financial and public relations teams of the subsequent recall proved so devastating for its maker that the company went bankrupt.

To the consumer, recalls have become synonymous with cars, which accounted for a 45% share of all the products called back by manufacturers in every industry last year (table, page 251). But the automakers have no corner on problem-prone products. The roster of recalled products in 1978 alone includes a tobacco container that could explode and start a fire, chocolate liqueurs containing metal filings, a baseball pushing machine with a propensity for hitting people instead of balls, even in the "off" position, brittle-infested Easter baskets, a rifle that may fire without anyone pulling the trigger, pros androgynous tables prone to collapse, a cookbook containing a recipe for "silky caramel slices" that omitted an ingredient (water), and thus might cause a crockery cook to explode and another book with a recipe calling for a variety of rhubarb that could be poisonous.

Fire Drills

Not uncommon, a number of companies may hit with recalls are gearing up for a procedure that is becoming practically inevitable by conducting mock recall exercises. As part of its annual plant audit, Pillsbury Co., selects a product at random and launches a "trial" to find out specifically where an entire product run may be in the distribution pipeline. "We don't call it a recall," cautions Van President John Haaland. "That's a federal word." At General Mills, which claims that it has never had a food recall, a similar "dry run" is conducted periodically, but plant and distribution personnel are never told of the operation until the recall is imminent. "A fire drill," says Warren Schwartz, director of quality control of the consumer foods group. "I hope we never have to use the procedure for real."

He may be breathing in the dark. According to the Conference Board's McGuire, who monitors the action in product safety, the inevitabilities of mounting recalls is due to "a confluence of several factors in an equation that guarantees: Emergency recalls: The FDA once sent bond trucks through Philadelphia streets, warning of tainted fish..."
Despite the proliferation of recalls, Made-in-America products are safer and of better quality than goods produced five years ago, according to one authority on safety.

Recall City

It's a sad and predictable story. Every few years, some company, realizing that it has a recall on its hands, announces that a defect in its product has caused a number of injuries and deaths. The phrase is now so familiar, it's almost laughable. But it's also a sad reality. The cost of recalls is immense, both in terms of money and human lives. And it's not just the automotive industry that is affected. Everything from toys to medical devices can be recalled if a problem is identified. The cost of recalls can be enormous, and the damage to a company's reputation can be irreparable.

The Government's Business

Yet, despite all the back-and-forth between the government and businesses, there seems to be a lack of transparency and accountability. The government has the power to issue recalls, but it often does so without enough information to make a decision. And when a recall is issued, it's often too little, too late. Businesses are forced to bear the brunt of the cost, and consumers are left to wonder whether their safety is being protected.

The Future of Recalls

Looking ahead, it's clear that we need a new approach to recalls. We need stronger laws, better enforcement, and more transparency. The government must be held accountable for its actions, and businesses must be held responsible for their products. Only then can we begin to make real progress in protecting consumers.
RECALL ROLL CALL

Apart from the almost total recall of Detroit's automotive products, scarcely an industry was not affected by recall action in 1978. Herewith a roster of the year's representative recalls.

<table>
<thead>
<tr>
<th>Product</th>
<th>Manufacturer</th>
<th>Units Recalled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breakfast bars</td>
<td>Carnation Co.</td>
<td>14.1 million</td>
</tr>
<tr>
<td>Water Wiggle toys</td>
<td>Wham-O Mfg. Co.</td>
<td>2.5 million</td>
</tr>
<tr>
<td>Riviton construction toys</td>
<td>Parker Brothers</td>
<td>900,000</td>
</tr>
<tr>
<td>Stuffed animals</td>
<td>Knickerbocker Toy Co.</td>
<td>500,000</td>
</tr>
<tr>
<td>Extension cords</td>
<td>Black &amp; Decker Mfg.-Co.</td>
<td>200,000</td>
</tr>
<tr>
<td>Rifles</td>
<td>Remington Arms Co.</td>
<td>200,000</td>
</tr>
<tr>
<td>Smoke detectors</td>
<td>Pittway Corp.</td>
<td>115,000</td>
</tr>
<tr>
<td>Skin creams</td>
<td>Avon Products</td>
<td>104,000</td>
</tr>
<tr>
<td>Slide projectors</td>
<td>Eastman Kodak Co.</td>
<td>100,000</td>
</tr>
<tr>
<td>Rock polishers</td>
<td>Martin Yale Industries</td>
<td>50,000</td>
</tr>
<tr>
<td>Mayonnaise</td>
<td>Kraftco</td>
<td>48,000</td>
</tr>
<tr>
<td>Ping pong tables</td>
<td>Sears, Roebuck &amp; Co.</td>
<td>36,000</td>
</tr>
<tr>
<td>Refrigerator defrosters</td>
<td>Chadwick-Miller Inc.</td>
<td>23,600</td>
</tr>
<tr>
<td>Diet supplements</td>
<td>Peerpark Corp.</td>
<td>12,500</td>
</tr>
<tr>
<td>Hair relaxers</td>
<td>Revlon, Inc.</td>
<td>11,000</td>
</tr>
<tr>
<td>Sunlamps</td>
<td>General Electric Co.</td>
<td>9,000</td>
</tr>
<tr>
<td>Stepladders</td>
<td>Sears, Roebuck &amp; Co.</td>
<td>8,000</td>
</tr>
<tr>
<td>Baseball pitching machines</td>
<td>Master Pitching Machines, Inc.</td>
<td>7,500</td>
</tr>
<tr>
<td>Stuffing mixes</td>
<td>Stop and Shop Inc.</td>
<td>7,400</td>
</tr>
<tr>
<td>Woman's Day Crockery Cuisine</td>
<td>Random House</td>
<td>3,000</td>
</tr>
</tbody>
</table>

THE POWERS OF TOTAL RECALL

Although 90% of all product recalls are considered "voluntary" actions by manufacturers, most are "influenced" by the four major federal agencies empowered to monitor products for dangerous defects. Their growing influence over the past five years is seen below.

<table>
<thead>
<tr>
<th>Agency</th>
<th>Recall Campaigns</th>
<th>Product Units Recalled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food and Drug Administration</td>
<td>1,153</td>
<td>1,112</td>
</tr>
<tr>
<td>National Highway, Traffic Safety Administration</td>
<td>251</td>
<td>241</td>
</tr>
<tr>
<td>Environmental Protection Agency</td>
<td>29</td>
<td>29</td>
</tr>
<tr>
<td>Consumer Products Safety Commission</td>
<td>3</td>
<td>128</td>
</tr>
</tbody>
</table>
It now begins with a letter from an auto repairman to the company involved in the defect. As the defect is reported to the company, it is then examined by the company to determine if there is a defect in the product. If a defect is determined, the company must report it to the National Highway Traffic Safety Administration (NHTSA). The company must also notify all owners of the vehicle of the defect. The company must then conduct a recall of the vehicles affected by the defect. The recall must be completed within a certain period of time, typically within a few months.

As the recall process unfolds, it involves several key steps. The company must determine the severity of the defect, the number of vehicles affected, and the cost of the recall. The company must then notify the owners of the vehicles, usually by mail, and offer a voluntary recall. If a voluntary recall is not accepted, the company may be required to conduct a mandatory recall. The mandatory recall is enforced by the government, and the automaker must complete the recall within a certain period of time.

The company must also determine whether the defect is significant enough to require a recall. If the defect is deemed to be significant, the company must file a recall report with NHTSA. If the report is approved, the company must then conduct the recall. If the report is not approved, the company may be required to make changes to the vehicle before a recall can be approved.

The recall process is a complex one, requiring extensive planning and coordination. It involves a wide range of stakeholders, including the automaker, the NHTSA, and the affected vehicle owners. The process is designed to ensure that safety is the top priority, and that all affected owners are informed and given the opportunity to have their vehicles repaired.

In conclusion, the recall process is a critical component of the automotive industry's commitment to safety. It is designed to identify and correct defects in vehicles, and to ensure that all affected owners are informed and given the opportunity to have their vehicles repaired. The process is a complex one, requiring extensive planning and coordination, but it is essential to ensuring that safety is the top priority in the automotive industry.
The Language of Recalls

Invisible, to the agencies telling the public how to recall their products, the recalls are the language of recalls. The language is the way the agencies tell the public what to do about recalls, and the way the public responds to them. The language is the way the agencies and the public communicate about the recalls.

The Language

The language of the recalls is often written in a way that makes it difficult for the public to understand. The language is often technical and difficult to read. The language is often written in a way that makes it difficult for the public to understand. The language is often written in a way that makes it difficult for the public to understand.

The Language of Invisibility

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The Language of Visibility

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The Language of Non-Visibility

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The Language of Visibility and Non-Visibility

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Consumer protection groups want the government to get a lot tougher on recalls. One critic, claiming that no agency is doing a fabulous job, gives them a grade of only B -
DEBATE PROPOSITION TWO

RESOLVED THAT: THE FEDERAL GOVERNMENT SHOULD ESTABLISH UNIFORM STANDARDS FOR THE REGULATION OF COMMERCIAL ADVERTISING

There can be no doubt that advertising plays an important role in the American economy. As they have for years, advertising expenditures continue to account for over 2 percent of our Gross National Product. On a per capita basis, the United States spends three times as much as the number two-ranked country, West Germany. Yet while few would disagree that advertising has been, and will continue to be, a vital factor in the economic growth of this country, a number of critics say that much of present-day advertising is wasteful, manipulative, and too frequently false, unfair, or deceptive.

The regulation of advertising reflects a conclusion that consumers are for the most part not in a position to protect their own interests, because there are simply too many products for consumers to test for themselves, and the process of testing is too expensive compared to the cost of most products. Furthermore, the regulation of advertising can also have pro-competitive consequences. Misinformation not only defies consumers from an opportunity to make a choice on the merits of rival products, thereby misallocating economic resources, but misinformation also creates the immediate danger that true invention and innovation will be replaced by spurious advertising campaigns. Similar anticonsumer and anticompetitive effects can occur where all companies in an industry maintain silence with respect to strategic product data, without which consumers cannot make a sensible choice among rival brands.

While most observers agree that some regulation of advertising by the Federal Government is necessary and desirable, many are convinced that it is vitally important that Federal involvement be kept to a minimum. The advertising industry in the United States has a long history of heavy reliance on self-regulation in order to prevent further intervention, however well-intended, by outside parties whose efforts could seriously impair the proper function of advertising without making any significant contribution to the effectiveness of advertising regulation.

The principal Federal agency charged with the responsibility of regulating advertising is the Federal Trade Commission (FTC). The standards the FTC employs in regulating commercial advertising are grounded in its statutory mandate and shaped by the opinions of the courts. Several key cases have been decided by the Supreme Court during the last few years concerning the protection accorded commercial speech under the Constitution's first amendment. These and related matters are discussed in the following articles.

(257)
Critic\'s who call for more social responsibility in advertising obviously think that something is wrong with it, or at least with some of its manifestations. They are calling for an improvement in business performance in advertising—voluntarily if possible, or by government enforcement if not.

In recent years these criticisms of business advertising have been coming from many points of the compass. They are not all consistent with each other, and economics does not endorse all of them. Indeed as economics has been critical of advertising, it has focused mainly on two issues. One is the effect of advertising on consumer preferences. Economists have debated whether it does in fact have much influence on consumer choices, and if it does, whether business should be more responsible in exercising it and whether the government should regulate advertising if responsibility fails in some essential way. The other is the possibility that advertising may create monopoly power on the seller.

If that should be the general effect of advertising, hardly anyone would think that voluntary exercise of business responsibility would be an effective remedy. But it is not easy to say what public policy would be called on to do about the problem.

Advertising and the Primary of Wants

Concerning the first issue, the effect of advertising on preferences, economics has had some difficulty putting it in perspective. The theory of value usually assumes that consumer wants are "given," primary elements which the market economy, for all economic system having consumer welfare as its main purpose, attempts to satisfy. But advertising, at first glance, seems to turn the system on its head. If preferences—wants—can be altered or created by advertising, they no longer seem so primary. Instead, they seem to be produced by the very economic process that seeks to satisfy them.

But these apparent conflicts survive a second glance. We have to remember that the assumptions of theory are for convenience only. They do not purport to describe the real world. Few economists really believe that consumer preferences are nothing but an output resulting from advertising input, or that advertising can actually create wants independently of the fundamental drives and behavioral propensities of consumers. It may influence them, just as other circumstances of society can influence them; people are not born into the world with their tastes and preferences fully formed. But all that is beyond the reach of the economist. It is the sphere of the sociologist and the developmental psychologist. Human beings enter the field of won of economics when they appear in the market, the workplace, the queue, the polling booth, the bank, or the welfare office.

Choice and Affluence

What appears to be the responsiveness of consumer behavior to advertising is probably due largely to the cost of information and image formation in the affluent American economy. It does not mean that producers of goods and services can shape wants and preferences to fit their requirements. Models in the economic textbooks are apt to assume that consumers always know exactly what they want, what goods and services will satisfy their wants and to what degree, where these goods are to be found, and how similar goods differ from each other—all without anyone's having provided them with this information and without experimenting with different combinations.

There may have been a time when the average family's consumption consisted of allocation of a severely limited income among a few staple commodities so as to gratify, as far as possible, a few simple and urgent wants. In a subsistence economy, where the typical consumer must spend most of his income on basic foodstuffs and rudimentary shelter and clothing, he does not need much information on the nature and availability of commodities. There is no point in advertising yams to the Melanesians or rice to Burmese peasants. Advertising develops when goods become so abundant that they must compete for the consumer's attention. The American economy is far beyond the point of meeting a few stable and pressing wants. The increasing effort devoted to marketing and selling is largely due to the advance level of want satisfaction it has achieved and the great proliferation of means of satisfaction.

From the standpoint of an individual seller of goods, this...
Consumer loyalty to certain brands under certain conditions, but advertising seems not to be the principal agent in creating loyalty or prolonging it.

Advertising, Competition, and Concentration

In business, the concept of advertising is often associated with creating a competitive advantage through the promotion of goods and services. Consumers, on the other hand, define competition as a market situation where buyers form Önly small groups and a price of goods is determined. Sometimes, the advertising activities of a business may influence market conditions. If consumers are not aware of certain factors, such as price, quality, and brand reputation, they may be influenced by advertising campaigns. Advertising, therefore, can be considered a tool for creating loyalty and influencing consumer behavior. The presence of advertising can lead to changes in market conditions and influence consumer preferences. When consumers are exposed to advertising, they may develop a preference for certain brands, which can lead to loyalty and repeat purchases.
This does not mean that concentrated industries will show no effects of advertising on sales that are not concentrated in sales, or that there are equal. A relatively uncompetitive industry such as general reading by department stores or food retailing often shows quite high levels of advertising to sales, because of the unsatisfactory nature of the commodity. Concentration in a advertising sales while other industries are quite high, indicates that advertising has an important effect on advertising in two. The question is, on what basis possible sales for advertising, but it is quite predictable relation to non-speech concentration in a much larger proportion.

We are apt to form strong impressions about advertising from television, the most visual medium for image formation. The large, expensive, sellable, or consumer goods with extensive brands on TV campaigns, gives the viewer a sense of relative pressure for the same brand even though the advertising outlet can be proportionally no greater than that in uncompetitive industries that rely more on other media. The major TV advertisers have come to consider advertising itself proprietary drugs and toilet items, beer, soap and detergents, but drinks that are non-alcoholic. Establishmene products are among the largest spenders, and their advertising has been very low, as is a 1960. Although it is not an advertising problem, but the market is substantially competitive. In many industries, as in long as banks and appliance industries, has the same ratio of competitive pressure on the sales with a small fraction of the output of Proctor & Gamble. To trace the effects of advertising on monopoly, there is an almost unattainable problem.

Entry

Advertising is said to have erected barriers to entry in certain consumer goods industries. In some industries with high advertising outlays, these expenditures are offset by the main reason for lack of entry. Hence advertising must have other purposes in consumer goods industries. For example, the establishment of product preferences, thus creating a considerable investment in advertising. This effect may be a barrier to entry. If the firm is not interested in a specific brand but sales promotion, this may lead to advertising importance. However, as we have seen, advertising may be the only avenue for entry. Through previous studies, advertising as a barrier to entry, "product differentiation" as a barrier is best known to economists through the writings of Joan Robinson, who observed that "the advantage to established sellers accruing from buyer preferences for their products as opposed to potential entrant products is on the average larger and more frequent in occurrence of large values than any other barrier to entry." In a sample of 20 industries surveyed for that study, Robinson found that product differentiation alone was responsible for the very high barriers to entry in cigarettes, liquor, and quality fountain pens, and combined with production scale economies to produce extremely high barriers in automobiles, tractors, and typewriters.

That was in the 1950s. While these examples, however, looked at from 1950s, there is a sense that drawing final conclusions on advertising as a barrier of monopoly power. The liquor industry has been heavily battered by the seemingly automatic shift of consumer tastes toward vodka and wine, and by several sales-promotion campaigns by the dominant distillers that bombed out the quality fountain pen industry has practically erased its advantages to established sellers seen, which the industry has been shaken up rather severely by the Ford typewriter. Automobiles, typewriters, and quality fountain pens, and combatted with productivity and equipment advances. Volkswagen and Mercedes, Toyota and Datsun were able to out-flank the established sellers, unable to match the fast response, and by several sales-promotion campaigns by the dominant distillers that bombed out. The quality fountain pen industry has practically erased its advantage to established sellers seen, which the industry has been shaken up rather severely by the Ford typewriter. Automobiles, typewriters, and quality fountain pens, and combatted with productivity and equipment advances. Volkswagen and Mercedes, Toyota and Datsun were able to out-flank the established sellers, unable to match the fast response, and by several sales-promotion campaigns by the dominant distillers that bombed out.
There are probably more widespread business benefits of advertising than are obvious, and the increased business without which it enabled the previously market monopolies to survive may well have been in addition to those benefits. E.g., when the American market on a scale of market power which accounted for an increase in the number of businesses that were large, whether advertising would have had to be any less voluminous and extensive to achieve its purpose even if the "national" radio networks had been pervasive advertising there are at, say, half of their actual level. Not did the advertising of the latter example help build or retain the product market in which aspirin and talcum powder were marketed. Everything that makes a socially optimum advertising policy difficult for the responsible firm would also create difficulties for government regulation.
Does this mean that the government has to take over the job of policing in this area? As the government frequently has to do what there are large external effects of private firm decisions. I doubt it. Everything that makes a "socially optimal" advertising policy difficult for the responsible firm would also create difficulties for government regulation. The problem is not the same, as, say, environmental pollution. The government has its best opportunity for an unequivocal contribution in high-risk situations, where lack of consumer protection has a high probability of serious injury. In addition, it may be able to deal effectively with the problem of big and small business misleading advertising, though the Better Business Bureaus have also made contributions toward lessening that problem.

Both the business community and the government seem to agree that the benefits are shifting. Consumers are valuing information more highly, assimilating it better, and showing greater awareness in judging the accuracy of factual content.

Regulation of Advertising Conduct

Though regulatory policy does not always mean public opinion exactly, the principal thrusts of policy usually indicate what the public is concerned about. At present the principal ones appear to be (1) to require advertisers to provide information when the absence would greatly harm the buyer; (2) to prohibit unfair advertisements that misinform consumers; and (3) to protect the consumer from serious harm when he cannot protect himself.

These are worthy goals, but a misdirected or excessive enforcement can produce bad results. Emphasis on information can lead to information overload, a product known only as well that people transmit information, beyond a point. At another extreme it leads to a preoccupation with "truth" as a mere physical imperative. Some advertising concern is "information" only in the McLuhanesque sense of transmission of images. If "truth" is used as a principle of exclusion, to protect transmission of nothing but "truth," that would put not only advertising but education out of business. Other concern with injury by competition can lead to "centrality and blight the effectiveness of competition. Excessive concern with consumer protection against misrepresentation can lead to a policy of saving consumers from their own folly of moulding the whole content of their wants.

Examples of all of these excesses of regulation are easy to find. So are examples of excessive preoccupation with consumer "need" to understand the sandwich-sharing scandal, which serves no purpose other than to entertain the events of government regulation. Nevertheless, the fact that Big Business is watching has certainly had some effect in discouraging fraudulent and deliberately deceptive advertising which could do real harm to the public. Though most advertisers would not take that path even in the absence of regulation, the exceptions would not turn up, some get through the shanks of regulation even now.

The Limits of Economics

Many of the questions addressed by either regulation or a search for greater social responsibility are not questions in which economics can make a useful contribution. It costs and benefits cannot be computed, or worth, some popular terminating factors under consideration, economics becomes more in a less spectator. For example, one of the leading questions at present advertising directed at children is, "What is the risk, as it creates?". It is a critically important question for some industries, such as ready-to-eat breakfast cereals. Economics considers the "household" as the unit that makes consumption decisions, protection of children in view of their insularity and lack of integrative perceptions, or protection of parents against children's demands created by advertising, are matters that do not concern it directly. At most we can call for better information, say, the amount of sugar in the food and its effects on nutritional balance and dental health, as necessary data for cost-benefit analysis. I listen to add that advertising directed to children does concern economics, as parents and citizens.

But, of course, society never has regarded economic wants registered on the market as a driver of social welfare in all cases, we would not have laws against narcotics if we did. I hope that these particular problems of advertising to children can be largely controlled by voluntary social responsibility, since it seems an unreasonable area for regulatory intervention.

There is also the question of last: I could wish for fewer, Demonstrable ads, for less dedication to oversized, over-sold, in order to evade their refusal, for fewer episodes of complex advertising geared to each other, awareness of more frequent "bit" or coter, for fewer mawkish in automobile, fur, and beer ads, fewer appearances by Harry the Hound and the Nifty, less rapid appreciation of every new popular phrase, style, or attitude in the advertising market, and above all for fewer appealing toddlers commonly doing advertisements, ads for products to be consumed by adults. But in saying that, I have taken the economist's hat and joined the general public, whose tastes are not all necessarily the same as mine. If enough solves principle the same message, of course, businesses will sooner or later respond to it, as the government will transmit the message.

March-April 1979
Advertising and Information

Roger M. Swagler

Toward A Consumer Perspective

A Consumer Viewpoint

Regardless of who you are or where you happen to be as you read this, you have almost certainly been exposed to some kind of advertising today. In the last chapter I spoke of ways in which the consumer can seek out information, but with advertising, the situation is reversed; it seeks you out, coming into your home over the television and radio and in newspapers and magazines. Advertising is an integral part of American life, and billions of dollars are spent each year to ensure that it stays that way. However, despite such massive expenditures, it isn’t at all clear what advertising does for or to consumers. It is clear that all those dollars spent on advertising haven’t fulfilled the consumer’s need to know about products. There is evidence, in fact, that the opposite is sometimes true; advertising may confuse consumers and in some cases even mislead them.

The irony of this situation can be traced to basic differences in how advertising’s function is perceived. Thus far we haven’t spoken of information in terms of telling consumers what they ought to do. We have treated information as impartial evidence that consumers evaluate as they make independent judgments. The intended outcome is a purchase that will promote greater satisfaction; presumably, informative advertising would embody these same elements.

At this point, a conflict arises because advertising intends to sell a particular product. It follows that the function of the ad must be...
Advertising and Information

to persuade the individual to buy the product. Thus, persuasion replaces impartial evaluation and any persuasive technique that works will be employed. Success is measured in terms of increased sales, and any ad that boosts sales is by definition 'good. If an ad for Scrubbo Cleanser shows a celebrity extolling its virtues and that gimmick happens to sell Scrubbo, that's all that matters.

There's the rub, the difference in perception mentioned above. Information is meant to provide consumers with a better basis for making independent decisions; advertising is meant to persuade consumers to buy a product. Advertisers are interested in informing the public only if that information will help sell the product. That is why most of what is written about the subject is of little or no value to the student inquiring about advertising from the consumer's point of view. Advertising has been analyzed mainly from the seller's perspective, which views the consumer as someone to be attracted (some would say manipulated) rather than someone to be given information.

Dollars and Sense

This raises an obvious question: Should advertising be asked to perform an information function? In answering that question, remember that while information can be gotten to consumers more cheaply than it is now, someone still has to pay the cost of getting it there. Two possibilities suggest themselves: government and business. The government reduces information costs to consumers by forcing businesses to disclose key facts, establishing standards, or providing information directly. The costs are then either forced back on business or paid out of tax monies. If government bears the costs directly, it is ultimately the consumer as taxpayer who shoulders the burden. This may be a more efficient approach, but information costs have only been reduced, not escaped.

If business is forced to bear the cost of providing information to the consumer, this cost, like any other cost of production, would be reflected in the final price of the product. The degree to which this price increase would be passed along to the consumer depends on the degree of competition in the market. In most cases, however, the consumer will end up paying some, if not all, of the added costs through higher product prices. Again it is the consumer who ultimately pays the costs of information. If it has occurred to you that you are already paying higher prices to cover advertising and promo-

* The less competition there is, the easier it is for firms to pass higher costs along to consumers. In more competitive markets, there are more firms, so consumers have more choices, and it is harder for a single firm to manipulate price.
Toward a Consumer Perspective

Tional costs, then you see the point. Look carefully at the data in Table 6.1. The dollar amounts are impressive (nearly one-half billion dollars for Procter & Gamble), but the percentages may be more significant. The percentages can be read as the number of cents out of each dollar spent that go to pay for advertising.* Among the top 100 national advertisers, advertising expenditures run as high as one-fourth of sales [6, p. 30]. Few are that high, but it remains clear that a significant portion of the consumer's dollar goes directly to advertising.

This is precisely why information is so important. If advertising efforts were channeled into providing information, there would be a net gain to consumers, who would then be receiving something for the costs they are already paying. In that sense, informative advertising would be relatively cheap in that it would be available at little or no extra cost. Remember, too, that the potential for advertising as

Table 6.1 Advertising Expenditures: In Dollar Amount and as a Percent of Sales for the 15 Leading National Advertisers: 1976

<table>
<thead>
<tr>
<th>Company</th>
<th>Ad Expenditures* (in millions)</th>
<th>Ad Expenditures As Percent of Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Procter &amp; Gamble Co.</td>
<td>$445.0</td>
<td>8.4</td>
</tr>
<tr>
<td>2. General Motors Corp.</td>
<td>287.0</td>
<td>0.6</td>
</tr>
<tr>
<td>3. General Foods Corp.</td>
<td>275.0</td>
<td>7.6</td>
</tr>
<tr>
<td>4. Sears, Roebuck &amp; Co.</td>
<td>245.0</td>
<td>2.0</td>
</tr>
<tr>
<td>5. Warner-Lambert Co.</td>
<td>199.0</td>
<td>15.3</td>
</tr>
<tr>
<td>6. Bristol-Myers Co.</td>
<td>189.0</td>
<td>9.5</td>
</tr>
<tr>
<td>7. Ford Motor Co.</td>
<td>162.0</td>
<td>0.5</td>
</tr>
<tr>
<td>8. American Home Products Corp.</td>
<td>158.0</td>
<td>8.8</td>
</tr>
<tr>
<td>9. Philip Morris Inc.</td>
<td>149.0</td>
<td>3.5</td>
</tr>
<tr>
<td>10. Mobil Corp.</td>
<td>146.5</td>
<td>0.5</td>
</tr>
<tr>
<td>11. R. J. Reynolds Industries</td>
<td>140.3</td>
<td>2.4</td>
</tr>
<tr>
<td>12. Unilever</td>
<td>135.0</td>
<td>10.7</td>
</tr>
<tr>
<td>13. General Mills Inc.</td>
<td>131.6</td>
<td>4.5</td>
</tr>
<tr>
<td>14. Heublein Inc.</td>
<td>129.1</td>
<td>8.3</td>
</tr>
<tr>
<td>15. Colgate-Palmolive Co.</td>
<td>118.0</td>
<td>3.4</td>
</tr>
</tbody>
</table>

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* National advertising measured media only (includes newspapers, magazines, television, radio and outdoor).

* These figures actually understated the cost of advertising to the consumer because they do not include local advertising (Sears, Roebuck & Co., for example, spends more on local ads than on national) [6, p. 30]. The figures also omit the closely related costs of packaging and promotion.
a mechanism for providing readily available information is difficult to overestimate. The beauty of advertising, as we've noted, is that it reaches everyone; at present, that may be a mixed blessing, but the potential benefits are tremendous. There is no better way for consumers to obtain so much information so effortlessly.

Advertising and Information Content

An Overview of the Media.

Thus far we have talked about advertisements as a single group, when in fact there are important variations among them. The most obvious differences are among the media. Television, radio, magazine, and newspaper advertisements come to mind, but they don't cover all the possibilities; there are also specialty or trade publications, billboards, and other outdoor advertisements, flyers, loudspeakers, and other forms that attest to the ingenuity of individual advertisers. If, as Marshall McLuhan says, the medium is the massage, then it is important to understand something about the characteristics of advertising on the various media.

We begin by looking at the distribution of advertising expenditures among the media. A glance at Table 6.2 shows that the top ten advertisers rely heavily upon television (except for cigarette companies, which cannot advertise on television). As a group, these advertisers spent over $1.2 billion on television advertising. Smaller companies spend less on television, but it is the largest firms that represent the bulk of advertising expenditures. Thus, advertising expenditures are highly concentrated in a relatively small number of firms and those firms concentrate on television. The high cost of national television advertising, up to $150,000 for 30 seconds, indicates why television advertising looms so large in the overall expenditure picture [4, p. 74].

Television (particularly national television) is geared to a mass audience; thus, it is less likely that specialized information can be provided. The very nature of television also encourages less informative advertising. Because of its versatility, television can represent a variety of aspects of a product, and there is a natural temptation to use picture and sound to create a mood or an image rather than providing information. In short, television gives the advertiser a means to do a variety of things that don't provide much information.

Radio advertisements present a slightly different situation. These differences follow from the differences in the media, which in turn affect the pattern of radio broadcasting and advertising. This is reflected in the degree to which radio has become specialized; some
Table 6.2  Distribution of Advertising Expenditures by Medium: Top 10 National Advertisers: 1976

<table>
<thead>
<tr>
<th>Ad Rank</th>
<th>Company</th>
<th>Total Expenditures (in millions)</th>
<th>Newspaper</th>
<th>Genl. Mags.</th>
<th>Farm Pub.</th>
<th>% of Total Dollars</th>
<th>Network TV</th>
<th>Spot TV</th>
<th>Spot Radio</th>
<th>Network Radio</th>
<th>Outdoor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Procter &amp; Gamble Co.</td>
<td>362,345.5</td>
<td>1.8</td>
<td>4.5</td>
<td>—</td>
<td>40.2</td>
<td>53.4</td>
<td>0.1</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>2.</td>
<td>General Foods Corp.</td>
<td>225,150.0</td>
<td>3.8</td>
<td>0.1</td>
<td>—</td>
<td>29.5</td>
<td>57.3</td>
<td>0.4</td>
<td>0.1</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>3.</td>
<td>General Motors Corp.</td>
<td>203,784.3</td>
<td>10.1</td>
<td>18.2</td>
<td>0.9</td>
<td>13.3</td>
<td>35.3</td>
<td>10.0</td>
<td>0.8</td>
<td>2.4</td>
<td>—</td>
</tr>
<tr>
<td>4.</td>
<td>Bristol-Myers Co.</td>
<td>152,032.7</td>
<td>0.9</td>
<td>10.0</td>
<td>—</td>
<td>11.6</td>
<td>67.3</td>
<td>3.3</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>5.</td>
<td>American Home Products</td>
<td>145,100.3</td>
<td>1.5</td>
<td>4.4</td>
<td>0.3</td>
<td>23.1</td>
<td>87.1</td>
<td>2.5</td>
<td>1.0</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>6.</td>
<td>R. J. Reynolds Industries</td>
<td>138,012.0</td>
<td>40.1</td>
<td>30.2</td>
<td>—</td>
<td>4.9</td>
<td>4.2</td>
<td>—</td>
<td>20.8</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>7.</td>
<td>Philip Morris Inc.</td>
<td>134,378.5</td>
<td>33.2</td>
<td>26.9</td>
<td>—</td>
<td>4.7</td>
<td>18.2</td>
<td>1.3</td>
<td>—</td>
<td>13.0</td>
<td>—</td>
</tr>
<tr>
<td>8.</td>
<td>Ford Motor Co.</td>
<td>131,919.7</td>
<td>11.3</td>
<td>10.1</td>
<td>1.7</td>
<td>21.4</td>
<td>37.9</td>
<td>0.5</td>
<td>1.6</td>
<td>1.5</td>
<td>—</td>
</tr>
<tr>
<td>9.</td>
<td>General Mills Inc.</td>
<td>117,034.0</td>
<td>3.3</td>
<td>9.3</td>
<td>—</td>
<td>33.9</td>
<td>40.5</td>
<td>4.0</td>
<td>0.1</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>10.</td>
<td>Unilever</td>
<td>105,560.2</td>
<td>2.7</td>
<td>4.5</td>
<td>—</td>
<td>35.2</td>
<td>57.1</td>
<td>0.5</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

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* Includes only major media categories for national advertising.
stations broadcast only music—rock, country and western, or classical—while others specialize in news. In metropolitan centers, there are stations that serve particular ethnic groups, while in rural areas, there are farm-oriented stations. Some churches have their own stations, and so do some colleges and universities. With this diversity, it is difficult to generalize about radio advertising. Yet the nature of the medium itself forces certain constraints on radio advertising that limit all stations, regardless of orientation.

It is harder to talk about something than to show a picture of it. If advertisers are going to talk about the product anyway, there is a chance that they will say something informative (although it is possible to talk without saying anything substantive). Most companies have a multimedia advertising package, so that their radio ads complement their television efforts; some companies even run the sound tracks from their television ads.

The printed page is the oldest form of modern communication. It was through the printed media that advertising got its start and took on its present form. Many newspapers and magazines lost advertising revenues to such an extent that some well-known ones have ceased publication. At the same time, others are prospering because they fill a special need of advertisers. There are implications in this situation that directly affect the information that the ads pass along to the consumers.

Newspapers contain a type of advertising that is purely informative—classified ads. These serve the consumer directly by locating items and in effect creating a market. These ads perform the classic function of bringing buyer and seller together. If you were interested in buying a used lawnmower, you might reasonably assume that someone in the area had one for sale; your problem would be finding that someone. It would be very difficult without classified advertising. In its early form, most advertising was of the classified type. Other examples survive, such as the announcements on bulletin boards in neighborhood supermarkets. For the most part, however, advertising has gone beyond these elementary functions and now concerns itself with persuasion and advocacy.

For day-to-day operations in the marketplace, newspapers remain one of the consumer's greatest assets. This is hardly surprising, because newspapers are an important means of local advertising. They afford local advertisers the chance to let consumers know what they have, what specials they are offering, and other information concerning hours and location. In terms of price information, newspaper advertising is probably more useful to consumers than any other type.

Magazine advertising includes a wide variety of approaches. Where color is involved, there is a tendency toward showy, but not neces-
Advertising and Information Content

In the past, advertising was generally informative, but like radio and newspapers, magazines have become more specialized, a trend that has hurt mass-circulation magazines. This is significant for consumers, because the general circulation publications contain more general, less informative ads. The specialty magazines, on the other hand, are aimed at a particular audience. It can be assumed that persons reading one of these publications have an interest in the particular topic and perhaps some information about it. During the late 1970s, however, the rising costs of television advertising have renewed advertisers' interest in magazines. At this time, it is impossible to tell how this trend will develop, but to date it has meant more magazine advertising, with the largest increases going to more general, less informative national ads.

A Standard of Judgment

To this point I have discussed advertisements in rather general terms as being more or less informative. Such judgments obviously require some kind of standard or measure of information content. Various standards have been suggested, but the most common is the content analysis approach used by the Federal Trade Commission (FTC). The FTC is the agency within the federal government that is charged with monitoring advertising; its efforts are gaining more attention, and from time to time you will see that the agency has charged that a certain ad is misleading and must be removed. Such judgments are based on standards that the FTC has developed to classify advertisements into three categories: informative, ads that provide significant information; puffing, ads that ballyhoo the product without really saying anything about it; and misleading, ads that either directly or implicitly misrepresent the product.* These are not necessarily mutually exclusive categories, but they do provide a structure for analyzing information content [13 and 15].

According to the FTC, informative ads provide information on price or relative price, functions of the product, construction specifications, and performance standards. I recall an ad for a chain saw that meets these criteria almost to the letter. The ad shows the saw in use, gives the price ("under $100"), details its features (metal body, self-oiling chain, automatic-recoil start, and so on), and tells something about what the saw will do ("cuts up to 20 inches in diameter"). If you were in the market for a chain saw, that ad would be helpful: it tells you enough about the saw for you to evaluate it.

Puffing ads, on the other hand, do not provide the consumer with

* The FTC uses deceptive instead of misleading.
that type of service. They substitute superlatives, endorsements by leading personalities, or claims of uniqueness for hard facts on price and performance. They are fluff (rhymes with puff) and while they may be entertaining, they are not very informative. Soft-drink commercials, which show happy, beautiful people downing gallons of a particular brand, fit into the puffing category. Magazine ads for liquor, which typically feature a close-up of the bottle, are another example. Puffing ads do not mislead, but they do not inform either; as their middle position suggests, they represent a sort of neutral territory.

That may be damning with faint praise, but it is more than can be said for misleading advertisements. Such ads feature unsupported—and often unsupported—claims and rigged or irrelevant tests, and they portray the product in unnatural situations. These are typical traits of misleading advertisements, but since the range of possibilities is so broad, it is difficult to limit them. Ads may be misleading without resorting to outright lies, though that it not unknown: An advertisement is misleading if it portrays the product as something it is not. There are many examples of misleading advertisements in the history of television, including plastic placed over floors to show a "true wax shine" and shots apparently taken through an automobile window to demonstrate that the glass is distortion-free, when in fact the window had been wound down.

The FTC guidelines sound straightforward enough, but you should appreciate that there are a variety of problems involved in their implementation. First of all, the advertisement may not fit neatly into a single category. An ad may contain features of two or more types. Reliability also deserves mention: One can read, or view, between the lines of advertisements, but it is necessary ultimately either to accept or to reject what the advertisement says. An ad may appear to be quite informative, providing details about the product and demonstrating its effectiveness through different tests. Appear is the key word, for it is not always possible to trust what is being said. The track record of advertisers hardly inspires confidence.

Even with standards and a set of criteria for making evaluations, there is bound to be an element of personal judgment in their application. If the price of a product is $99.95, is it misleading to advertise it as "under $100"? Is it misleading to advertise soft drinks with those happy people and their beautiful smiles without mentioning that the drink promotes tooth decay? Most people would probably feel that to call these examples misleading would represent an overly strict application of the standards, but others might not agree.

* As a check, students are urged to repeat the evaluations reported in the following sections. See suggested projects.
Given that judgments are involved, no absolute standard can be imposed. The real question is whether the FTC's system of content analysis is a workable approach. To test that question, the FTC guidelines were applied to a sample of actual national television advertisements. The results are enlightening in terms of both the approach and the advertisements.

Information in National Television Advertising

For several reasons, television is the logical place to apply the FTC guidelines. As noted above, television accounts for the greatest portion of advertising expenditures, so it is necessary to look to television to see where advertisers spend their money. National ads were selected not only because of their predominant position in advertising budgets (see Table 6.2), but also because they have a greater impact and are not subject to variation from one area to another. Finally, we should note that television advertising is important because the medium is such an integral part of the American lifestyle. Television affects the way we perceive the world and absorb its images. Thus, television not only reflects modern life, it is part of that life.

The results reported here are based on a sample of 321 thirty-second ads videotaped from the three national commercial networks during February 1977. In implementing the FTC guidelines, two intermediate categories were introduced: informative puffing and puffing misleading. This provides a place for ads that are largely puffing but do give some information, or ads that puff away to the point of becoming misleading. The sample was drawn from four designated time segments: weekday afternoon, prime time, news programming, and sports advertising.* Thus it is possible to compare information content for different time segments.

Two raters were trained in the use of the FTC guidelines and each rated the ads independently. The two agreed on their ratings for 84 percent of the ads, and in only 3 percent of the cases did their ratings disagree by more than one category. This suggests that despite variations among individuals, the FTC scale can be applied in a uniform fashion.

The results of the survey are summarized in Table 6.3. A glance at the "total" column shows that half of the ads fell into the puffing category. Puffery, then, is the norm for national television advertising.

* Time segments were defined as follows (all times EST): weekday afternoon, 1-3 p.m.; prime time, 8-11 p.m.; sports programming, weekend afternoons; news, weeknight network evening news programming. Note that no children's programming was included in the survey.
Advertising and Information

ing, which means no substantive information is provided. About 10 percent of the ads were judged to be informative. That is not very impressive when you consider that the sample is drawn from about 20 hours of viewing time. So, if you watched 20 hours of television, you would have 17 minutes 30 seconds of informative national ads.

It might be heartening to note that there were so few ads judged to be actually misleading. It is possible, however, to argue that there should not be any misleading ads. When the misleading and puffing-misleading categories are pooled, nearly 10 percent of the sample contained ads with some misleading elements. The puffing-misleading ads generally earned that designation by exaggeration, gross overstatement, or implications that misrepresented the product. These may be only venial sins, but they still have a negative impact on the viewer consumer.

An interesting pattern emerges when we look at information content by time segment. No striking differences are apparent. Puffing ads predominate in all time segments, although afternoon programming features slightly more puffery and slightly less information than other segments. The most significant feature of the time-segment breakdown is the concentration of misleading ads during the afternoon. Afternoon programming features game shows and soap operas that are commonly oriented toward women; the significance of that relationship will be discussed in the following section. The overall conclusion from the time-segment breakdown is that, in terms of the information content the ads provide, it doesn't matter a great deal when you watch television.

By way of summary, we must say that national television adver-

<table>
<thead>
<tr>
<th>Time Segment</th>
<th>Daytime</th>
<th>Afternoon</th>
<th>Prime</th>
<th>Sports</th>
<th>News</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misleading</td>
<td>7</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Puffing-Misleading</td>
<td>9</td>
<td>7</td>
<td>3</td>
<td>2</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>Puffing</td>
<td>68</td>
<td>30</td>
<td>33</td>
<td>30</td>
<td>161</td>
<td></td>
</tr>
<tr>
<td>Informative Puffing</td>
<td>33</td>
<td>15</td>
<td>30</td>
<td>18</td>
<td>96</td>
<td></td>
</tr>
<tr>
<td>Informative</td>
<td>12</td>
<td>11</td>
<td>8</td>
<td>4</td>
<td>35</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>129</td>
<td>63</td>
<td>74</td>
<td>65</td>
<td>321</td>
<td></td>
</tr>
</tbody>
</table>

Source: "The Relationships Among Information Characteristics and Sex-Role Portrayal in Network Television Advertisements."[24]
Advertising provides very little information; it is difficult to reach any other conclusion. There are some bright spots—nearly 40 percent of the ads contained some information. Some information, however, isn't a very good showing when you consider the amount of money spent on television advertising and the degree to which it saturates the country. Had local ads been included, the percentage of informative ads would probably have been higher; local ads can provide specific price and product information more easily. However, a higher percentage of informative ads would not mean that the percentage of advertising expenditures going to information would be correspondingly higher. A local tire company may advertise a sale and provide the consumer with a great deal of useful information (price, size, and so on). However, that ad will cost only a tiny fraction of the price paid for prime national advertisements. From the consumer's point of view, the local ad is probably a better "buy," but that also means that the bulk of advertising expenditures are going to less informative national ads.

The Problem of Experience Goods

Thus far we have discussed ads in terms of their information content, without reference to the products being advertised. If, however, we are to address the problem of improving information content, we must now broaden our investigation to include consideration of the products in the ads. The basis for that need goes back to our discussion of search and experience products in the last chapter. Search products, you will remember, are those goods that the consumer can evaluate prior to purchase (the horsepower of an engine or the color of a suit); by contrast, information on experience goods can only be obtained by actually using the product (the taste of a cup of coffee or the effectiveness of a deodorant) [20, p. 315].

You should recognize that experience products are heavily advertised, particularly on television. Foods, toiletries, soft drinks and beer, patent medicines, and many other personal consumption items fall into the experience category. Furthermore, other products, such as automobiles, combine search qualities with significant numbers of experience qualities. In the sample discussed in the previous section, 223, or nearly 70 percent, of the 321 ads surveyed were judged to be for experience goods [24].

By now you should see the problem. If the only way a consumer can obtain information about a product is to use it, how can any real

* The third category discussed in the previous chapter was credence goods. These products and services are not heavily advertised at this time. Some products, such as patent medicines, may have credence qualities, but these can be analyzed in experience terms.
information about the product be provided in an ad? No ad can tell you how a soft drink will taste, how a hair spray will work, or how you will feel in a particular article of clothing, and yet hundreds of products in these categories are advertised regularly. Since it is the experience that counts, the advertiser must try to convey a feeling for the product through the ad; the experience may be second hand, but if you see all those happy people drinking cola, you might remember the brand name and try the product yourself.

The result, of course, is puffery, which helps explain why that category dominates advertising. The advertiser has little choice but to puff, because there is little that can be said about the product.* Nelson, who developed the distinction between search and experience goods, was the first to make this point [19]. His hypotheses were supported by the sample of television ads discussed earlier: the search goods in the sample showed a significantly higher level of information content than did experience goods [24]. Other researchers have found similar results [23].

In some cases, advertisers choose to use puffery when they don’t have to. Advertisements for automobiles, for example, can give precise information on price, engine specifications, and construction. Often, however, that opportunity is neglected in favor of showing the car in luxurious settings, where the emphasis is on mood and style and superlatives replace substance (“the most glamorous Buasmobile ever”).

Even though some discretion is involved, it remains true that many ads simply cannot be made more informative. It follows that it would be impossible to dictate that advertisements must provide information without forcing significant changes in current advertising patterns. Puffery may be toned down, but it cannot be eliminated because of the very nature of the products being advertised. This presents a serious obstacle to any program designed to improve the overall level of information content in advertising.

An Alternative Approach

The difficulty with experience goods is not the only problem with the content analysis approach of the FTC guidelines. A potentially more serious concern is stated in the question: At what point does a statement become misleading or deceptive? Suppose, for example, that a gasoline ad claims to “Put a tiger in your tank!” That statement is...

* Price is always a search quality, but these products tend to be relatively inexpensive and price differentials may not weigh heavily in the consumer’s decision.
false, and yet hardly anyone would consider the ad misleading. The reason is that everyone knows the statement is false and was not meant to be taken literally.

That is clear enough in the case of the tiger, but what about other ads in which phrases like “lowest price ever,” “best buy yet,” or “runs forever” are thrown around? At what point can the consumer reasonably be expected to differentiate between intended puffery and intended fact? The Federal Trade Commission’s answer to the problem is the average man concept.* An ad is not considered deceptive if the average man can be expected to recognize the intent of the message [1, p. 571].

Given the manner in which the term average is abused, that approach doesn’t really solve the problem. Are we speaking of the average man in terms of intelligence, education, or experience in the marketplace? If we’re talking about the average man on an average day, we must remember that the average man makes mistakes and take that into account. Not surprisingly, there have been a large number of court cases on this point.

The concept makes sense only when some kind of rule of reason is applied and the whole question is viewed in a behavioral context. The question revolves around what individuals are going to believe and how those beliefs affect behavior. Thus, in order to make the content analysis approach work, human behavior has to be taken into account. This fact has prompted some experts in the area to suggest an alternative approach to the deception problem. An ad should be considered deceptive, they argue, only if it affects the consumer’s beliefs and she or he then acts on those beliefs in a harmful way [17].

Briefly put, there would be no deception if no one is deceived. An act might misrepresent a product and thus be termed misleading under the FTC’s system, but if no one believes the ad, then there would be no real deception. This behavioral definition of deception focuses on the impact of the ad on the consumer’s behavior. In order to be put into effect, the behavioral approach would require extensive screening of ads before groups of consumers representing a cross section of the population. The technical aspects of that process would be complex and would quite probably generate disputes.

The behavioral approach doesn’t really address the question of improving the overall level of information in ads and is therefore of limited value in that regard. However, it is valuable as a reminder that the ultimate significance of an advertisement lies in its impact on the individual. It is the interpretation of the ad that finally matters.

* Presumably, the average man could be a woman.
which means some attention should be given to the manner in which individuals treat information from advertising.

There is some evidence to show that most consumers approach advertising with a critical eye. Most people assume that advertisers exaggerate; therefore, individuals tend to discount much of what they hear or see in ads. Under such circumstances, it is difficult to deceive a person: the individual’s reluctance to accept advertising claims at face value turns out to be the first line of defense against deception. Given that situation, there is a possible danger in efforts to promote truth in advertising. If individuals come to believe that ads must be truthful, they will be more vulnerable to deception. Unless the law is perfectly enforced, advertisers would have more incentive to try and mislead consumers because there would be a greater chance that their efforts would pay off [19]. Things would not have to turn out that way, but they could; the possibility emphasizes the need to take consumer behavior into account when considering advertising. Unless the situation is analyzed fully, well-intentioned efforts could end up having harmful effects.

Current Trends and Developments

Combating Negative Information

The preceding sections dealt with information and deception in advertising in general terms. Before we proceed with the question of the information potential of advertising, we should look at some specific cases and see how these issues are actually working themselves out in the marketplace and the courts. To a considerable extent, that story centers around the Federal Trade Commission. The responsibility for monitoring advertising has been part of the FTC charge since it was founded in 1914; however, it was not until 1938 that the commission was given specific authority to prosecute for misleading advertising when only the consumer interest was involved (see Chapter 8). It would be wrong, however, to assume that the FTC has acted alone. The following examples show that private consumer groups have been active, and, in some cases, have been responsible for forcing the Federal Trade Commission to act.

One example that shows the impact of private initiative is the...
Current Trends and Developments

advertising campaign run by the Shell Oil Company several years ago. You may recall the ads that billed Shell's Platformate as an additive that added significantly to mileage. It showed car after car crashing through a paper barrier, having gone farther than cars using gasoline without Platformate. Unfortunately, the campaign was as flimsy as the paper barrier. True, the cars using gasoline with Platformate did go farther, but as Consumer Bulletin was the first to point out, Platformate (or something like it) is found in nearly all gasoline meant for use in automobiles [21]. You could not buy the kind of gasoline Shell was using in the test. Any gasoline purchased from any pump would have Platformate in it and would go as far as Shell's.

Shell maintained that since the ad merely said that cars go farther on Platformate, there was no deception involved. No one bought that argument, however. Advertising Age, the trade journal for advertisers, sounded an "Amen" to a letter written by an agency executive that said: "This is the kind of deception that gives all of advertising a black eye and makes the task of the honest practitioner of the craft just that much harder. It's also great fuel for those who promulgate government control of advertising..." [3].

Pain relievers represent another area of apparent deception and certain confusion. Aspirin is the main ingredient in such products, and aspirin, it turns out, is aspirin. A 1962 study published in the Journal of the American Medical Association indicated that statistically there is no difference in the performance of the five leading brands of pain relievers [12]. That was over fifteen years ago, yet producers still turn out advertisements that claim that their brand is superior, supporting their arguments with supposed scientific tests. Students who are familiar with statistical testing techniques know that such claims must be taken with a grain of salt (or perhaps aspirin). There is no evidence that if they were repeated on a larger population the results would be the same.

Nevertheless, the claims continued unabated until finally, in 1973, the FTC entered the case. The FTC filed suit against the major pharmaceutical companies, maintaining they must either provide acceptable scientific evidence to support the claims made for their pain relievers or take the ads off the air. Five years of litigation have not resolved the case and there appears to be no prospect of an impending settlement.

If the Geritol case is any precedent, the question of pain relievers could be in the courts for years to come. Geritol claimed to "strengthen iron-poor, tired blood" or "iron deficiency anemia." No one was quite sure what tired blood was, but experts agreed that iron deficiency anemia is rare in the United States and, in any event, is not
Advertising and Information

usually associated with a lack of iron in the diet [9]. The FTC brought suit, but the case was in the courts for over a decade before the questionable ads were removed.

Protracted litigation is also underway in the Listerine case. For most of this century, Listerine has been advertised as an effective agent against colds. In fact, it is simply a mouthwash, and as Listerine ads now state, it does nothing to kill germs or fight colds. Even so, it took a series of court battles before the claim was removed from Listerine's advertising, and, even now, the notion that the product is something more than a mouthwash may linger on [5]. Because of that possibility, the FTC asked Listerine to do more than simply remove the ads; the company was asked to pay for corrective advertisements. Corrective ads, as the name implies, are meant to correct previous misinformation provided to consumers, and are also involved in the Geritol and pain reliever cases (in the latter, the FTC is asking that 25 percent of the companies' future advertising expenditures go to corrective ads).

The FTC had earlier required corrective advertising of a fruit juice company (for false nutritional claims about its drink) and of a diet bread (which claimed to have fewer calories, but in fact was only sliced thinner). In these cases, however, the corrective ads had limited impact because they were so mild. It wasn't really clear to consumers that the companies were admitting any wrongdoing. If corrective advertisements are to be effective in making up for deception, they must be clear and straightforward.

The problems with corrective advertisements are further illustrated in the STP case. As was true with Platformate, it was a consumer organization that originally raised questions about the product (an oil additive). In 1971, Consumer Reports indicated that STP was at best unnecessary, and at worst a possible danger to the car's engine [11, p. 422]. The issue was unresolved and STP continued to expand its operations; in so doing, it included performance claims in its advertising, claims that were supported by a series of tests conducted by independent laboratories.

Those tests, however, proved questionable and the FTC brought suit. The case was settled in early 1978 when STP agreed to pay a $700,000 fine and pay for a series of corrective advertisements. The ads were labeled "FTC Notice" and referred to "certain allegedly inaccurate past advertisements." Included in the ad was the statement "Agreement to this settlement does not constitute an admission by STP that the law has been violated" [26, p. 14]. Not only were the ads confusing and seemingly contradictory, but they were run mainly in business publications. The idea was to get the message across to other businesses that the FTC itself meant business; however, the
Current Trends and Developments

campaign did little to clear up misconceptions that individual consumers might have had about STP.

It is evident that the Federal Trade Commission has become more active in dealing with possible deception in advertising, but the impact of that activity is not yet clear. Advertisers have at least taken notice, but whether future ads will be any different is unknown. If enforcement is sustained, gradual change could take place. If, however, the FTC's activities are seen as isolated events, change seems unlikely.

Children's Advertising

The Federal Trade Commission's activities with respect to advertising have not been limited to the prosecution of individual cases. In an effort to deal with more general concerns, the commission has employed a broader approach in certain problem areas. Children's advertising offers a notable and well-publicized example. The implicit assumption in the average man concept is that individuals can make critical judgments about advertising content. In the case of children, that assumption may not be warranted, which marks children's advertising as a topic of special concern.

That concern, however, is a fairly recent development. A decade ago, no special attention was given to children's advertising. Then, in 1968, a group of Boston-area women formed Action for Children's Television (ACT) in an effort to improve the quality of children's programming; advertising was among their first concerns. ACT called for a ban on children's advertising, basing its request on four problem areas:

1. Developmental — young children have not yet developed the cognitive skills to evaluate material presented in advertisements. Thus, children are particularly vulnerable and impressionable [16].
2. Family life — pressure from children to buy advertised products could have a negative effect on the parent-child relationship.
3. Nutritional — concern was expressed with both the dubious nutritional information contained in ads and the poor nutritional content on many heavily advertised snacks and cereals.
4. Content — it was maintained that products (particularly toys) were oversold, leaving a misleading impression of the product's capabilities [18].

The FTC called hearings on these matters, but no further action was taken. However, pressure from ACT brought about a degree of self-regulation by the industry. The number of minutes of commer-
Advertising and Information

Officials per hour of children's programming was cut from 16 to 9½ and
performers on children's shows no longer were to promote products.
Also, a clear distinction had to be made between the programming
and advertising (usually by a fade out or graphic design) [18]. Pressure
from consumer groups also induced three vitamin manufacturers
to withdraw their advertisements from children's programming.

Through all of this, the FTC's position remained vague; the com-
mmission seemed to support the reform efforts, but resisted efforts to
force change on the industry [2]. The FTC's period of inactivity
stretched into 1977, but then increasing concern with nutrition
prompted staff investigations. As a result of the investigations, the
following proposals were approved by the commissioners in early
1978. The FTC proposes that:

1. All advertising aimed at children under six be banned.
2. The advertising of candy and highly sweetened cereals be
   banned from all children’s programming.
3. Companies that advertise lightly sweetened cereals be required
to spend an equal amount on purely informative nutritional
   advertising [7].

At this writing, hearings are being held on the FTC proposals. It
appears that at least some of the recommendations will be imple-
mented; it is also probable that court challenges await any action the
FTC takes. Recent court decisions extend First Amendment rights
(freedom of speech) to advertisers, and it appears that litigation will
be based on that argument. Whatever happens, the FTC's action
(after a decade of indifference) illustrates the power that public
opinion can have when it is organized and directed.

The controversy over children's advertising deserves a final com-
ment. The entire argument is built around the idea that advertising,
particularly on television, is more than just a way to sell products; it
affects the whole pattern of living. That point is particularly relevant
to children, but it can be applied more broadly. I've suggested
throughout this chapter that advertising is a part of what we com-
monly call lifestyle; any effort to discuss the issue in narrower terms
runs the risk of dangerous oversimplification.

Advertising by Professionals

While the FTC is attempting to limit advertising geared to children,
the commission is seeking to promote advertising by professionals—
medical doctors, lawyers, pharmacists, and so on. Few professionals
of this type have advertised in the past, in part because tradition held

273
that advertising was unprofessional and apart because professional associations banned advertising. The FTC began its efforts to promote advertising by professionals in 1975; a ruling by the Supreme Court in 1977 upheld the right of professionals to advertise and accelerated the rate of change [10, p. 70].

In the last chapter, I indicated that information about professional services falls into the credence category, goods or services that cannot be fully evaluated even after they are consumed [20, p. 315]. Professional competence, not advertising, seems to be the key issue. Furthermore, it would be difficult to advertise prices in many cases until diagnosis and treatment were complete. To confound the issue, it is impossible to repress the image of a doctor doing a television commercial in the manner of a used car dealer ("Special, Today Only . . .").

Surely such jokes have circulated around the FTC, but that is not what the commission had in mind. The ban on professional advertising, the commission maintained, denied information to consumers and thus represented a restraint of trade. The logic of the argument is based on the fact that although many professional services are complex and involved, others are routine. A will for a middle-income family, for example, is a rather straightforward document and is relatively inexpensive. However, if there is secrecy about prices, the client-consumer won't know if he or she is actually paying a reasonable price.

The same logic holds for the advertising of prescription drug prices. Once the drug has been prescribed by the doctor, the patient-consumer ought to know where it can be filled most economically [2, p. 1632]. Such drugs must meet federal standards, so there is little risk to the individual. Even in more complicated situations, comparative price information should be helpful. If you find out, for example, that your family doctor is the most expensive in town, it hardly seems unreasonable that he or she be able to justify the expense. The doctor might be worth the price, but if patient-consumers aren't aware of relative prices, they won't be able to inquire.

One of the problems with the pricing of professional services has to do with price discrimination, which means charging different individuals different prices for the same service. In the marketplace, most products are sold at a single price to all consumers, which means that those who would be willing to pay more for the product are getting a bargain; it is easy to see that if each individual is charged the maximum that he or she would be willing to pay, the seller would benefit.*

* Price discrimination is legal in such cases and may be justified on the grounds that the poor thus receive treatment more cheaply.
Because of the nature of their services, professionals are able to practice price discrimination, but disclosure of fees makes the practice more difficult. Advertising should reduce the range of prices for similar services. Some professionals may resist advertising for that reason.

It is difficult to provide an overall evaluation of the impact of advertising by professionals. Contrary to the expectations of those on both sides of the controversy, it is unlikely that advertising will bring about any great changes. For example, allowing doctors to advertise isn't the answer to rising medical costs. However, in a small way the consumer should benefit. The change isn't momentous, but it is reasonable, and, as in the examples mentioned above, it should help the consumer. There may also be a more subtle, long-range benefit to consumers: more candid information about professional services should promote a more objective approach to the subject, and that should serve the consumer's interest.

Problems and Possibilities

Catching Up to the Present

Our discussion of advertising and information has ranged over a variety of issues: it is hoped that as you covered the material, your thinking about advertising has changed somewhat. The various problems addressed above cannot be dealt with until consumers begin to perceive the possibilities that advertising affords. There are limitations, to be sure, but advertising still has a potential educational and informational value beyond the capabilities of most alternatives. It is nothing less than a resource, a badly abused and misused one, but a resource nevertheless.

Putting advertising in that context serves another purpose: It helps us break out of the mental rut we are in when it comes to thinking about the question. Advertising is such a part of our lives that it is difficult to think of it except as it currently exists. Our thinking about advertising is badly out of date. Even when advertising has the potential to reach into every American home instantly, we still think of it in terms of the medicine show or the weekly newspaper. During the last century, advertising was unregulated and often outrageous, but that hardly mattered. If the medicine show advertised a cure for fallen arches, heart attacks, and sore backs, it did so to a small group that could evaluate the product and the advertising. Even if someone was suckered into buying the product, the amounts involved were probably small.
Problems and Possibilities

Technological change, however, has altered the situation radically. Faster presses, the introduction of color, and widespread distribution improved the traditional media. Radio and television have spread the reach and potential effectiveness of advertising still further. Frederick Lewis Allen chronicled these changes during the 1920s. The ads of fifty years ago make today's look like the picture of responsibility. For example, Allen tells of the unhappy people who had

...succumbed to pyorrhea, each of them with a mercifully concealing his unhappy mouth.... The woman undoubtedly do something about B.O. if people only said to her what they really thought.... These men and women of the advertising pages, suffering or triumphant, became part of the folklore of the day. [8. p. 73, emphasis added]

Those people, or their grandchildren, have become part of American culture and they are treated with a degree of nonchalance that masks their real importance. Consumers continue to treat advertising lightly even though increasing complexities in the market and technological change have reduced consumers' abilities to counter the forces of advertising. You should recognize this argument as an aspect of the more general consumer problem—the consumer's inability to work in a changed environment. Consumers do not seem to have caught on to the fact that the environment has changed, which has permitted the freewheeling and largely unchallenged development of the advertising establishment. The implications of advertising for consumers and its potential usefulness have not really been grasped.

Notice that I have come out in favor of advertising, not against it. My criticism has to do with certain aspects of the way products are advertised, not with advertising itself. Unfortunately, even the mildest criticism of advertising tends to polarize opinions. Some groups seem to feel that there is something sacred about the current content and structure of advertising; they equate the status quo with what they call "our free enterprise system." Whatever that is, it is not a very good description of advertising and the American economy in the 1970s. Advertising expenditures are highly concentrated among a small number of firms. This concentrates a tremendous amount of power in a few hands. It can be argued that, rather than support free enterprise, massive advertising expenditures actually promote monopoly elements by giving an extra advantage to certain firms. Advertising becomes a way of maintaining control of a market and suppressing competition. Thus, a doctrinaire approach only masks the real issues and confuses the question.
Advertising and Information

Some New Directions

Any change in advertising must begin by educating the public to what advertising could be. The success of Action for Children's Television shows that if it is properly organized and directed, public pressure can bring about changes in advertising. Most changes thus far have emphasized limitations, but change can also be cast in positive terms, with the emphasis on realizing advertising's informational and educational potential.

However, it should be clear that it isn't enough to simply say to advertisers: "Thou shalt be informative." As noted, some ads (for experience goods) cannot be really informative. We can reasonably assume that most consumers recognize this fact; the emphasis in such cases should then be placed on preventing distortions and deception. In areas where more informative ads are possible, however, higher levels of information content should be encouraged (and in some cases required).

We can assume that businesses act in their own self-interest, which means that more informative ads will be forthcoming when such ads are in the company's self-interest. That will only happen when consumers begin to demand more information. This is a realistic possibility if consumers are aware that information is available; public service broadcasting might encourage this trend by stressing the kinds of information consumers can expect.

A significant problem with this proposal is validating the information provided in advertisements. Here is where a national information policy comes into the picture. Information provided through advertising would be an integral part of that overall policy. The Environmental Protection Agency has been criticized for its mileage ratings, but at least they have put an end to the gross exaggerations that formerly characterized mileage claims.

EPA ratings must be included in automobile ads, but other public information could be used voluntarily. If tests showed that the Clomp-Clomp lawnmower was the safest, most economical, and most dependable mower on the market, then Clomp-Clomp should be able to use those findings in their ads. The public would know that the company was not just making wild claims, since the information would have been validated. Thus, advertisements would be a way of getting quality information to the public.

Where does that leave companies whose products do not measure up well in such tests? They would not be forced to say that in their ads, but they would not be able to make any claims of performance of quality either. That would provide a powerful incentive to improve their product. Better information flow would therefore bring
pressure on producers to offer quality products, which is precisely the way markets are supposed to work. Now producers can hide behind the consumer's lack of information and pass off inferior products.

I have treated advertising at great length simply because it has the potential to provide high-quality, low-cost information to all segments of the population. Information needs to be interpreted very broadly in this context. That is, it includes not only information about products per se but also about types of products and services. In short, advertising could perform a genuinely educational function. Insurance advertisements, for example, could include detailed information about types of insurance, strengths of each type, and the best insurance package under different circumstances. Similarly, advertisements for banks or other financial institutions could include sound financial advice. By the ingenuity of advertisers, this information could be put across in an easily understandable fashion. It is difficult to think of a more effective way to get information to a broad cross section of the public. As people were continually exposed to this sort of advertising, they would gradually develop a more sophisticated understanding of these complex issues. Citizens might decide that some percentage of total advertising time should be given over to such educational efforts. In this case, I am not talking about advertising a product, but rather providing information on a class of products or services. Because ads of this type would be different from product advertising, public trust should be greater.

A program of this sort is based on the idea that advertisers have a responsibility to provide information to consumers. If that information is not contained in ads for particular products, it would be presented in the more general, educational ads. Some people may feel that advertisers should not be forced to assume a social responsibility, but the proposal only assumes that those who benefit from a system should in turn work toward improving it. Companies have a right to advertise; they also have a responsibility to the public. This is not a very radical idea.

If you think the changes suggested here sound like pipe dreams, remember that changes have already taken place in advertising. It

* Advertisers could be required to set aside a percentage of their total advertising budgets to fund such efforts. These costs would be passed along to the consumer, but considering the potential value of such a program, the expense should be well worth it in terms of individual consumer's savings.

† Some hint of this idea is contained in the FTC proposals for children's advertising. Companies that advertise certain types of cereals would be required to pay for ads about nutrition. By extending the idea, advertisers of medicines could fund ads on health, and so on.
Advertising and Information

was not too long ago that cigarette advertisements, now banned from television, were making health claims about their products. Similarly, the very idea of corrective advertising would have seemed radical a few years ago. Thus, it is not unrealistic to suppose that advertising over time can be made to convey information. The changes will not take place overnight and the program will not come in a single package. Progress generally comes in small steps. In this case, the ultimate goal makes the journey worthwhile.
The Federal Trade Commission (FTC) has been for many years the principal Federal agency concerned with the regulation of national advertising. At its inception and during its early years, however, this role was negligible. This is so because the Commission's enabling legislation, the Federal Trade Commission Act, was passed by the Congress at the request of President Woodrow Wilson after a long political fight arising out of what was then called the "trust problem." President Wilson envisaged an agency of experts to protect businessmen from unfair acts by competitors. Consumer protection, including protection from unfair and deceptive advertising, was not one of the agency's initial concerns or responsibilities. In the original 1914 Act there was no specific reference to advertising or consumer protection.

It has been through a slow, evolutionary process that the Commission has assumed its present day importance in the field of advertising regulation. This report examines the Federal Trade Commission's activities in this area over the last 65 years, placing special emphasis on new developments during the last decade.

Part I offers an historical perspective on the growth of the advertising industry since the turn of the century. Part II provides a brief discussion of the legislative framework within which the FTC operates. Despite the increase in vigor of the Commission's regulation of advertising that began just about a decade ago, its legal authority that governs this field has changed relatively little over the years.
The few changes which have taken place have evolved mainly from changes in approaches to enforcement and reinterpretations of existing legal authority. Part III presents a summary of the traditional approaches that the Commission has employed in carrying out its mandate to protect consumers and competitors from false, misleading, deceptive, and unfair advertising. Part IV reviews new developments in advertising regulation during the last decade.

**HISTORICAL PERSPECTIVE**

Modern advertising is a key element of marketing for business enterprise. It has flourished chiefly in countries and in periods in which private industrial capitalism has been able to achieve rapid and sustained economic growth, support a considerable degree of leisure activity, and provide a high level of consumption for the bulk of the population. Advertising in some form has operated in societies whose markets have been state-controlled, and to a small degree it even thrived in pre-industrial America and in 18th-century England. In neither form, however, did it resemble the type of advertising which has developed during recent decades in the English-speaking nations, and particularly in the United States.

**19th Century Development**

The unique importance and complexity of the advertising industry in America is clearly the result of a number of factors which, though individually restrictive to this country, have been combined perhaps more...
I favorably in this country than anywhere else. The industrialization which accompanied and followed the Civil War opened the way for manufacturers to seek ever larger markets within which their expanding production could be accommodated.

It was also during this period that many food processing and consumer-goods manufacturing firms began to advertise their brand names, to package goods under their labels, and generally to induce consumers to look for their products on store shelves. Previously, most consumer goods sold in retail shops were "generic" goods (not differentiated according to manufacturer—often not even identified as to the source). Many products were sold from barrels or jars, with no effort to inform the consumer as to the manufacturer’s name.

The last third of the 19th Century was also marked by a continuation and broadening of the transportation revolution, which had already brought to the American economy improved wagon highways, steam navigation on inland waterways, oceans, canals, and the steam railroad. Indeed, as has been said, the late nineteenth century belonged peculiarly to the railroad. The construction of railroads absorbed an enormous portion of American resources and energies. The new railroads, in turn, were of critical importance in stimulating economic expansion. They were the commercial lifelines of an industrializing society.

Simultaneously, mass media expanded on a scale made possible by the cheapness of newsprint, new techniques in periodical publishing, an increasingly mobile population, and the generally powerful political influence of publishers who were able to obtain legislation favorable to the wide circulation of periodicals at low costs to themselves.

As a consequence of these and other developments, estimated expenditures on advertising—mainly in newspapers and magazines, but also on billboards and barns alongside roads, and in streetcar and railroad stations—rose from only about $5 million in 1865, to $200 million in 1900 and to almost $800 million by the end of the century.

By the time the Federal Trade Commission was established in 1914, what has been called the "golden age of advertising" was in full swing. The advertising agency N. J. Ayer & Son, which was founded in 1869, had already obtained the first $1,000,000 account and launched the first national campaign—for Uneeda biscuit—using newspapers, magazines and outdoor advertising. Automobile advertising was already big business. By 1914, the car makers were spending more than $4,000,000 a year to advertise. The country was already very much advertising conscious.

The Atlantic Monthly and the Yale Review ran articles on the subject of advertising, declaring it to be the most conspicuous feature of American
Concern was expressed about its effect on the morals, tastes and health of the nation.

Indeed, during the period between 1900 and World War I, concern about advertising was very great. The muckrakers, as they came to be known, unleashed a furious attack on phony advertising, starting with patent medicines. Next came exposes of fraudulent financial advertising.

In 1909, Cyrus Curtis, the most successful magazine publisher in America, formulated the Curtis Advertising code, which set forth in specific terms the kind of advertising that would not be carried by Curtis publications. This covered mainly copy "knocking" competitors, medical copy claiming a cure, and advertisements for alcoholic beverages.

What has since become the Advertising Federation of America helped launch a campaign in 1911 for truthful and ethical advertising. The association drew up a code and adopted the slogan "Truth in Advertising." Subsequently, Printers' Ink, the industry's leading magazine, joined the campaign and published the Printers' Ink Statute, which was a model state law penalizing false and misleading advertising. Working together, the magazine and the federation lobbied the model statute through 37 state legislatures by the time the FTC Act was enacted.

The war Years

Following the first World War, during which time much advertising was devoted to the war effort, business enjoyed a marked expansion. A mass market for automobiles came into being, and advertising saw million-dollar budgets become fairly commonplace.\(^1\) With a major assist from the new medium of radio, total advertising expenditures increased from $2,282,000,000 in 1919 to $3,426,000,000 in 1929.\(^2\)

With the Depression, advertising volume slumped some 25%, falling back to about its 1915 level. During the 1930s there was a searching examination of the economic system that had allowed such a debacle as the Depression to happen. One of the frequent targets was advertising. Critics attacked not only its excesses and the products it promoted, but also the very concept of advertising. A parade of best-selling books "exposed" advertising as an unscrupulous exploiter of the consumer.

Some of the opposition to advertising was directed toward legislative initiatives. The proposed Tugwell bill, for example, called for compulsory grade labeling of canned goods, drugs, and cosmetics. A much-modified version of the bill was passed in 1938 as the Food, Drug, and Cosmetics Act. And, it was against this backdrop that the Wheeler-Lea Amendment of 1938 was passed which substantially broadened the power of the Federal Trade Commission to regulate advertising.

\(^1\) Advertising Age. Nov. 21, 1973, p. 6.

\(^2\) Advertising: It's Role in Modern Marketing. p. 34.
Advertising began to thrive again with the advent of World War II. Unlike World War I, there were few advertisers who abandoned or reduced their advertising efforts for the duration. Despite shortages and scarcity, advertisers deemed it prudent to keep their brand names prominently displayed even when their branded products could not be purchased. This approach paid off in an unprecedented demand for post-war products and services.

Modern Advertising

The period since the close of World War II has witnessed a number of developments that have been conducive to a dramatic growth in advertising expenditures. The extraordinarily strong and diversified growth of the post-war economy has been, of course, fundamental. This growth brought with it a rapid and sustained increase in discretionary income which paralleled and contributed to a shift toward product differentiation. For a major portion of the population, the post-war period meant a dramatic increase in consumer choice and a significant increase in the money available to spend on those choices.

Probably the most significant direct contributor to the growth of advertising expenditures in this period is television. Printers' Ink made the first computation of television advertising expenditures in 1949: $57 million. By 1977, the figure had risen to well over $7 billion.

The advertising industry today is large by any standards and continues to play an important role in the economy. Advertising expenditures totalled estimated $42.9 billion in 1978 or slightly more than 2% of Gross National Product. And, it is estimated that advertising expenditures will increase at an annual rate of 8% over the 1978-83 period, reaching $63 billion by 1983.1/

LEGISLATIVE FRAMEWORK

The Federal Trade Commission Act

The Federal Trade Commission Act, passed in 1914, provides the basic federal authority for controlling advertising abuse. Specifically, Section 5 of the Act gives the Commission its basic mandate by conferring jurisdiction over "unfair or deceptive acts or practices in commerce." The legislative history of the Act indicates that this was to be an expansive grant of authority:

The committee gave careful consideration to the question as to whether it would attempt to define the many and variable unfair practices which prevail in commerce and to forbid their continuance or whether it would, by a general declaration condemning unfair practices, leave it to the Commission to determine what practices were unfair. It concluded that the latter course would be better...2/

The first case to reach the courts from the new Commission involved the regulation of advertising. The Seventh Circuit upheld the power of the FTC to control deception in advertising, declaring that the Commission had authority to "stop all those trade practices that ... injure competition directly or through deception of purchasers." Thus, promotional advertising quickly became a target in regulation of business practices. In the 1922 case of FTC v. Winnetka Hosiery Co., the Supreme Court added its approval of such regulatory activity by holding that labeling goods containing less than ten percent wool as "woolen" was deceptive and injured commerce by diverting trade from truthful firms.

In three other early cases, however, the Court interpreted the Act so as to limit significantly FTC power over advertising. In 1920, a majority held in FTC v. Gratz that it was proper for the courts to review de novo Commission determinations that a given practice was an "unfair method of competition" in violation of section 5. The Court further held that the range of unfair practices within the Commission's jurisdiction was limited to those unfair practices regarded in 1914 as "opposed to good morals or "against public policy because of their dangerous tendency unduly to hinder competition or create monopoly."

1/ Sears Roebuck & Co. v. FTC, 258 F. 307, 311 (7th Cir. 1918).
2/ 258 U.S. 483.
This was in large part the consequence of the preoccupation of the framers of the Act with the Commission's role in supplementing antitrust enforcement. Thus, the Commission's intended role, if any, as an agency for protecting consumers against fraud (except in the unlikely circumstance in which fraud might facilitate monopoly) was left wholly undefined. In FTC v. Kleene,\textsuperscript{1} nine years later, the requirement was established that the harm to the public interest caused by an unfair practice must be "specific and substantial." The most serious obstacle to FTC policing advertising activity was presented by the Court's 1931 holding in FTC v. Rela Dem Co.\textsuperscript{2} that the Commission must find that competitors and not merely consumers were injured by the misrepresentation.

Later during the 1930s the Commission was accorded a more receptive treatment by the Court. Recognition of the value of flexibility in determining the bounds of legality under section 5 replaced the static conception of "unfair methods of competition" expressed in \textit{urate}. The FTC's potential ability to deal with novel deceptive practices was bolstered further by a narrowing of the scope of review,

\textsuperscript{1} Posner, Richard A. Regulation of Advertising by the FTC. Washington, American Enterprise Institute for Public Policy Research (1973) p. 11.

\textsuperscript{2} 280 U.S. 19 (1929).

\textsuperscript{3} 283 U.S. 644.

so that greater deference was given to the Commission's determinations of public interest.

The Wheeler-Lea Amendments

A number of these conflicts were resolved and the jurisdiction of the FTC was affirmed by the Wheeler-Lea amendments of 1938. The important Section 5 was rewritten to read: "(a)(1) Unfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce are hereby declared unlawful." The addition of the phrase "unfair or deceptive acts or practices" made it no longer necessary for the Commission to show that competition was injured. If there was injury to the public, the FTC was empowered to act.

2/ In 1975 "in or affecting commerce" was substituted for "in commerce". Public Law 93-637.
The legislative history of the amendment affords strong evidence that Congress believed that the new Section 5 prohibition of "unfair or deceptive acts or practices" (as well as special sections covering the advertisement of food, drugs, medical devices, and cosmetics), provided the Commission ample authority to regulate advertising.

The definition is broad enough to cover every form of advertising deception over which it would be humanly practicable to exercise government control. It covers every case of imposition on a purchaser for which there could be a practical remedy.1

Subsequent court decisions have confirmed the conclusion that the Wheeler-Lea Act firmly established the jurisdiction of the FTC over advertising.2

The Wheeler-Lea Act, however, did not provide the FTC with much greater scope than had been granted prior to 1938. Its contributions lie in the confirmation and clarification of the Commission’s authority over all types and degrees of deception and its improvement of procedures for enforcement.3 Previously, the FTC was required to go to the courts for enforcement of an order. If an order was violated, the Commission had to ask the Court of Appeals for an injunction directing the violators to

2/ See, e.g., Fresh Grown Preserve Corp. v. FTC, 125 F.2d 917 (2d Cir. 1942) (false-labeling and misbranding); Zenith Radio Corp. v. FTC, 143 F.2d 29 (7th Cir. 1944); Gulf Oil Corp. v. FTC, 150 F.2d 106 (5th Cir. 1945).
obey. In 1938, the Wheeler-Lea Act gave final effect to orders issued by
the Commission if such orders are not appealed by the respondents within
60 days. However, cease and desist orders are still reviewable by the
U.S. Court of Appeals and thereafter upon writ of certiorari to the U.S.
Supreme Court.

TRADITIONAL PRINCIPLES OF ADVERTISING REGULATION

Since the Federal Trade Commission's inception, national advertising
has been regulated to a large extent under section 5 of the FTC Act which,
as has been discussed, declares "deceptive" or "unfair" acts or practices
to be unlawful.

Deception in Advertising

The standard for "deception" has been the "ordinary" or "average"
person in the audience addressed by the advertisement, taking into account
that many who may be misled are unsophisticated and unwary. Aside from the
"ignorant, the unthinking, and the credulous," an advertisement may have
a greater or lesser capacity to deceive because of the special suscepti-

In measuring deception (it is only recently that the "unfairness" as-
pect of section 5 has been frequently viewed or asserted as an independent
standard against which claims might be measured), the traditional FTC

1/ Aronberg v. FTC, 132 F.2d 165, 167 (7th Cir. 1942).
practice has been to look at the total impression generated by the advertisement and to reject literal truth as a defense if that impression was false. It is this general principle that supports the rule that if an advertisement is capable of being interpreted in more than one way, and one of those interpretations is false and likely to mislead a substantial portion of the audience, the advertisement is unlawful under section 5.

If an advertisement is deemed to be misleading based upon the evidence, issues of materiality and causality relating to whether consumers were influenced in purchasing decisions by the false claim are largely avoided by the FTC rules that the Commission need show only capacity to deceive, rather than actual deception, and capacity to affect purchasing decisions rather than actual effect.

**Commission Decides What Is Deceptive**

The meaning of an advertisement is a matter entrusted to the discretion of the Federal Trade Commission. Because this seemingly simple fact is a principal reason in the FTC's managing to prevail in the appellate courts in the vast majority of its decisions that have been appealed, it warrants further examination.


2/ Charles of the Ritz Distrib. Co. v. FTC, 143 F.2d 676, 680 (2d Cir. 1944).

The most noted case in this regard is *Zenith Radio Corp. v. FTC*, where the Commission challenged two sets of claims in a series of advertisements for Zenith radios. First, Zenith asserted in an advertisement that "Europe is talking to you every night in English. . . . You can hear all the leaders. . . . all the daily news broadcasts." In truth, atmospheric conditions prevented satisfactory reception of foreign broadcast every day. It was the conclusion of the Commission that the effect of the claims was to lead people to believe that radio reception difficulties would be completely overcome, particularly because public knowledge of difficulties of radio reception was limited. The second series of claims designated the number of tubes in the radio (e.g. "Eleven-Tuber superheterodyne with Rotor wave magnet Aerial"). The Commission defined tubes as devices that perform, "the primary function of detecting, amplifying, or receiving radio signals." Several of the "tubes" Zenith relied on to arrive at a total number of eleven had to do with tubing or converting alternating current into direct current, and therefore did not qualify under the Commission's definition. The Commission held against Zenith after finding that a substantial portion of purchasers believed that a radio is better and more powerful if it has a large number of tubes.

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1/ *Zenith Radio Corp. v. FTC*, 143 F.2d 29 (7th Cir. 1944).
2/ 143 F.2d at 30.
3/ 143 F.2d at 31.
In affirming the Commission's decisions on both sets of advertising claims, the court of appeals concluded:

The Commission was not required to sample public opinion to determine what the petitioner was representing to the public. The Commission had a right to look at the advertisements in question, consider the relevant evidence in the record that would aid it in interpreting the advertisements, and then decide for itself whether the practices engaged in by the petitioner were unfair or deceptive as charged in the complaint (emphasis added). 1/  

Deceptive Comparative Price Advertising

One of the traditional enforcement approaches which best illustrates the shift or change in emphasis which began approximately ten years ago concerns the FTC's 1958 Guides Against Deceptive Pricing. 2/ During the 1960s as many as thirty percent of all cease-and-desist orders sought by the Commission related to deceptive (i.e., "fictitious") price claims, such as price claims that a product will be sold at "10% off list" or at an "all time low price." With the exception of instances where deceptive price claims have been a part of a broad pattern of fraudulent operations, enforcement of this provision during the last decade has been negligible.

Judging from deceptive pricing cases brought prior to 1969 in which the Commission wrote an opinion, the seller's representation was usually accurate—the sale price was lower than the former price; the compared price was the bona fide manufacturer's list price—and the Commission's

1/ Ibid.
complaint was that the seller did not have many sales at the former price, or that, due to widespread discount selling in the local area, the manufacturer's list price was not a common selling price there. Still, the problem with most fictitious price cases is the question of determining what possible consumer or competitive injury occurred. For the most part consumers realize that the price reductions are commonly motivated by the seller's inability to move the item at the former price and that many products are never sold at the manufacturer's list price. The Commission's policy to deemphasize enforcement against alleged deceptive (fictitious) pricing, thereby allowing some exaggeration and ambiguity in price claims, appears consistent with the principle of minimum enforcement where consumers, as opposed to competitors, are unlikely to be seriously injured and where rigid substantiation requirements might suppress a useful form of competition.

Phony Mock-Ups

A second area that received considerable Commission attention during the late 1950s and 1960s concerned the phony use of mock-ups in television advertising. These deceptions occur when the advertiser falsely


distorts qualities of its own or competitive products in order to create in the consumer's mind a perception of product qualities that the product does not possess.

The FTC's campaign against mock-ups culminated in the Supreme Court's decision in FTC v. Colgate-Palmolive Co. In that case, the advertiser sought to demonstrate that "Rapid-Shave" had super-moisturizing properties which permitted the shaving of sandpaper, and thus that it would be effective in shaving the toughest beards. Because sandpaper appears in television transmission as plain colored paper, the cream was applied instead to plexiglass covered with sand, which was then swept clean by a razor. The record showed that sandpaper could not be shaved unless it had been soaked for some eighty minutes, and therefore the demonstration was a clear deception without reference to the mock-up. The Supreme Court went on to find, however, that even if sandpaper could be shaved exactly as demonstrated in the commercial, it was a separate violation to use an undisclosed mock-up, since the advertiser was found to have represented to the public that it was presenting an actual demonstration of its product's qualities. The Court limited its holding so as not to extend to use of scenery as a backdrop, or actors playing roles in "slice of life" commercials, or even the use of mashed potatoes to simulate ice cream, where no product claim is made relating to the simulated demonstration.

As with the fictitious pricing cases, the major question that the Commission found itself asking about the mock-up cases is what is the extent of injuries that consumers suffer as a result of the deceptions. Judging from the fact that the FTC has not filed a single mock-up complaint in the last eight years, it would appear that the Commission determined that it can best allocate its resources in other areas, and it is probable that national advertisers have taken notice of the legal problems that can result from using these types of deceptive practices.

Violations of section 5 are actionable where the injury is to either competitors of the advertiser or to consumers. When the FTC acted as "a surrogate enforcement arm for competitors," as it frequently did prior to a decade ago, it characteristically became entangled in nit-picking, literalistic disputes over the meaning of words in advertisements. During the 1950s and 1960s, a large number of enforcement actions were the result of complaints received from competitors and appear to have been basically intended to shield sellers against competition from less expensive substitutes.

In the 1969 Report of the American Bar Association To Study The Federal Trade Commission, Richard Posner goes into considerable detail describing hundreds of cases he reviewed involving forced disclosures of


what he believes to be irrelevant facts. Former concludes that insignificant cases "constitute a significant part of the FTC's total output over the years" and that the FTC achieved "precious little consumer protection."

**NEW APPROACHES TO ADVERTISING REGULATION**

Beginning about 1969, the Federal Trade Commission has initiated a large number of proceedings which have challenged major national advertising campaigns as false, misleading, or unfair. During this time there have been unprecedented efforts by the government to require by rulemaking and adjudication the disclosure of relevant product information. These recent efforts are in sharp contrast to those of earlier years which included many challenges against claims made by small companies selling re-refined oil, hair restorers, combination fruit trees, etc. And while the traditional rules concerning deception, the use of "puffery" in advertising as a defense, and Commission authority to determine the meaning of ads have continued to govern the disposition of most advertising cases in the last decade, the FTC has taken major steps to augment the protection these principles afford.

First, the FTC has developed a separate category of "unfairness" violations, including the failure to undertake prior substantiation of advertisements. Second, the FTC has shifted its efforts away from protecting

1/ ibid., p. 111.
...in part by virtually abdicating its extensive prior efforts to regulate competitive price clauses and knock-out demonstrations as discussed in the preceding section. Finally, the Commission has undertaken some significant innovations in the imposition of remedies.

"UNFAIRNESS" VIOLATIONS

The 1972 decision in FTC v. Sperry & Hutchinson Co. has encouraged the challenging of advertising claims that are "unfair" as opposed to deceptive. Sperry & Hutchinson (S&H) had tried to suppress operations of trading stamp exchanges, small firms in the business of swapping or selling for a fee stamps necessary to fill books for the redemption of merchandise.

By arguing that section 5 applied only to practices which violate the letter or spirit of the antitrust laws or are repugnant to public morals, S&H successfully defended against an FTC suit challenging its practice as unfair. In reversing the decision, the Supreme Court authorized the FTC to enforce section 5 "like a court of equity," taking into account such factors as whether a practice (1) "without necessarily having been previously considered unlawful, offends public policy" as established "by statutes, the common law, or otherwise"; (2) is "immoral, unethical, oppressive, or unscrupulous"; or (3) causes "substantial injury to consumers (or competitors or other businessmen)."

2/ Ibid. p. 244-45.
Although the Supreme Court’s broad grant of authority to the Commission to develop new rules in the area of consumer protection is not specific enough to provide meaningful enforcement guidelines, three types of nondeceptive advertisements emerge that might plausibly be regarded as “unfair”: claims published without reasonable prior substantiation; claims which tend to overreach or exploit particularly vulnerable groups; instances in which sellers fail to provide consumers with the necessary information upon which a choice can be made from among competing products.

Substantiation Of Advertising Claims

There is evidence that prior to 1972 advertisers frequently published claims for which they had little prior substantiating data. That situation changed rapidly, however, as a consequence of the FTC’s decision in the Pfizer case.

Although the FTC has required since 1963 that advertisers have substantiation for claims relating to health and safety prior to the dissemination of the advertisements in which the claims are made, it was not until the Pfizer decision a decade later that the prior substantiation requirement was extended to other types of claims.

2/ Pfizer Inc., 87 F.T.C. 23 (1972).
The case involved claims by Pfizer that its product "Unburn" contained a special ingredient that anesthetized nerves in sunburned skin. The Commission challenged the claims and unanimously held that it is "unfair" under section 5 to make an affirmative product claim (puffery excepted) without reasonable prior substantiation. Although the law already required that claims must be nondeceptive and truthful when made, the Pfizer decision went further and concluded that even nondeceptive claims not relating to health and safety would be in violation of the law if they were not supported by adequate prior substantiation.

The Pfizer opinion notes that it is impractical to expect individual consumers to run tests on the thousands of products they purchase and that it is more efficient for the seller to run tests once for each product claim. Beyond this, the opinion asserts that consumers are "entitled" to the substantiation information and "should not be compelled to enter into an economic gamble to determine whether a product will or will not perform as represented." The opinion, however, is vague in explaining the justification for ad substantiation and fails to consider the costs that might be generated by a substantiation program.

During the first few years after the Pfizer decision, the FTC launched a series of publicly announced, industrywide "ad substantiation rounds" in

1/ Pfizer, Inc., 81 F.T.C. 23 (1972) at 62.
which all major advertisers of a particular product, or all advertisers making a certain type of claim, were required to turn over their supporting data to the FTC. The material is examined by the Commission, complaints are issued where the FTC thinks claims are unsupported, and eventually the data are made public.

In the last few years, however, while the Commission has routinely sought substantiation of ad claims from individual companies that it has investigated, it has only infrequently asked for ad substantiation on an industrywide basis. In 1978, for example, only one such request which covered ads that promoted energy-saving appliances and other devices was initiated. One reason, as recently conceded by Chairman Michael Petrick, is that industry self-regulatory programs have been effectively carrying much of the burden of keeping national advertising honest.

But there is concern at the Commission that advertisers and advertising agencies may be getting complacent about the threat of FTC action and that the Commission may be losing some of the momentum it built up with its highly publicized cases of a few years ago.

One of the major forces behind the heavy use of ad substantiation rounds in the first few years after Pfizer was the influence of Robert Pitofsky who pioneered its use when he was chief of the FTC's Bureau of

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Consumer Protection in the early 1970s. Now that he has returned to the
FTC as one of its commissioners, it is felt by a number of industry observers
that the program will again receive heavy emphasis.

In January 1979, Commissioner Pitofsky, speaking about indus-
trywide ad substantiation rounds, said, "It's a bit of a burden on the
staff to analyze the data, but I think it's awfully effective at putting
reviewers of advertising [inside companies and agencies] in the position
of saying, 'we need this substantiation before you can make that claim.'"

Vulnerable Groups

Another category of "unfairness" which the FTC has begun to attack
during the last decade concerns the exploitation of vulnerable audiences.
This concept could be relied upon to declare certain ads illegal even
if the ads were true because they offend some other standard of accep-
tability; define truth differently when ads are directed to special
audiences such as children; or duplicate the concept of deception already
in the law.

1/ Ibid.

2/ At least to the extent that such action would not violate the first
amendment. For a discussion on this point see: Robert Pitofsky,
beyond Nader, pp. 671-73.

3/ Ibid., pp. 675-77
So far, the only Commission decision dealing with unfairness since Sperry & Hutchinson has been its case against ITT Continental Baking Co. That case dealt with the charge that the advertising for Wonder Bread was both deceptive and unfair because, in stressing special nutritional features of the product by broadcasting dramatic growth sequences of children, it "exploited the aspirations of children (and) parental concerns for rapid growth and development." After holding that the ad was deceptive, the Commission stated that although the same practice could conceivably give rise to both an unfairness and a deception violation, the record in the Wonder Bread case failed to provide evidence of a separate unfairness violation.

Writing in the Harvard Law Review, Robert Pitofsky said, "Reliance on 'unfairness' in the regulation of stylistic excess in advertising is likely to be minimal. First, standards for what constitutes 'exploitation' of 'vulnerable' groups will be exceptionally elusive. Moreover, charges that an ad, though not deceptive, tends to take advantage of a vulnerable group will usually raise controversial questions of excessive government paternalism." Of course, this is exactly the charge that

1/ 83 F.T.C. 865, modified, 83 F.T.C. 1105 (1977), aff'd, 514 F.2d 207 (2d Cir. 1979).
2/ Ibid., at 872.
3/ Ibid., at 871.
4/ Ibid., at 874.
5/ Pitofsky, Robert. Beyond Nader, p. 684.
has been made in response to the FTC's controversial proposed trade regulation rule on children's advertising. Pitofsky concludes his discussion on the subject by saying, "Thus, despite the blank-check authorization provided to the Commission in S & H, new limitations on ad "exploitation" grounded on unfairness have not been developed." One year later, the FTC staff report on children's advertising broke new ground by citing the S & H case and this principle in support of their proposal.

Failure to Disclose

The most far-reaching charges the Commission has taken in the area of "unfairness" concern instances in which sellers fail to provide consumers with information necessary to make choices among competing products. While traditional advertising enforcement included efforts to force disclosure of pertinent information, success was relatively limited.

One of the traditional approaches attacked advertisements for deception based on silence. This approach is exemplified by the advertisements of the iron tonic "Geritol." The impression conveyed was that if you suffered from "tired blood," the iron in Geritol would perk you up. What the ads did not tell you (hence, alleged deception through failure to disclose is) that most fatigue ("tired blood") has nothing to do with iron deficiency anemia.

1/ ibid., at 55;
The other traditional approach required a finding by the Commission that, in light of express claims in an ad or the nature of the product, failure to disclose pertinent information would be misleading. Thus, in a case in which the FTC failed to make any such findings of deception or of other special circumstances it was reversed with the appellate court noting that the Commission does not have the authority to require advertisers to provide more information.

In contrast, the Commission has brought numerous cases in recent years based on the principle that the failure to disclose is "unfair". At least a dozen cases have involved vocational school advertising where there was no disclosure of the percentage of enrollees who failed to complete the course, percentage of graduates who did not obtain employment, and the salaries and employers of graduates who did obtain jobs; along similar lines, in complaints challenging allegedly fraudulent land sales schemes, separate violations have been charged for not disclosing


specific information about future land development programs and for not informing buyers that the purchase price of lots did not include everything such as sewers, utility hookups, etc. 1/

In the area of requiring the disclosure of product information, the FTC has also been quite active. In the mid-1970s a number of rules were promulgated that require the disclosure of information concerning such things as the durability of light bulbs, 2/ care labeling of textile wearing apparel, octane ratings for gasoline, mileage per gallon for automobiles, and tar and nicotine content of cigarettes. In the past few years, the FTC has also proposed disclosure of information with regard

1/ See, e.g., AMREP Corp., [1973-1976 Transfer Binder] Trade Reg. Rep. (CCH) # 20,846 (FTC 1975); Horizon Corp., [1973-1976 Transfer Binder] Trade Reg. Rep. (CCH) # 20,845 (FTC 1975). In these cases, the purchase price did not include paved roads, sewer systems, or phone services. Electricity and water were available only at unreasonable prices.


to the potential side effects of over-the-counter antacids, the effectiveness of hearing aids, and the nutritional quality of food.

**COMMISSION REMEDIES**

Perhaps the most important developments during the last decade in Federal regulation of advertising concern the Federal Trade Commission's efforts to devise a set of effective sanctions for unfair and deceptive claims. The traditional remedy in deceptive advertising cases was the cease and desist order. These defined, generally in fairly broad terms, those categories of claims which had been found to be illegal. Ensuing false advertising of the same type with respect to the same category of products can lead to penalties of $10,000 per day per violation. The only meaningful alternative to these "go and sin no more" orders was to require future advertising to contain affirmative disclosure of particular product information where silence or implications from other express advertising would be likely to lead to continuing misconceptions about the product in the average consumer's mind. This approach is exemplified by the requiring the disclosure of health hazards in connection with smoking cigarettes.

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4/ This was recently raised by statute from $5,000. See 15 U.S.C., sec. 45(a)(1)(b) (Supp. IV 1976).
Many advertisers and advertising agencies, faced with the FTC's insufficient remedies, violated the law with impunity. Given the limited resources of the Commission and the huge amount of advertising it was required to review, many advertisers could determine that their chances of being detected and prosecuted were remote. Furthermore, inasmuch as the average time for investigation and trial of a deceptive advertising case took more than two years, and since most advertising themes are developed to run for a year or less, the challenged advertising campaign usually had disappeared or was about to disappear prior to the time an order could be entered. This lack of effective Government remedies against false advertising was compounded by the virtual unavailability of private remedies and the paucity of counter-advertising by competitors which could expose unsubstantiated or exaggerated advertising claims.

Remedial innovation at the Commission has concentrated on efforts to eliminate this vacuum in law enforcement. In a consent order agreed to in April 1979 involving J. Walter Thompson Co., the world's largest


2/ Ibid. p. 28-31. (Delays of three to five years between complaint and order were found to be common).

advertising agency, a new remedial approach was offered as an alternative. In a consent order settling Government charges that it prepared deceptive dishwasher advertisements for Sears, the advertising agency was offered an alternative to its the responsibility to substantiate client product claims: advise the client of “all performance claims” it reasonably believes are contained in the ad. The burden of substantiation then would be largely on the client.

Corrective Advertising

Probably the most significant development in remedial innovation, however, has been the use of corrective advertising. These orders direct advertisers found guilty of disseminating false and misleading claims to inform consumers, usually through the same advertising media that was originally used to disseminate the false claims, of the facts with respect to the claims.

The FTC has asserted several times since 1970 its view that it has the authority to impose corrective advertising, but it was not until 1977, in a proceeding against Warner-Lambert involving advertising of the mouthwash Listerine, that the Commission finally got a Federal court to agree.

The FTC case, based on a 1972 complaint, involved the Commission’s contention that for more than a half a century Listerine ads have created the false impression that the product prevents or lessens the severity of colds and sore throats.

In April 1978, Warner-Lambert exhausted its last avenue of appeal when the Supreme Court refused to review a 2 to 1 court of appeals decision that upheld a 1975 FTC order requiring that $10,000,000 of future Listerine ads carry the message, "Listerine will not help prevent colds or sore throats or lessen their severity." The lower court had, however, deleted from the FTC's correction a "confessional" phrase ("contrary to prior advertising") the Commission considered important.

In the only major corrective order contested in the courts since the Listerine case, an FTC administrative law judge ordered last September that $24,000,000 of future Anacin ads must disclose that "Anacin is not a tension reliever." American Home Products, the maker of Anacin, is one of three companies named in 1973 complaints challenging performance claims for their analgesics products. The $24,000,000 figure is the FTC's estimate of the average annual Anacin ad budget from 1968 to 1973. The one year run imposed for the correction is the same rule of thumb upheld by the courts in the Listerine case.

Even though the tension relief claims were dropped in December 1973, the judge said that the evidence showed that consumers continue to believe that tension relief is an important attribute of Anacin.


Authority to Order Corrective Advertising

The Commission has not brought any major corrective ad cases recently. It has, however, negotiated quasi-corrective settlements with Firestone and STP.

As with all FTC remedial authority, the power to order corrective advertising stems from the broad delegation of discretion under section 5(b) of the Federal Trade Commission Act, which empowers the Commission to order parties to "cease and desist" unfair or deceptive acts or practices in commerce. Traditionally, the courts have accorded the Commission wide latitude, particularly in antitrust enforcement, to develop remedial approaches.

Critics of the corrective advertising approach focus on the established rules that all FTC orders must be "prospective" and -- a related point -- that its orders must not be punitive. They argue that the process of trying to rectify past wrongs places the remedy beyond Commission authority.

Proponents say the fallacy of this argument is the assumption that FTC remedies must be exclusively prospective. This, they maintain, is an interpretation of Commission power that the agency has never accepted and the courts have not imposed. To the contrary, the courts have said that

1/ Jacob Siegel Co. v. FTC, 317 U.S. 606, 613 (1943) (judicial review of FTC remedies is limited because the "Commission has wide discretion in its choice of a remedy deemed adequate to cope with the unlawful practices in this area of trade").

the real question is not whether remedy is prospective but whether it is punitive. That FTC orders prevent some significant future illegal effect is the only requirement imposed, and corrective advertising meets that requirement if the effects of prior deceptive advertising campaigns continue to influence consumer purchasing decisions for a substantial period of time after campaigns have been discontinued. Only the use of corrective advertising orders, they say, can dissipate the lingering effects of false advertising.

A principal concern of those who support this new remedial approach is the applicability of the standards put forth by the Commission in the Listerine case to future cases. The record in Warner-Lambert did support each of the findings under the formulation put forth by the Commission, but the Listerine advertising campaign was most unusual. For more than fifty-five years, the manufacturer had claimed in major ad campaigns (broadcast to the date of the suit) that the mouthwash was effective in ameliorating, preventing, and curing colds and sore throats. Additionally, persuasive evidence was presented that purchasers believed the claim at least up to the time of the suit. Finally, Warner-Lambert had conducted, at a cost in excess of $100,000, its own surveys (to test consumer recall of past advertisements) which were introduced into evidence against it. It is reasonable to conclude that comparable proof of “deception memory” influence would be virtually impossible in most advertising cases.

2/ Pitofsky, Robert. Beyond Nader, p. 695-96.
SUMMARY

Procedurally, there are three fundamental areas in which the Commission can initiate change in order to attempt to better carry out its advertising regulation mandate. The first area involves the legal approaches it employs, i.e., the principles of law upon which its actions are based. The second concerns the priorities it assigns to the various kinds of enforcement activity that are available to it. The third consists of the types of remedies it imposes on those who violate the rules and laws it is charged to uphold.

Legal Approaches

The last ten years have seen the Commission move away from almost total reliance on "deception" as the basis for developing rules and initiating orders towards the challenging of advertising claims that are "unfair". Following the Supreme Court's 1972 decision in FTC v. Sperry & Hutchinson Co., the Commission has attacked various ad campaigns involving three different types of nondeception. In Pfizer, claims for the product "Unburn" were challenged for lack of reasonable prior substantiation. In ITT Continental Baking Co., unfairness with respect to exploitation of vulnerable audiences was charged. Finally, the Commission has promulgated several rules requiring disclosure of product information based on the theory that it is unfair for sellers to fail to provide consumers with information necessary to make choices among competing products.
Enforcement Priorities

In this area, the FTC has substantially deemphasized two areas of traditional enforcement activity. First, cease and desist orders related to "fictitious" price claims have been negligible since 1969 while product quality claims have been more likely to be challenged. Second, the Commission has in effect abandoned enforcement in the area of phony mock-ups in television advertising.

Remedies

In efforts to devise a set of effective sanctions for deceptive or unfair advertising campaigns, the Commission has experimented with correcting advertising orders which direct advertisers found guilty of disseminating false and misleading claims to inform consumers, usually through the same advertising media originally used, of the facts with respect to challenged claims. Although the Commission has achieved some degree of success, most notably in Warner-Lambert, it will take future corrective ad cases to determine how far the Federal Trade Commission can go.
Marconian Problems, Gutenbergian Remedies: Evaluating the Multiple-Sensory Experience Ad on the Double-Spaced, Typewritten Page

Albert H. Kramer*

The unconscious depth-messages of ads are never attacked by the literate, because of their incapacity to notice or discuss nonverbal forms of arrangement and meaning. They have not the art to argue with pictures.1

The initial observation that must be made about contemporary advertising is that it is enormously effective. Whatever one thinks of America's ability to solve its social problems or repair its automobiles, it is indisputable that America is very good at selling itself goods and services. The advertising community is marvelously skilled at transporting the consumer of an advertisement to a wooded mountain stream and creating the apparently contradictory impression that smoking a cigarette will cool him off.

It is in fact this ability to successfully suggest a sensory experience to the recipient of an ad that makes advertising effective. This phenomenon has only recently come to be understood. Traditionally, both the advertisers and the regulators of advertising have viewed the effectiveness of a message in terms of the linear written word.2 Now, however, the media have changed. The media

* This article is adapted from remarks of the Director, Bureau of Consumer Protection, Federal Trade Commission, prepared for delivery to the Advertising Law Conference, Shoreham-Americana Hotel, Washington, D.C., October 20, 1977.

These remarks are the views of the author and do not necessarily reflect the views of the staff of the Commission or a majority of the Commissioners.
2. See M. MCLOUHAN, UNDERSTANDING MEDIA 204 (Signet ed. 1964).
have left the written word behind in a cloud of dust and have created a new environment of multiple-sensory experience of which the written word is a minor part.

Communications theory experts tell us that health warning messages on cigarette advertisements are seldom noticed. The reason they are seldom noticed is that advertisers spend a great deal of money learning to make them go unnoticed. They spend their resources creating a sensory experience (the wooded mountain stream, for example) to which the health warning is extraneous. The advertiser tests different ads to determine the most effective presentation of the central message of the ad, and implicitly, the least effective presentation of the "extraneous" health warning.

We have made great progress in communication theory over the last decade or two. No other industry has exploited social science data as advertising has exploited communication theory. This exploitation is not necessarily evil. Communication theory can be abused, of course, but such techniques, as long as they are not illegal, are perfectly proper components of the American marketplace. It is imperative, however, that regulators of commercial advertising be equally versed in communication theory. A very serious problem arises when regulators evaluate the possible falsity, deception, or unfairness of an ad without considering it in the same "sensory experience" context that the ad sought to instill. Despite all the lessons of communication theory—lessons the advertising technicians have learned very well—the regulators and the judges who review their work persist in using a relatively ancient method for evaluation: they first reduce the total sensory experience of the ad—voices, music, graphics, movement, colors—to the written word, via the double-spaced, typewritten memo or brief.

"Those who have spent their lives protesting about 'false and misleading ad copy,'" wrote Marshall McLuhan, "are godsendsto advertisers, as teetotalers are to brewers. . . . Since the advent of pictures," he continued, "the job of the ad copy is as incidental and latent as the 'meaning' of a poem is to a poem, or the words of a song are to a song. . . . [T]ypography is itself mainly subliminal in effect. . . ."

A recent case illustrates the difficulty of the current approach to advertising regulation.

3. Id. at 205 (emphasis added).

Refund." In reality, this "Instant Tax Refund" was merely an invitation to the consumer to apply for a loan from Beneficial at the normal rates and using the normal qualification procedures—information which was not communicated by the total impression conveyed by the radio and television commercials. An administrative law judge of the Federal Trade Commission found that the total sensory experience of those commercials was deceptive and misleading. More important, he found that there was no possible way to modify the phrase "Instant Tax Refund" so that the ad would not be deceptive and misleading. Therefore, he concluded, Beneficial could no longer use the phrase.

The U.S. Court of Appeals for the Third Circuit reversed, 2-1, on that portion of the order and held that the administrative law judge could not require excision of the phrase because of its quasi-trademark value and the First Amendment's general disfavoring of prohibitions on protected speech. A "less restrictive alternative" to deletion would have to be found.

This author does not quarrel with the court's application of First Amendment theory, nor dispute what consumer perceptions of the ad might have been. He does, however, quarrel with the fact that the judges did not evaluate the potential deceptiveness of the ad via the sensory experience it created. Rather, they evaluated the deceptiveness only via the ad's script, reduced to the double-spaced, typewritten page.

A necessary corollary of this view is that as the ad is dulled by reduction to print, the gravity of any perceived falsity, deception, or unfairness is lessened. Implicit in this discussion of the Beneficial case is the belief that the deception of the "Instant Tax Refund" ad is far more stark when the entire commercial is viewed or heard—when one is exposed to the entire sensory experience of the ad.

Marshall McLuhan has noted that advertisers strive to find and exploit the sensory experiences to which audiences are most responsive. "The need is to make the ad include the audience experience," he wrote. "The product and the public response

5. Id. at 614.
6. Id. at 618.
7. Id. at 618-20.
8. Id. at 620.
10. Id.
become a single complex pattern. The steady trend in advertising is to manifest the product as an integral part of large social purposes and processes.\textsuperscript{11}

In his widely praised book \textit{The Responsive Chord},\textsuperscript{12} radio-TV ad creator Tony Schwartz put it even more bluntly. Both, the FTC and advertising agencies focus on the "truth" of an ad, which may be a very small part of the total sensory experience. The Commission focuses on "truth" because of its statutory responsibilities and the agencies, because, as Schwartz puts it, "they want to appear truthful."\textsuperscript{13} However, he concludes that both are dealing with "an irrelevant issue. Neither understands the structure of electronic communication. They are dealing with TV and radio as extensions of print media, with the principles of literacy setting the ground rules for truth, honesty, and clarity."\textsuperscript{14}

The only important question for the regulators to ask, according to Schwartz, is

> What are the effects of electronic media advertising? For an advertiser, the issue of concern should center on how the stimuli in a commercial interact with a viewer's real-life experiences and thus affect his behavior in a purchasing situation. . . .

From the FTC point of view . . . government agencies responsible for safeguarding public well-being should concern themselves with understanding the effects of a commercial, and preventing those effects that are not in the public interest.\textsuperscript{15}

Judge Bazelon has also noted the importance of evaluating the effect of advertising as follows:

> In an age of omnipresent radio, there scarcely breathes a citizen who does not know some part of a leading cigarette jingle by heart. Similarly, an ordinary habitual television watcher can avoid these commercials only by frequently leaving the room, changing the channel, or doing some other such

\begin{itemize}
  \item \textsuperscript{11} \textit{Id.}
  \item \textsuperscript{12} T. SCHWARTZ, \textit{The Responsive Chord} (1973).
  \item \textsuperscript{13} \textit{Id.} at 20.
  \item \textsuperscript{14} \textit{Id.} An analogous situation can be found in the fact that the Federal Communications Commission has recognized that visual techniques, as well as words, may be subject to regulation in its handling of "subliminal perception" advertising. Subliminal perception techniques generally involve a superimposed statement, such as "Buy It," flashed on the screen for such a short duration that the viewer may not consciously see the message. In a Public Notice on January 24, 1974, the Commission noted that "[w]hether effective or not, such broadcasts clearly are intended to be deceptive" and are against the public interest. 44 F.C.C.2d 1016, 1017, 29 R.R.2d 395 (1974).
  \item \textsuperscript{15} SCHWARTZ, supra note 17, at 20-22.
\end{itemize}
affirmative act. It is difficult to calculate the subliminal impact of this pervasive propaganda, which may be heard even if not listened to, but it may reasonably be thought greater than the impact of the written word.\(^\text{16}\)

In contexts other than advertising, regulators seem to recognize their obligation to tailor their method of review to the sensory experience of the medium.\(^\text{17}\) Films generally have been considered as distinct from other forms of expression for First Amendment purposes because of the inherent characteristics of the medium.\(^\text{18}\) Moreover, in obscenity cases, the U.S. Supreme Court has recognized that it is the dominant theme of the material taken as a "whole" that must be considered\(^\text{19}\) and has recognized a duty to review allegedly obscene material in its chambers before making a determination on obscenity.\(^\text{20}\) In the famous "sound truck" case, Mr. Justice Frankfurter made very explicit the notion that different forms of media deserve different analysis:

The various forms of modern so-called "mass communications" raise issues that were not implied in the means of communication known or contemplated by Franklin and Jefferson and Madison. Movies have created problems not presented by the circulation of books, pamphlets, or newspapers. Broadcasting in turn has produced its brood of complicated problems hardly to be solved by an easy formula about the preferred position of free speech.\(^\text{21}\)

Thus, in other contexts, the Supreme Court has often acknowledged a principle that seems to impeach the fairly widespread practice among regulators of accepting a sensory experience via the double-spaced, typewritten pages of a brief. The Court's approach is instructive for regulators who must evaluate allegedly false, misleading, or deceptive ads and shape an appropriate remedy.

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\(^{17}\) Despite this, Article's emphasis on sensory advertising in electronic media, it may be possible that its analysis would be equally valid if applied to the print media. None of these remarks is intended to eliminate that possibility.

\(^{18}\) Burstyn, Inc. v. Wilson, 343 U.S. 495, 501-02 (1952). (While the Court acknowledges film as a significant medium for the communication of ideas, any "capacity for evil" it may possess is relevant in determining the permissible scope of community control, but not allowing "unbridled censorship.")


\(^{21}\) Kovacs v. Cooper, 336 U.S. 77, 96 (1949) (Frankfurter, J., concurring) (citations omitted) (prohibition against the use of any sound truck or computer located upon public streets or places emitting "loud and raucous" noises).
The problem this Article has addressed is part of a broader one. The media have become so powerful that they have shaped many societal institutions, including the First Amendment itself. The media have molded "expression" into an image which promotes their power—because the media need the First Amendment. The time has come to recognize that the First Amendment protects expression itself, not just the representation of expression. To the extent there is any mandate to regulate false, deceptive, or unfair advertising expression, regulators must be sure to consider the expression itself and not just a representation of the expression.

If advertising regulation is to be effective against advertising that makes its point through use of advanced communications techniques, it is imperative that both regulators and the courts take account of the media revolution, of the advanced market research that enables advertisers to know just what effect a certain message will create, and of the handicap under which they, as regulators, labor if they continue to prescribe ancient, pedestrian remedies for sophisticated but false, deceptive, or misleading sensory experiences that advertisers have created.

Only then will the regulators be dealing in the same currency as the advertisers they regulate.

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2. Cohen v. California, 403 U.S. 15, 26 (1971) (the "Fuck the Draft" case) (A state may not, consistently with the First and Fourteenth Amendments, make the public display of a four-letter word on one's jacket a criminal offense. The Court noted that much linguistic expression "conveys not only ideas capable of relatively precise, detached explication, but otherwise inexpressible emotions as well.").
No Matter What the Sheepskin Looks Like; It's Still the Same Old Wolf: A Reply to Mr. Kramer

Wesley J. Liebeler*

Having been a misfit even at the "Old" Federal Trade Commission because of my insistence on viewing problems in a market context, it comes as no surprise that I have difficulty understanding what the leaders of the "New" Commission are all about. While I think I understand the words, I must admit that somehow the total sensory experience of Mr. Kramer's message tends to pass me by. After some reflection though, a familiar strain comes through: it's the government that knows what's really good for you.

At first Mr. Kramer's argument seems simply to be that the true meaning of some advertisements that include voices and pictures cannot be determined solely by reference to a transcript of what the voices said. That, of course, is a perfectly obvious proposition. A pictorial sequence could show the same person being carried into the baths at Lourdes as a cripple and coming out like a track star. The voices could say nothing or, more appropriately: perhaps, they could provide information on train schedules in southwestern France. In a more modern context we might substitute Geritol for Lourdes, but the result would be the same. In neither case would the obvious claim of restorative power be reflected in a written transcript of the advertisement.

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Few of us would attempt to evaluate advertisements like these by "protesting about 'false and misleading ad copy.'" The pictures, sounds and so on are just as much a part of the advertisement as the meaning of the words involved. Indeed, in the examples I have given, the non-verbal part of the ads carries the real message.

The usual approach would be to take the words and music (or pictures) together, to place ourselves in the "environment of multiple-sensory experience," if you must, and specify the claim which the two (or more) different forms of communication state. Sometimes, as in the Lourdes and Geritol examples, the pictures and other "multiple-sensory" part of the advertisement will expand the claim that is made by the words alone. At other times the non-verbal portion of the ad will constrict the apparent claim being made by the words alone. An example of this may be found in the recent Commission proceeding against "Dry Ban," where the pictures were used to limit and restrict the meaning of a verbal claim that the deodorant in question was "dry."

In either case, however, whether the non-verbal portion of the ad constricts the claim of its verbal segment or expands that claim, the total ad is examined so as to state the specific product claim which the ad is making. That product claim can, of course, be expressed in words, whether it was actually made in words or in some other way. I would, indeed, have thought that it was necessary to express that claim in words if its truth or falsity were to be made a legal issue. That necessity, of course, arises out of even a modest regard for advising respondents of the nature of the claims being made against them.

Be that as it may, it would be hard to quarrel with Mr. Kramer if his only point was that we should look at all parts of an advertisement in our attempt to state the precise claim which the ad makes, the truth or falsity of which claim is to be assayed in our proceeding. As I have said, that is a perfectly obvious proposition; the Commission already does it.

2. *Id.* at 36, quoting M. McLuhan, *Understanding Media* 205 (Signet ed. 1964).
4. In the Dry Ban case the administrative law judge not only had the filmed commercials themselves, he also had marketing surveys which had been conducted by the respondent which showed how viewers perceived the ad, i.e., what message they received from it. But there was more. Commissioner Hanford reported:

Judge Hanscom's finding that these representations were false is based primarily on an experiment which was performed by complaint counsel.
REPLY TO MR. KRAMER

But Mr. Kramer is saying much more than that. He is not concerned that we look to the entire ad to guide our statement of its claim. He positively rejects the idea that we should attempt to draw from the entire ad any statement whatever of its perceived claim. He objects that: the old-fashioned regulators "persist in using a relatively ancient method for evaluation: they first reduce the total sensory experience of the ad—voices, music, graphics, movement, colors—to the written word, via the double-spaced, typewritten memo or brief."5

Of course, if we are not to "reduce the total sensory experience of the ad . . . to the written word," of an ad claim, we need not concern ourselves with the truth of such a claim or even with the question of whether an intelligible claim has been made at all. Apparently, the only thing that counts is the effect of the advertisement:

The only important question for the regulators to ask, according to Schwartz, is "[w]hat are the effects of electronic media advertising? For an advertiser, the issue of concern should center on how much the stimuli in a commercial interact with a viewer's real-life experiences and thus affect his behavior in a purchasing situation. . . ."

From the FTC point of view . . . government agencies responsible for safeguarding public well-being should concern themselves with understanding the effects of a commercial, and preventing those effects that are not in the public interest."6

What are these effects? Which ones are "not in the public interest"? One possibility is that Mr. Kramer wants to measure effect in terms of the "sophisticated but false, deceptive, or misleading sensory experiences that advertisers have created."7 This, of course, would make the Federal Trade Commission the guardian of our fantasies, or at least of those fantasies that are somehow prompted by commercial speech.

A more likely possibility is that Mr. Kramer would view an ad's effect in terms of its ability to affect consumer "behavior in a

in his presence and replicated on videotape. In this experiment, Dry Ban was sprayed on glass and on a human forearm and was found to be "wet, runny, liquid and watery" and to leave an "obvious residue." Respondents, however, object to a finding of wetness based on this demonstrative evidence because of the fact that in the experiment the product was sprayed downward, contrary to ordinary usage.

5. Kramer, supra note 1, at 36.
6. Id. at 38 (emphasis added).
7. Id. at 40.
purchasing situation,** I suppose that we may put aside all ads that
do not have the ability to induce a positive response from consum-
ers; they will presumably not be around very long in any event.
How do we determine which of the remaining ads, those that do
have an ability positively to affect consumer behavior in a purchas-
ing situation, produce effects that "are not in the public interest"?

I cannot avoid the conclusion that the ads that are not in the
"public interest" must be those ads that effectively induce us to
buy products that it is not in the "public interest" for us to buy.
What is in the "public interest" for us to buy is, I venture to
suppose, a matter for Mr. Kramer and his colleagues at the "New"
Federal Trade Commission to decide.

The basic problem with Mr. Kramer's approach is that it turns
the purpose of advertising regulation at the Commission on its
head. The Commission is supposed to police advertising so that
consumers can more efficiently learn about real options open to
them in the market. Armed with this information they (we) then
make choices that seem best to them (us). The fact that some, or
even many of us will choose to eat "junk" food, smoke cigarettes,
buy "gas guzzlers" or do something else that fails to meet with the
approval of those who run the Federal Trade Commission is abso-
lutely irrelevant. When the Commission acts to reduce the flow of
true (non-deceptive) messages that would lead us to purchase such
"unworthy" goods it substitutes its judgment for ours. It is in that
way and to that extent that Mr. Kramer's approach reverses the real
purposes of the Commission's program to police false advertising.

The difference between Mr. Kramer's proposal and the
Commission's more orthodox approach is not merely a differen-
tce of degree or a shifting of emphasis. These two approaches are in
fundamental and irreconcilable conflict with each other. Kramer
would concern himself with the effects or end-state of the market
process, of which advertising is only a part. If those effects or
results do not measure up to some exogenous standard, one that is
not derivable from the choices that consumers actually make, the
process itself (or at least the advertising portion of it) stands
condemned.

A market approach to the policing of advertising—the ap-
proach on which the Commission's original charter in this area is
presumably based—is legitimately concerned only with the process
by which consumers receive the information on which they base
their purchasing decisions. This approach does not concern itself
with the nature of the choices which consumers make. The public
Interest in the production and sale of particular goods and services is something that is determined by the purchasing decisions of consumers themselves.

While I could develop the differences between these two different approaches to the policing of advertising in an extended theoretical discussion, let me close by contrasting these different approaches in the context of some recent remarks by the Commission's chairman. The Commission must confront, Mr. Pertschuk is reported as having said:

... the realities of a marketing system run amok, a system in which neither incentives nor rewards bear any rational relationship to society's needs, a system which most rewards the sellers of the least healthful foods, a system which in its cumulative impact has produced a bounty of malnutrition.

We are similarly witness to a bizarre market system which rewards the delivery of health care services—whether or not they are needed—but provides little or no rewards for the preventer of disease—for example, the physician who would devote his life to teaching consumers about the relationship between nutrition and health.

By removing competitive restraints on the providers of health care, we free them to communicate with consumers on the importance of diet and sound nutrition as well as on the costs of medical services. We are in effect promoting a competitive system in which medical practitioners teach consumers about the relationship between nutrition and health; consumers demand better quality food; and an increased supply of nutritious food products results.

Mr. Pertschuk objects to the food marketing system because of the result which he claims it produces—"a bounty of malnutrition." Aside from the fact that his characterization of that system resembles more the carping of a chronic malcontent than a realistic description of the food marketing system, it is additionally deficient in that it does not explain what aspects of the food marketing process produce this unfortunate alleged result. The system is wrong because it produces results that Mr. Pertschuk does not like—we consumers are simply not eating enough health foods. A market approach to this "problem," if such it is, might ask what it is that prevents existing firms in the food industry, or new entrants into it, from advertising the virtues of eating nutritious foods, presumably in connection with their efforts to sell the same. What
prevents these purveyors of wholesomeness from hiring doctors and other professionals to spread the word that will both meet "society's needs" for an increased demand and supply of "better quality food" and at the same time increase their own profits? Nothing as far as I know.

The Commission's approach to the health care industry, the other matter addressed by Mr. Pertschuk, was quite different. Here, and in the related fields of prescription drugs and eyeglasses, the Commission identified specific factors that directly impeded the efficient operation of the market process itself. With prescription drugs and eyeglasses, a skein of state laws and regulations prevented price advertising at the retail level. The Commission moved directly against those restrictions on the operation of the market for price information. With medical services, there are restrictions, both legal and "professional," on advertising of prices and other factors important to consumers in their selection of medical suppliers along with a virtually endless system of other guild-like restrictions on the effective operation of the market for medical services. The Commission is also moving against these restrictions.

The justification for the medical services, prescription drug and eyeglass programs is vastly different from what Mr. Pertschuk seems to have in mind as regards nutritious foods. The former programs are based on the proposition that various legal and institutional factors in those markets are interfering with the ability of consumers to get information that would enable them to make better choices in the market in terms of their own standards. Reduced to its fundamentals, Mr. Pertschuk's problem in the nutrition field seems to be that people are eating too many Twinkies and drinking too much Coke, when they should be on a diet of bean sprouts and papaya nectar. As every sensible person ought to know, that is bad for our health.

Could be. But I doubt that the harm is equal to that which would be produced by the remedy that Messrs. Pertschuk and Kramer seem to have in mind.
New U.S. Supreme Court Philosophy on Advertising Faces Opposition

The U.S. Supreme Court is currently in the process of establishing a revolutionary doctrine that assures the right of consumers to receive certain information and the right of proprietors of the information to disseminate it. In establishing this doctrine, the Court is pulling together dicta from both "access" and "commercial speech" cases. At the same time, there appears to be a movement under way in some segments of society that in many ways is in direct conflict with the Court's developing doctrine. The resolution of this conflict may have profound implications for the future of advertising.

The Supreme Court's Doctrine: The first major case in the enunciation of this new doctrine, Kleindienst v. Mandel,1 decided in 1972, sprang from the denied request of a Belgian Marxist theoretician for temporary admission to the United States to participate in several academic conferences. Mandel and the group of American university professors who wished to hear the Belgian speak appealed the denial and contended that the First Amendment was violated by the statute used to refuse Mandel's entry.

Although the high Court denied Mandel's right to enter the U.S., it took this opportunity to re-inforce the contention of the appellants—a point the Court itself had made in several earlier cases.2 The right of citizens to receive information is indeed contained within the ambit of the First Amendment.

Kleindienst vs. Mandel, in dealing with the right to receive political information, was a philosophical vestige of the '60s. All subsequent major cases in the development of the new doctrine emanated not from movements to receive political information, but from ones to receive commercial messages.

In Bigelow v. Virginia,3 the right of a newspaper to carry certain kinds of advertising was at issue. Although abortion during the first trimester of pregnancy was held lawful by the U.S. Supreme Court in 1973, the state of Virginia continued to enforce a statute which prohibited encouraging or prompting abortion through advertising. Bigelow, managing editor of a weekly newspaper in Charlottesville, carried an advertisement for a New York abortion service and was convicted of violating the Virginia law.

In reversing Bigelow's conviction, the Supreme Court deviated from an earlier line of cases which had placed commercial speech beyond the scope of the First Amendment, and established the doctrine that speech is not stripped of its constitutional protection merely

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1 408 U.S. 133 (1972)
2 "It is now well established that the Constitution protects the right to receive information and ideas. The freedom of speech and the press necessarily protects the right to receive ..." (319 U.S. 141 (1943), p. 143. "Schenck v. United States 249 U.S. 47 (1918), p. 534.
3 421 U.S. 809 (1975)
The Supreme Court and Advertising

because it appears in the form of a paid political advertisement.

Bigelow is important not only because it establishes protection for commercial messages but also because it justifies that protection on the basis of the public's need for the information contained therein. In so doing, the Court erases the theretofore important legal distinction between speech falling into the political or public interest (i.e., speech necessary for the maintenance of democracy) and thus protected category, and speech falling into the commercial (i.e., speech not related to self-government) and therefore non-protected category. Thus the Court is admitting that at times political and commercial speech may be one and the same.

The rationale for affording Constitutional protection to commercial speech was expanded in a third major case, Virginia State Board of Pharmacy v. Virginia Consumer Council.

Pharmacists had long been part of an elite group of professionals including medical doctors, lawyers and certified public accountants who refused to allow their membership to advertise their services under pain of expulsion from the professional society. This prohibition on advertising by pharmacists was challenged in the present case by a group of prescriptive drug users who felt that their constitutional rights were violated.

In supporting the consumers' contention, the Supreme Court stressed the fact that there are two addressees of First Amendment protection: the disseminator and the receiver of information.

The Court reaffirmed this when it answered the assertion of the dissent that freedom of speech may be abridged when the speaker's listeners could come by his message by some other means, such as seeking him out and asking him what it is. Nor have we recognized any such limitation on the independent right of the listener to receive the information sought to be communicated.

Although the dissent in this case seems to be focused on the distribution of information, the motivation behind this focus is an attitude toward commercial speech. In Valentine v. Chrestensen the high Court had ruled that speech which is wholly commercial is outside the ambit of the First Amendment. Although in the 34 years since that ruling the Court had faced the question of constitutional protection for commercial messages several times and had even begun in recent years to afford some such protection to advertisements, as in Bigelow, it had never explicitly brought commercial speech under the mantle of the First Amendment, partly because it had always been able to attach the constitutional shelter to some "editorial" element in the advertising copy. In Bigelow, this requirement was satisfied by the Court's belief that some Virginians would be interested in the advertisement for abortion due to a curiosity regarding the laws of other states.

In the Board of Pharmacy case, because no argument was made favoring protection for the advertisement based on viewing some element in it as editorial matter, the Court felt compelled to face the issue squarely.

Quoting prior cases that dealt with the issue of constitutional protection for commercial speech, the Court noted:

Our question is whether speech which does 'no more than propose a commercial transaction,' is so removed from any 'exposition of ideas' and from 'truth, science, morality and arts in general in its diffusion of liberal sentiments on the administration...'
Although this case is usually remembered because it brought commercial advertising under First Amendment protection and because it broke the barrier that had kept members of professional societies from advertising, Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council went a long way toward securing the rights of consumers interested in receiving commercial messages. The Court did this by establishing the fact that many Americans' interest in commercial information may be keener than their interest in political issues. And this interest may be based not only on personal preference but also on economic realities:

Those whom the suppression of prescription drug price information hits the hardest are the poor, the sick, and particularly the aged. A disproportionate amount of their income tends to be spent on prescription drugs; yet they are the least able to learn, by shopping from pharmacist to pharmacist, where their scarce dollars are best spent. When drug prices vary as they do, information as to who is charging what becomes more than a convenience. It could mean the alleviation of pain or the enjoyment of basic necessities.

The Court went on to upgrade the status of commercial information by explaining that the "public interest element," ordinarily considered a precondition to affording constitutional protection to any form of speech, is inherent in advertising of the sort at issue:

Advertising, however tasteless and excessive it sometimes may seem, is nonetheless dissemination of information as to who is producing and selling what produce, for what reason; and at what price. So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable. And if it is indispensable to the proper allocation of resources in a free enterprise system, it is also indispensable to the formation of intelligent opinions as to how that system ought to be regulated or altered. Therefore, even if the First Amendment were thought to be primarily an instrument to enlighten public decision making in a democracy, we could not say that the free flow of information does not serve that goal.

In this eloquent defense of advertising's value in a capitalistic democracy, the Court seems to be retiring the dichotomy it begot 34 years before in Chrestensen between speech in the public interest category—speech which is necessary for the maintenance of democracy—and speech in the commercial category—speech which is not related to self-government.

Lest there be any question that this was indeed the intent of the Court, it took the opportunity to apply the reasoning of Virginia State Board of Pharmacy to another set of facts when it adjudicated a case dealing with advertising by attorneys, Bates v. State Bar of Arizona.

Bates grew out of a complaint filed by the Arizona State Bar Association against two attorneys who violated a State Supreme Court disciplinary rule by advertising their legal services in a newspaper. The Arizona State Supreme Court upheld the bar association conclusion. In reversing the decision of the high Court of Arizona, the U.S. Supreme Court began with an affirmation of its judgment in Virginia State Board of Pharmacy that speech should not be denied constitutional protection "merely because it proposed a mundane commercial transaction." But the Court was not content to simply re-assert protection for commercial speech. It went on to justify this protection by elaborating on the theme of consumer needs argued so effectively in the Virginia case:

The listener's interest is substantial: the consumer's concern for the free flow of commercial speech often may be far keener than...
The Supreme Court and Advertising

his concern for urgent political dialogue. Moreover, significant societal interests are served by such speech. Advertising, though entirely commercial, may often carry information of import to significant issues of the day. And commercial speech serves to inform the public of the availability, nature and prices of products and services, and thus performs an indispensable role in the allocation of resources in a free enterprise system. [Citations omitted.]13

This acknowledgement on the part of the Court that when advertising fulfills the informational needs of consumers it serves an "indispensable" role in the smooth functioning of our free enterprise system reflects the Court's consciousness of an important fact: in the second half of the 1970s, the attention of many Americans is not focused on the philosophical/political concerns of the 1960s but rather on the conditions of economic survival.

Advertising Restrictions: Ironically, it is at this time when the relative position of advertising as a form of free speech has been elevated and its significance noted by the Supreme Court that we see the growth of counter movements in several sectors—movements, in some instances triggered by these very cases, aimed at restricting or inhibiting the advertising of certain products and services.

Although these two developments are serving opposite purposes, both spring from the same source: they are based on an increased awareness of the importance and influence of advertising in contemporary society.

Most groups or individuals attempting to curb a type of advertising appear to focus their attention against radio and television commercials. Apparently because of a belief in the assumed power of the electronic media.14 The movement that most typifies this conviction is one aimed at restraining advertising directed toward children.

A number of disparate groups are presently lobbying to control the kinds and number of commercials directed toward children. Legislatures in California and New York are considering laws that would regulate children's television advertising. The public interest group Action for Children's Television has recently received a $40,000 grant from the Rockefeller Family Fund to aid its attempt to limit the number and kinds of advertisements broadcast during Saturday morning television. And the National Association of Broadcasters has asked the former chairman of the Federal Communications Commission Richard Wiley to update the children's television guidelines for the NAB Television Code.

But the organization most likely to have an impact on the exposure of children to television commercials is the Federal Trade Commission under the leadership of consumer-protection-oriented Michael Pertschuk. The FTC chairman's drive to regulate advertising aimed at children is based on the desire to debunk the assumption that the standards applied to television commercials directed at children need be no different from those governing print ads directed at adults:

Children are not sophisticated consumers. One advertising man described the role of ads directed toward kids as "guided missiles." That's a very vigorous image. It raises the question of whether children of 2, 3, or 4 are properly the subjects of well-developed techniques of promotion and manipulation through the most powerful medium the world has ever known.15

The Federal Trade Commissioners are presently studying an FTC staff report on television advertising to children which focuses on commercials for products high in sugar which are aimed at young children. This report suggests that the Commission institute a rulemaking procedure to determine whether it should a) ban all television advertising aimed at children under eight years of age, b)
ban television advertising of products that pose a serious dental health risk to children under 12 years of age, and c) require that advertisers of products high in sugar content balance these commercials with nutritional and/or health disclosures paid for by the advertisers themselves.18

The staff report argues that such rules would not violate the First Amendment rights articulated in Bigelow, Virginia State Board of Pharmacy and Bates, since advertising aimed at children can be distinguished from other types of commercial speech precisely because of the primary role advertising plays in our society: according to the FTC staff, the Supreme Court brought commercial speech under the First Amendment because the Court viewed material presented in the advertisements in question as essential to rational market behavior.

The staff report argues that since "children lack the maturity to make difficult consumer decisions based on an assessment of factual information," coupled with the fact that present televised advertising for sugared products to children is also "false," "misleading," and "deceptive," banning television commercials aimed at children would not violate the rational-market-behavior theory of protection for advertising propounded in Bates and its forerunners.

This argument's logic cannot be employed in an attempt to restrain commercial messages aimed at adults. Two recent efforts to limit advertising of certain products and services provide examples of various arguments used to restrict the flow of commercial information.

The first deals with an issue analogous to the one presently before the FCC, a movement to restrict radio and television advertisements for products containing saccharin without banning the products themselves. In March 1977, the Pure Food and Drug Administration decided that since saccharin was determined to be carcinogenic in laboratory tests conducted by the Canadian government, products containing it should be removed from markets in this country beginning in July 1977.

Because of questions regarding the validity of the Canadian tests plus the popularity of sweet but sugarless foods in America, an outcry ensued from both the public and the food industry. In an attempt to reach a compromise, bills were introduced into both Houses of Congress which mandated more study of the issue during an 18-month moratorium on the product ban. An amendment to the Senate bill called for restricted saccharin product advertising on radio and television during the moratorium. The rationale for the amendment, sponsored by Sen. Edward Kennedy, was that consumers should be told in advertising that products containing saccharin may increase the risk of cancer.

Although both Houses defeated measures to restrict saccharin product advertising, it should be noted that the Senate Amendment which was to require the inclusion of a health warning in all broadcast ads for artificially sweetened products was defeated only after intense and costly lobbying on the part of broadcasters19 by the not-so-wide margin of 52-42. A second Senate vote to reinstate the amendment and end all saccharin product advertising on radio and television was defeated, 55-39.20

A second attempt to limit the flow of commercial messages to adults is apparent in the responses of the individual states to the aforementioned Bates case.

Because the facts of Bates posed the issue of advertising in newspapers, the Court not only did not deal with the question of extending constitutional protection to radio and television commercials promoting legal services, but also pointed out that "the special problems of advertise
The Supreme Court and Advertising

Advertising on the electronic broadcast media will warrant special consideration. The justices left it to state supreme courts to stipulate procedures that attorneys who wish to advertise in the print media should follow in grappling with the "special problems" of radio and television advertising. It should be noted that the Court did not distinguish between print and broadcast advertising in either Bigelow or Virginia State Board of Pharmacy.

At its annual convention in August 1977, the American Bar Association discussed the issue and recommended that the states allow lawyers to advertise via print media and radio, but that left the question of television commercials in limbo. The concern of the ABA, and that of many individual lawyers, appears to be that television advertising will diminish the dignity and professionalism of the law because of the entertainment context of virtually any television commercial coupled with what some ABA members consider the tastelessness of many commercials.

Various state medical associations have begun to emulate the bar associations in moving to restrict certain kinds of advertising in the wake of Bates. The California Medical Association, for instance, has approved a stringent set of guidelines controlling print advertising and ruling out broadcast advertising entirely.

Conclusion

It would seem that a number of important elements in society—administrative lawmaking bodies, various professional associations, and concerned citizen groups—are determined that advertising must be placed under a number of restrictions if society is to be best served. It would also seem that the Supreme Court is moving in a direction that would culminate in the removal of most restrictions on commercial advertising. At some point these differing philosophies will come into more direct confrontation, and the resolution of that confrontation will have major implications for both advertising and the media it supports.

433 U.S. 350(1977) p. 344

The Defense of a False Advertising Case

By ROBERT A. SKITOL

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I MUST SAY that my assigned topic conveys a false and misleading impression. The topic is "The Defense of a False Advertising Case," which of course implies that the Federal Trade Commission (FTC) is still in the business of bringing cases against false advertising. While the word "false" still appears in many FTC advertising complaints, a better description of the Commission's current approach is that it is in the business of bringing cases against perceived implications which the advertiser insists were not conveyed by its advertising but which the Commission nevertheless alleges to have been conveyed without a "reasonable basis," whatever that means.

In short, these days many of the respondents in FTC advertising complaints have become respondents not because they have made false, or unsubstantiated, claims on purpose but because they did not anticipate how the FTC would later interpret or perhaps misinterpret, their advertising. While the advertiser may have gone to great expense to develop substantiation for every representation thought to be included in the ad copy, the advertiser developed nothing to substantiate the truth of implications the Commission later alleged.

I would not venture any blanket statement as to the reasonableness of the Commission's interpretations of advertising. It is safe to say that sometimes the Commission's interpretation is quite far-fetched, and the advertiser could not have anticipated any such reading. Other times, however, the representation found by the Commission probably is conveyed to many consumers, and the advertiser...
tiser's failure to foresee the problem is a product of its own tunnel vision; some advertisers read ads literally and fail to consider possible implications conveyed by a viewing of the ad as a whole. In the interests of diplomacy, I will not express an opinion as to which of these circumstances best explains the majority of FTC complaints.

Substantiation

Of course, even if an advertiser has the foresight and ingenuity to anticipate every possible reading of its ad that may later occur to the Commission and its staff, and even if it goes to great lengths to assemble substantiation for every such reading before the ad is disseminated, it could still end up on the receiving end of a Commission complaint. As to any one of several implications, the Commission may consider the assembled substantiation insufficient to constitute a "reasonable basis."

The Commission's definition of "reasonable basis" is like Mr. Justice Stewart's remark about obscenity: "I can't define it, but I can recognize it when I see it." In every decision to date, the Commission has explained the reasonable basis doctrine in vague generalities, insisting that its meaning is to be determined "on a case-by-case basis." This entirely ad hoc approach—what is reasonable in your case may be held unreasonable in mine—offers little guidance to those intent on avoiding trouble with the Commission.

I'm sure no one disagrees with the principle that advertising claims should not be made up out of thin air; an advertiser should have a factual basis for a product claim before it is disseminated. This proposition is about as controversial as apple pie and motherhood. The problem is, however, that according to the Commission, you need something more than any factual basis; you need what at least three of the five Commissioners will consider "reasonable" under all of the circumstances surrounding your claim.

Thus, the Commission's advertising cases now tend to focus on two issues: whether the challenged ads conveyed the representations alleged in the complaint and, if so, whether the advertiser possessed and relied upon a reasonable basis for them. I would like to offer a few thoughts on how to deal with these issues, before as well as after the Commission comes knocking at your door. I would then like to comment on several other issues likely to arise in an advertising case.
The Issue of What the Ad Represents

On the issue of whether the ads conveyed the representations alleged in the complaint, the Commission staff will rely heavily on what they regard as a black-letter rule of FTC law, namely that the Commission can properly determine the meaning of an ad from its own reading of the ad itself, without any evidence of how the ad was actually perceived by consumers. But to hedge their bets, the staff will often introduce evidence to support their view of what the ad represents. In some cases, the staff has relied on market surveys obtained from the advertiser’s files. The surveys that have been used for this purpose include those generally used by advertisers to test consumer recall of a particular advertisement, or to gauge consumer attitudes toward the advertised product after some exposure to the advertising. While such surveys may not have been designed to determine how consumers interpret the advertising, the staff’s expert witnesses will find that they support the staff’s own view as to what the ads represented.

In defending against this kind of evidence, the respondent can certainly call its own experts to refute the staff’s experts and attempt to explain away whatever surveys have been introduced. Beyond that, however, the respondent may develop its own survey evidence as a part of its defense, commissioning a survey geared to the specific representations alleged in the Commission’s complaint. Any such effort should, however, proceed with caution. It is not beyond the realm of possibility that a specially designed survey for this purpose would end up supporting the complaint allegations. More often than not, the results will be mixed; given almost any random but sizeable group of consumers, there will be at least some who read the ad the way the Commission alleges. If the survey shows that 90 percent of consumers read the ad the way the respondent contends but the other 10 percent read it the way the complaint alleges, you will have produced a nice piece of evidence in support of the complaint.

This set of circumstances suggests some steps that might be considered before the FTC ever gets around to considering a complaint. First, whenever an advertiser reviews the results of market surveys concerning its ads, thought should be given to how those results might be construed as suggesting an implication that was not previously intended to be conveyed. If any such implication is found, 

2 83 F.T.C. 865 (1973), aff’d, 532 F.2d 207 (CA-2 1976).
and the truth of the implication cannot be substantiated, the advertising copy should promptly be revised to remove that problem.

Second, the advertiser might consider conducting, at an early stage, a survey to assess how consumers interpret a new advertisement. If an objective survey of this sort is conducted before an ad is disseminated, and the results reveal no implications that are not fully substantiated, the advertiser will have a strong piece of evidence in its defense in the event of an FTC challenge.

The "Reasonable Basis" Issue

On the issue of whether the advertiser possessed and relied upon a "reasonable basis" for the alleged representation, the staff's position will be that whatever respondent did to support its claim it was not enough. If respondent relied on expert opinions, the staff will say that there should have been a "scientific test"; if there was such a test, they will say that that test was not good enough, or that its results supported at best, a narrower claim than the one actually made. The stage is then set for a battle of experts, those called by the staff testifying that the substantiation is worthless and those called by respondent defending the documentation as impregnable and conclusive.

There are other possibilities for defending on this issue, approaches not fully tested or explored in any case to date. I would argue that since the reasonable basis doctrine requires an assessment of the reasonableness of the steps the advertiser took to substantiate a claim before it was disseminated, it invites consideration of the steps other firms in the same industry take or have taken to substantiate the same or similar claims. What are the available testing methods, the usual standards applied, the prevailing practices throughout that industry? What is the "state of the art," the kind of substantiation generally recognized by responsible firms in the industry as a sound basis for such claims? The respondent should have a full opportunity to develop such evidence through pretrial discovery. I would caution, however, that there are dangers in this approach, and it could backfire in some cases. It also has a few worrisome implications in terms of the Commission's future development of the reasonable basis doctrine.

Another possibility is post-complaint testing designed to show that the representation at issue was and is truthful. Of course, such a showing may not in itself excuse the advertiser's failure to have
had a reasonable basis before the claim was disseminated. Post-complaint testing is, nevertheless, relevant to the issue of whether the documentation respondent possessed and relied on before the ad was disseminated was in fact "reasonable" from an objective standpoint. It may also be helpful in asserting and supporting a First Amendment defense—of which more later.

The "Reliance" Issue

One element of the reasonable basis doctrine, as it has been articulated to date, is that the advertiser must not only possess but also rely on adequate substantiation before a claim is made. In some recent cases, the staff has zeroed in on this requirement. The scenario is as follows. Shortly after an ad is disseminated, the advertiser receives an investigative demand, commonly called a "6(b) order", for all documentation in the advertiser's possession for certain representations allegedly conveyed by the advertising. The advertiser responds by denying that his ads conveyed the representations listed in the order. Not anticipating the staff's next move, the advertiser chooses to stand by that denial and, therefore, does not submit any substantiation for the representations listed in the demand. Shortly thereafter, the Commission issues a complaint alleging that the ad conveyed the representations listed in the 6(b) order, and alleging that they were made without a reasonable basis. The advertiser answers by denying that any such representations were made and, in the alternative, asserting that if they were made, they were supported by a reasonable basis. The staff then attempts to foreclose the advertiser from introducing evidence of any reasonable basis for the representations at issue. In effect, they argue that the advertiser is bound by its response to the 6(b) order; the failure to submit any documentation in responding to that order established conclusively that the advertiser had not relied on a reasonable basis before the ad was disseminated.

Exclusionary Rule

After several mishaps with this strategy, the staff asked the Commission to amend the rules of evidence to prevent an advertiser from coming in with new substantiating materials after a complaint is issued. After three years of thinking the matter over, the Commission has complied with the staff's wishes; a new rule entitled "Exclusion of Evidence in Adjudications" (also called the "Exclusionary..."
(Rule”) will go into effect on October 26, 1977. It provides, in sum, that if an advertiser is required through compulsory process to submit substantiation for an express or “implied” claim in an ad, the advertiser will not thereafter be allowed, in a reasonable basis proceeding, to offer in evidence anything that was required to be but was not timely submitted in response to the compulsory process. There is one exception built into the rule; materials not submitted in response to compulsory process will not be excluded if the advertiser demonstrates in a hearing, and the Administrative Law Judge finds, that “by the exercise of due diligence the material could not have been timely submitted in response to the compulsory process, and that the Commission was notified of the existence of the material immediately upon its discovery.”

The Commission expects this rule to simplify advertising cases; I have some doubt as to whether it will have any such effect. Indeed it may complicate and lengthen the proceedings by introducing issues as to what was “required” to be submitted previously and whether new materials could not have been submitted at an earlier time “by the exercise of due diligence.” The validity of this rule will also be challenged on a host of constitutional and statutory grounds. In the meantime, however, every advertiser should keep the rule in mind when faced with an order to submit ad substantiation. Such orders generally require the submission of “all” substantiation for designated claims. The word “all” must now be read literally, and the response must include everything which the company might later need for its defense at trial if a complaint is issued. Thus, such an order could require submission of roomfuls of documents, plus a great deal of corporate information and accumulated knowledge not generally kept in documentary form.

Fourth Amendment Standards

In short, this new Exclusionary Rule may have the unintended and undesired effect of requiring the Commission staff to wade through mountains of material not genuinely helpful to any concern for truth in advertising. It may also have the effect of rendering the Commission’s standard investigative demand for ad substantiation unreasonable on its face under Fourth Amendment standards. The

2 Id.
3 Id.
Commission will be forced to defend these demands in judicial enforcement proceedings, where they just might be held too broad and thus unenforceable.

My topic, however, is not the defense of a judicial proceeding to enforce a 6(h) order; that may become a very good topic for next year's conference. Returning to the defense of an advertising case, the best defense against the staff's new focus on the "reliance" element of the reasonable basis doctrine is making sure that what you do rely on to support a claim is reflected on paper before the claim is made. If, for example, the basis includes expert opinions, those opinions should be set down in writing. If the claim is susceptible to validation by a test of some sort, it would be advisable to conduct such a test and record the results before the claim is made. Then make sure that whoever in the company is ultimately responsible for approving advertising actually sees the assembled documentation— that he does rely on materials that may later become the advertiser's most important evidence in defending against an FTC complaint.

**Constitutional Issues**

Aside from the issues of what the ad represents and whether the advertiser possessed and relied upon a "reasonable basis," there are some basic constitutional issues which should not be overlooked. The reasonable basis doctrine has yet to be subjected to a full-scale review in the courts. To the extent that this doctrine imposes a new barrier—a vague, ill-defined "prior restraint"—to the dissemination of truthful advertising, it raises serious First Amendment questions. To the extent that it shifts the burden of proof in a Section 5 proceeding, it also raises due process questions.

The First Amendment issues are of particular interest, in light of the recent Supreme Court decisions confirming that truthful commercial advertising is indeed entitled to First Amendment protection.  Even if the reasonable basis doctrine, in and of itself, is not held to violate First Amendment rights, the kind of remedy the Commission is seeking in some of its pending advertising cases may be vulnerable to a First Amendment challenge. In some of these cases, the Commission seeks an order prohibiting any representation within a broad category unless it is supported by a "scientific test." Thus, even if a representation included in the specified category is truthful.

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*Bates v. State Bar of Arizona, 45 U.S. 516 (1977); Virginia Pharmacy Board v. Virginia*
and fully substantiated by materials other than a “scientific test,” it would be banned by the Commission’s order. This would appear to impede the free flow of truthful and informative commercial information, which, as the Supreme Court has held, the First Amendment protects.

In other cases, the Commission seeks an order of “corrective advertising,” requiring future ads to include confessions about prior ads. The fact that the Listerine corrective ad order has now been upheld by a court of appeals6 hardly ends the constitutional issues raised by that remedy. The Listerine order may still be reviewed by the Supreme Court, and other pending cases in which the Commission seeks corrective advertising present variations that may make such relief even more vulnerable to constitutional attack.

**Magnuson-Moss**

One part of the 1975 Magnuson-Moss amendments to the FTC Act may prove to have major implications for advertising cases. I am referring to the section which provides that “if the Commission determines in a proceeding under Section 5] that any act or practice is unfair or deceptive, and issues a final cease and desist order with respect to such act or practice,” the Commission may commence an action to obtain civil penalties against any company “which engages in such act or practice” with “actual knowledge that such act or practice is unfair or deceptive and is unlawful” under Section 5. In plain English, if the Commission finds, in a proceeding against company A, that a certain kind of advertising is unfair or deceptive and, thereafter, company B disseminates the same kind of advertising, the Commission need not waste time bringing an administrative proceeding against company B: it can sue company B in district court seeking imposition of heavy civil penalties.

This section raises several intriguing constitutional issues, which are not likely to be fully resolved by the courts for several years. In the meantime, the Commission will proceed with confidence that this new authority is constitutional; thus, its decision in a proceeding against one advertiser will have the effect of an order which is binding on every other company with “actual knowledge” of it. The “actual knowledge” requirement will prove unimportant; the Commission will simply mail its decision to all companies believed likely

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to engage in the practice it has found unfair or deceptive. In effect, every final adjudicative decision becomes the equivalent of an industry-wide rule.

Given the implications of this new authority, it is now quite clear that the named respondent in an advertising case is not the only company with a direct and substantial interest in the outcome. Particularly in a case involving a novel theory, where the Commission is challenging a fairly common practice as unfair or deceptive, numerous advertisers, or trade associations on their behalf, may have a strong claim to a right of intervention and active participation in the litigation.

Suppose that the Commission sues company A for engaging in a certain industry-wide practice. Company A may not have the resources, or the inclination, to litigate the case. On the other hand, company A may not wish to be subjected to an order which is not equally binding on all of its competitors. Negotiating a settlement in the standard manner will not result in an order binding on others; it is generally acknowledged that only Commission findings in a litigated case will trigger the new Magnuson-Moss provision. Thus, company A and complaint counsel work out a deal, a new way of "settling" an advertising case. Both sides agree on the form of the order which should be entered in the event that the Commission finds a violation. The parties then stage a perfunctory trial, putting in evidence in the form of affidavits—just enough to allow the Administrative Law Judge and then the Commission to make findings of fact and conclusions of law. The judge and the Commission make the prearranged findings and conclusions, and then issue the order that the parties had negotiated and agreed on beforehand. The Commission's decision and order are then mailed to every other firm in company A's industry. The Commission advises all of those firms that they are now bound by A's order, even though they did not participate and may not have even known about the proceeding.

What I have just described is not a far-fetched hypothetical case; it is, in substance, what is actually happening in the Commission's pending Block Drug proceeding. It may or may not result in Commission findings legally binding on Block Drug's competitors; any attempt to apply such findings to Block's competitors would seem vulnerable on a great many grounds. Nevertheless, Block Drug's competitors face an uncertain, and uncomfortable, future. If they had sought and been able to intervene and actively participate in this proceeding when the case began, they might have avoided this situation.
Settlement Procedures

Not all respondents in advertising cases will be inclined to follow the Block Drug approach; some may prefer the more conventional way of negotiating a settlement. Unfortunately, the Commission has just adopted a rule that makes the more conventional settlement procedure a bit more cumbersome. This rule provides that when a provisionally accepted consent agreement and order are published for the sixty-day period of public comment, they will be accompanied by "material submitted to the Commission reasonably related to the merits of the order that is not exempt from disclosure under the Freedom of Information Act, and any other information which [the Commission] deems helpful in assisting interested persons to understand the terms of the order." As the Commission noted at the time the rule was issued, this language means "that most documents submitted by the respondent in the course of settlement negotiations "would be made available to assist in public comment." That this rule may have a chilling effect on consent negotiations was clearly recognized at the time it was adopted; indeed the Commission stated that in view of "the risk to the negotiating process," it would "review the effect of this rule change after one year." 8

In the meantime, the message to all respondents is clear: avoid putting anything in writing, unless you are willing to have it made public if and when a settlement is reached and published for comment. Negotiating an order of any complexity without putting concepts and proposals in writing can be rather difficult, but that seems to be the prevailing practice since the new rule was promulgated this past August.

Conclusion

In sum, these days it is hard to devise an effective advertisement immune from some risk of an FTC "reasonable basis" complaint; it is hard to mount an effective defense when such a complaint is issued; and it is hard to negotiate a settlement. On the other hand, it is far from clear that the new Commission leadership intends to issue complaints in any substantial number. The Commission's resources are now so committed to, on the one hand, massive Magnuson-Moss rule-making proceedings and, on the other, an ever-increasing multitude of studies, evaluation projects, task forces and seminars that it seems unlikely to have many lawyers available for preparing and litigating

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*42 F. R. 39659 (Aug. 5, 1977)
*Id.

FALSE ADVERTISING
cases. The new Commission leadership has been strong on rhetoric, adroit at public relations, and quick to announce new initiatives. Whether it will deliver on its promises remains to be seen.

Of course, even without any new initiatives, the new directions this Commission inherited from its immediate predecessors (the Kirkpatrick, Engman and Cullier Commissions) are more than enough to keep advertisers on 24-hour alert. Given the Commission's avowed determination to protect consumers against even remotely deceptive implications in advertising; given the vagaries and uncertainties of the reasonable basis doctrine; and given the implications of the Exclusionary Rule and the threat that under the Magnuson-Moss provisions a proceeding against one advertiser may produce an order binding on a whole industry, more than ever before the advertising game is strictly hazardous duty.

[The End]
Selling to Children: Fair Play in TV Commercials

by JOHN CULKIN

A recent ad in Broadcasting magazine invited sponsors to buy time on TV during children's viewing periods. The Federal Trade Commission plans to hold hearings on the issue. One sponsor, Kellogg Foods, states that the commercials are for products children don't need. The advertisers say the commercials are for products children do need. The advertising industry is divided on the issue, with some sponsors favoring restrictions and others opposing them. The public is concerned about the impact of TV advertising on children. The Federal Trade Commission is considering regulating children's exposure to television advertising.

Where does the responsibility lie for regulating children's exposure to television commercials? Advertisers, regulatory agencies, and consumers all should bear some of the burden.

Advertisers and Broadcasters

William La Moth, the president of Kellogg Foods, states that the commercials are for products children don't need. The advertisers argue that they are providing information about the products. They believe that parents have ultimate control over their children's purchases and that the commercials are not harmful.

The Advertising Process

Let's return to the ad quoted at the beginning of this article. It represents the whole process in microcosm: sell to the parents by convincing the child. The sophisticated and technically apt advertisers are putting pressure on the children to want something so much that they will persuade their parents to buy it. Quite apart from the question of the real value of the advertised product, what is the propriety of the pressure of the sponsor convincing the parent for control of the child? When the products are harmful to the child's well-being, the process is inexcusable. Very young children are gullible and unsophisticated; they cannot make sound judgments about the quality of what is being sold to them.

The advertisers challenge this charge by arguing that parents have ultimate control at the point of purchase. This is hardly an adequate justification for entrusting children into wanting things that are bad for them. And even with products that may be good for them, it seems like an unwarranted invasion. Parents have enough difficulty in helping their children to make wise choices without skewing the process by 500 million dollars worth of counterpersuasion.

Jean Mayer, the well-known nutritionist and president of Tufts University, advanced as a rough rule of thumb: the nutritional value of a food varies inversely with the amount of money spent to advertise it. Research confirms that the more heavily advertised foods are the least nutritious. The advertisers argue that they are providing information about the products. The public is concerned about the impact of TV advertising on children. The Federal Trade Commission is considering regulating children's exposure to television advertising.


(357)
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mine the child's perception of television

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toward and a desire for certain product..
successful in creating positive attitudes
and advertising, the public interest groups have
difficulty in getting their combined bud-
gets up to $500,000. The battle is so
ti that federal regulatory agencies
have a responsibility to act on behalf of
the interests of children and parents. The
self-regulation favored by the broadcast-
ers and the advertisers does not work.
They have had to be forced to accept
al regulations put on their activities up to this point. Right now they
are organizing a massive campaign to oppose the PTC proposals.
No other agency in the world allows

Research on Young Viewers: The Policy Implications

In television advertising good or bad
for children? Opinions are firm on both
sides of the question, but little evidence
exists to support either view. Academic
research on the effects of television ad-
vertising on children is relatively recent,
and few investigations have been specif-
cally concerned with the field. Still,
according to a recent report by the RANN
(Research Applied to National Needs)/
Program of the National Science Foun-
dation, the current state of knowledge
on the subject is inadequate in many areas.
A deficit exists in others to provide meaningful
guidance to policymakers.

The report, Research on the Effects of
Television Advertising on Children
(Washington: National Science Founda-
cion, 1975), is a review of the literature
and gives recommendations for future
research. Two major conclusions emerge
from the review. First, "It is clear from
the available evidence that television ad-
vertising does influence children." Chi-
ldren can and do learn from commercials,
and advertising at least moderately
successful in creating positive attitudes
owned and a desire for certain products.

The most significant variable that deter-
demen the child's perception of television
advertising in a age. Numerous studies
have demonstrated that as children grow
older, they become more skillful in dis-
instructing among commercial messages
and are more easily persuaded by the spon-
or's sales pitch. One study of fourth-
through seventh-graders in Michigan
would be just fine if most of those shos
were away; others urge more publi-
funding for children's programming;
others contend that if the junk were elim-
inated from the ad content, there would
still be enough good products to meet
program budgets.

Regulatory Agencies

When the advertisers have $500,000-
000 in their budget for children's adver-
sing, the public interest groups have
documented that less than one-quarter think
that commercials always tell the truth.
Most of the children were also irritated
by the commercial interruptions.

The second conclusion is that "From
a policy standpoint, the most immedi-
ately relevant research is that which
either documents the effects of specific
advertising practices alleged to be mis-
leading or unfair to children's percep-
tions or which tests the efficacy of regu-
lation or which tests the efficacy of regu-
lation provisions in preventing such abuses." Several recent studies have
shown, for example, that the way in
which a commercial is worded and pre-
sented ("some assembly required" or
"battery not included") affects the
child's ability to understand and remem-
ber the message.

In reviewing the research, the report
focused on ten issues that seemed to be
of greatest interest to the parties Involved,
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such blatant exploitation of its children for commercial purposes. Australia, Canada, and the United Kingdom are in the process of further limiting and refining their already strict standards and practices for children's advertising. If, as we often too readily, children are our most important natural resources, then it is perfectly legitimate for the appropriate federal agencies to protect that resource from any harm. The process which is now beginning at the FTC will provide a visible forum for the public discussion of these issues over the next year. The staff recommendations on the public comments must be submitted to the Commission members by April 1979.

**Parents and Teachers**

Most of the debate before the FTC will legitimately focus on the rights and obligations of the broadcasters and advertisers. But parents and the schools who have responsibilities. Much are not fully discharged by merely calling in and taking action against the sources of the producers. Even the best of all possible programming does not justify the four hours a day spent by the average American in front of the TV set. In our less-than-perfect world, the uncomfortable fact is that we have in deference ourselves as well as the networks.

**Action for Children's Television** has been the most persistent and persuasive advocacy group in the field. ACT filed one of two petitions to which the FTC formally responded in its recommendations, the other was filed by the Center for Media Education. In its efforts to keep the issues of children and television before the FCC and the FTC, ACT has also encouraged parents to become more involved in controlling their children's viewing. In discussing television with them, ACT is encouraging parents to learn to adjust their children's television experience. The public help to develop a child's view by adjusting the family television set. It reads, "The ideal television is one that provides minimal exposure to commercialized programming. The FTC and the FCC can only help to narrow the channel. Parents, teachers, and other adults have the responsibility in shaping children's viewing habits, informed and dissuaded choices among what, indeed, go into their heads and what feeds into their stomachs. It has always made good sense for parents to let children learn an

**The Future**

Western Churchill has said, "We shape our buildings and thereafter they shape us." So with our television system. During the 1940s the United States opted for a limited-spectrum, commercially supported TV system. Once such a system is in place, it takes massive effort to produce minimal results: the attempt to regulate children's advertising is a good example.

The technology of the future is now being set in place. There will be multiple (up to 100) channel systems, with recording and playback capacity, with dial access potential allowing consumers to request specific programs, with large screens and direct view, satellite linkups.

The new television system will make it possible to serve the television needs of audiences in numbers far less than the 20 to 30 million people now required by network television. The new systems will give us a way to let people pay for what they want. It will provide television with a nucle to allow consumers to make direct choices as they do for books, films, and plays.

Two areas of reform we can think about now which are non-negotiable, which make children's lives better, are (1) the way television is used to serve the television needs and (2) the way television is used to serve the children's programming, and (3) the way television is used to serve the children's programming. The future is set in place. There will be multiple channel systems, with recording and playback capacity, with dial access potential allowing consumers to request specific programs, with large screens and direct view, satellite linkups.

**Even "ideal" television, however, does not guarantee an ideal world. We often overemphasize the positive power for good as well as for harm.** There is life after "hand-held" television, and it is the quality of this life that probably more determines the impact of television on children. There is life after any art and alive for their own bodies, emotions, and identities and whose lives are caught up in the networks of affluence and production. Living well is not the last resort but the best achievement.
NOTE

CAN'T GET ENOUGH OF THAT SUGAR CRISP:
THE FIRST AMENDMENT RIGHT TO
ADVERTISE TO CHILDREN

INTRODUCTION

On April 27, 1978, the Federal Trade Commission published proposed rules which may virtually eliminate commercial television advertising directed at young children. The proposals would lead to the promulgation of final regulations by 1980 and are part of the latest round of governmental efforts to deal with the effects of television advertising on young audiences. Since 1970, the FCC has


Although the FCC has primary responsibility for overseeing the use of the airwaves, it has delegated its authority to regulate unfair or deceptive broadcast advertising to the FTC. Liaison Agreement Between Federal Communications Commission and the Federal Trade Commission, 3 TRADE REG. REP. (CCH) ¶ 9652 (issued Apr. 27, 1972), noted in 34 F.C.C.2d 1120 (1972). Under the agreement, the FTC has “primary jurisdiction over all matters regulating unfair or deceptive advertising in all media.” Id. The FCC has not, however, wholly abrogated its responsibility toward advertising, and “will continue to take into account pertinent considerations” relating to advertising practices in making licensing decisions. Id. The FCC recognized, through the policy outlined in the Liaison Agreement that the FTC has the expertise to evaluate advertising, and that FTC remedies which are not available to the FCC, including the power to ban advertising, may provide more appropriate remedies for deceptive and misleading advertising than the licensing authority of the FCC. See Note, Fairness and Unfairness in Television Product Advertising, 76 MICH. L. REV. 498, 521-22 (1978) [hereinafter Note]. Fairness and Unfair-
the FTC.\(^4\) Congress,\(^5\) the courts,\(^6\) and well over 100,000 private citizens\(^7\) have participated in the debate over broadcast advertising directed at children. The difficult conflict between the government's power to regulate commercial speech and the first amendment rights of advertisers and broadcasters will undoubtedly be resolved in the courts.

The FTC has proposed to:

(a) Ban all televised advertising for any product which is directed to, or seen by, audiences composed of a significant proportion of children who are too young to understand the selling purpose of or otherwise comprehend or evaluate the advertising;

(b) Ban televised advertising for sugared food products directed to, or seen by, audiences composed of a significant proportion of older children, the consumption of which product poses the most serious dental health risks.

\(^{*}\) In 1977, the FTC considered and rejected a proposal that would have banned advertising of "premiums"—i.e., inducements such as toys included in cereal boxes, which are designed to make the products more desirable to children. Advertising of Children's Premiums on Television, Rejection of Proposed Guide, 42 Fed. Reg. 15069 (1977) (hereinafter Premium Report). In so doing, the FTC acknowledged the "evidence . . . concerning the vulnerability of children to television advertising" and announced that it would continue to closely monitor children's advertising on a case-by-case basis. Id at 15072; see text accompanying note 125 infra. In addition, FTC rulings on specific advertisements have noted children's alleged special vulnerability to advertised messages. See, e.g., ITT Continental Baking Co. v. FTC, 532 F.2d 207, 214 (2d Cir. 1976), Hudson Pharmaceutical Corp., 89 F.T.C. 82, 86 (1977). For a discussion of the FTC's involvement with children's advertising, see Thain, Suffer the Hucksters to Come Unto the Little Children: Possible Restrictions of Television Advertising to Children Under Section 3 of the Federal Trade Commission Act, 56 B.U.L. Rev. 651, 661-64 (1976).


\(^{6}\) The FCC reported the receipt of over 100,000 comments from private individuals and citizens' groups during its initial proceedings on the ACT petition. "This material falls into three main categories. formal pleadings, programming data from stations and networks, and informal expressions of opinion (letters and cards)." Children's Television Report, supra note 3, at 39096, 50 F.T.C. 2d at 2; see id at 39098, 50 F.T.C. 2d at 19-24 (summary of comments).
(c) Require televised advertising for sugared food products not included in Paragraph (d), which is directed to, or seen by, audiences composed of a significant proportion of older children, to be balanced by nutritional and/or health disclosures funded by advertisers.  

In justifying these proposals, the FTC Staff Report on Television Advertising to Children asserted that television advertising directed at viewers under the age of eight exploits an audience that does not comprehend the selling purpose of commercial advertisements and is more trusting and naive than adults are. Accordingly, the FTC staff contended that all advertisements seen by small children are inherently deceptive and unfair, and therefore should be removed from the air pursuant to the FTC's statutory authority to eliminate unfair business practices.  

The Staff Report also argued that the advertising of sugared products poses a health risk to all children, because such products promote tooth decay and create bad childhood eating habits that may result in obesity and other diseases later in life. Relying on its statutory authority to regulate as deceptive those advertisements that fail to reveal significant health risks, and on its claimed authority to ban "unfair" advertising which harms consumers, the FTC concluded that televised advertisements for highly sugared foods should also be banned.  

Since the ban on children's television advertising was first proposed, the FCC, three congressional committees, and a federal
have questioned whether such a ban is constitutionally permissible. Undoubtedly, televised advertising directed at small children is unpopular, but the first amendment was designed to protect unpopular speech from government censorship. The exception of commercial advertising from first amendment protection, originally relied upon by those arguing for the constitutionality of the proposed ban, has recently been replaced by the far less determinate doctrine of commercial speech, which does extend some constitutional recognition to the right to advertise. Hence, even commercial speech must be presumed worthwhile, and those who would ban it must provide proof that it must be banned in the public interest, rather than mere allegations of unpopularity.

The constitutional issues are more difficult because of the strong policy considerations on each side of the debate over television commercials and children. On one hand, the first amendment should not be used as a talisman for the protection of corporate profits against legitimate regulations that are necessary to safeguard the nation's children. However, if the Constitution shelters all who wish to promote their products legally and truthfully, then government suppression, even in the name of protection, must overcome a strong presumption of unconstitutionality. This Note examines the proposed ban on children's advertising in light of recent developments in the constitutional doctrine of commercial free speech. It concludes that the proposed regulations are overly broad and, therefore, unconstitutional.
THE FIRST AMENDMENT AND THE RIGHT TO ADVERTISE

A. The Emergence of the Right

Until recently, commercial advertisements were deemed outside the scope of first amendment protection: following the Supreme Court's 1942 decision in Valentine v. Chrestensen, most courts held that speech which merely proposed a commercial transaction could be regulated without the presumption of illegality which attaches to regulation of purportedly higher forms of speech. The courts upheld statutes regulating—and even banning—speech of a purely commercial nature, statutes that clearly would have been impermissible had the speech been outside the realm of commerce. When the Supreme Court invalidated regulation of advertising, it was forced to find some element elevating the regulated speech to a level more closely guarded by the Constitution.

But in 1976 the Supreme Court overruled Valentine and its progeny when it invalidated a state ban on the advertising of prescription...
drug prices. In Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 20 Justice Blackmun's majority opinion flatly rejected the "simplistic approach," 30 of the Valentine doctrine, and held for the first time that purely commercial advertisements are not devoid of constitutional protection. 31 The Court reasoned that society has an interest in the free flow of commercial information; 32 accordingly, the Court held that, in this case, the government could not "completely suppress the dissemination of concededly truthful information about entirely lawful activity, fearful of that information's effect upon its disseminators and its recipients." 33

In rejecting the absolutist approach of Valentine, the Court implicitly endorsed for commercial speech the balancing test set out in Bigelow v. Virginia, 34 which "assess[es] the First Amendment interest at stake and weigh[s] it against the public interest allegedly served by the regulation." 35 In Virginia Pharmacy, the Court found that the public interest in ready access to drug price information easily outweighed Virginia's stated purpose of avoiding the lowered professional standards among pharmacists that might result from advertising and competition. 36

Although the Court observed that a consumer's interest in commercial information may be even greater than his interest in the political debates of the day, 37 the Court did not elevate commercial speech to the same level of protection as that enjoyed by political expression. Concluding that purely commercial speech is "harder" in that the advertiser's profit motive will militate against any chilling effect of regulation, and that commercial speech is more readily subjected to empirical testing for truthfulness, 38 the Court declared that such advertising could constitutionally be regulated to ensure that

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30 New York University Law Review [Vol. 54:30

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354
"the stream of commercial information flow[s] cleanly as well as freely." 39

Since 1976, the Supreme Court has employed the Virginia Pharmacy doctrine to strike down state and municipal bans on advertising by lawyers, 40 advertisement and in-store displays of contraceptive products, 41 and real estate "for sale" signs. 42 In addition, lower courts have used the commercial speech doctrine to restrict FTC regulation of both published and broadcast advertisements; 43 and several courts have held that FTC rules prohibiting deceptive advertisements must be carefully and narrowly drafted to effect government policy with the least possible impact on advertisers' legitimate right to promote their products truthfully. 44 The Supreme Court has not yet considered a case involving federal regulation of advertising or the "special problems of advertising on the electronic broadcast

39 Id. at 772, accord, Ohradik v. Ohio State Bar Ass'n, 436 U.S. 447, 454-55 (1978), Bates v State Bar of Ariz., 433 U.S. 350, 360-61 (1977). The notion that different types of protected speech may warrant different levels of protection is consistent with the Court's more explicit rulings concerning non-obscene but sexually explicit speech. See FCC v. Pacifica Foundation, 438 U.S. 726, 744-48 (1978) ("offensive" words have less social value, and therefore may be regulated in certain contexts), Young v. American Mini Theatres, Inc., 427 U.S. 50, 68-73 (1976) (plurality opinion) (the lower first amendment value of sexually explicit films warrants zoning restrictions that might not be placed on theaters showing inoffensive films).


43 Standard Oil of Cal. v. FTC, 577 F.2d 653, 662-63 (9th Cir. 1978) (rejecting overbroad an FTC order that company cease and desist from any advertising that might be misleading, since such prohibition could discourage truthful advertising as well), National Comm'n on Egg Nutrition v. FTC, 570 F.2d 157, 164 (7th Cir. 1977) (acknowledging FTC regulatory authority but rejecting as overbroad an FTC requirement that egg industry disclose scientific concern over relationship between egg consumption and circulatory disease), cert. denied, 99 S. Ct. 86 (1978).

B. The Right to Advertise to Children

The FTC Staff Report asserted that advertising directed at children is entitled to no constitutional protection under the balancing test employed by the Supreme Court in Virginia Pharmacy. The report contended that the Court's only rationale for extending protection to commercial speech was the finding that such speech contributes to rational decisionmaking in the marketplace. Therefore, since children lack full capacity for reasoned decisionmaking, and since young children do not comprehend the commercial motivations of the marketplace, constitutional protection for advertising directed at young audiences is not justified.

By focusing on only one aspect of the Virginia Pharmacy opinion, this analysis fails to recognize the myriad of first amendment considerations surrounding the question of advertising and children. This section will discuss those considerations, and argue that the proposed advertising ban violates the first amendment rights of advertisers, children, and broadcasters.

II. The Rights of Advertisers

Although the issue of the rights of advertisers was not directly raised by the Virginia Pharmacy case, the protection of these interests is an essential element of the Court's opinion. Conceding that an advertiser's commercial speech interests are "purely economic,"
the Court nevertheless held that his financial concern "hardly disqualifies him from protection under the First Amendment." According to the Court, by promoting freely competing businesses, advertising helps to ensure the best general allocation of resources and is an "indispensable" component of the free enterprise system. This reasoning suggests that the interest of society parallels the interest of the commercial advertisers. The Staff Report failed to recognize this aspect of Virginia Pharmacy and thus ignored the rationale underlying the protection afforded to free speech in the marketplace.

2. The Rights of Children

In the proposed rulemaking, the FTC staff argued that while commercial information might be important for adults, "it is unreasonable to assume that very young children are able to rationally understand and evaluate conflicting or potentially harmful commercial messages." But the FTC staff's assumption that children therefore have no right to receive commercial information is inconsistent with prior case law. The Supreme Court has ruled repeatedly that children are entitled to constitutional protection, although speech directed at...
children may be subject to stricter governmental control than is speech directed only at adults.58 Specifically, the Court has held that "minors are entitled to a significant measure of First Amendment protection . . . and only in relatively narrow and well-defined circumstances may government bar public dissemination of protected materials to them."59 The Court has struck down limitations on the constitutional rights of children, when such restrictions were not reasonable and necessary to protect the health, morals, or welfare of the children.60

Because children have some constitutional right to information, then, the government may not suppress commercial speech directed at them absent a showing of harm compelling enough to overcome the presumption of unconstitutionality that normally faces limitations on protected speech.61 To the extent that the FTC can establish that advertising takes unfair advantage of the particular weaknesses of children, the FTC may be able to curtail such advertising. The degree to which the evidence against children's advertising might justify such a curtailment of rights will be considered in section II.62

3 The Rights of Broadcasters and Program Content

In the case of televised commercials, the rights of broadcasters must also be considered. The Supreme Court has ruled that radio and

59 Eisenmenger v. Cnty of Jacksonville 422 U.S. 205, 212-13 (1975) (citation omitted).
60 Id. at 212-14 (ordinance preventing drive-in movie theaters from exhibiting films containing nudity struck down as overbroad). Tinker v. Des Moines Independent Community School Dist. 393 U.S. 503, 509 (1969) (regulation forbidding students from wearing armbands to school struck down as unreasonable); see Prince v. Massachusetts 321 U.S. 158, 174 (1944) (Murphy, J. dissenting). It has been argued that the relatively recent child pornography cases stand for the broad proposition that regulators have a virtually unfettered right to determine what children may see and hear. See FTC Staff Report, supra note 9, at 243-49. It should be noted, however, that sexually explicit speech may enjoy less First Amendment protection than does other speech while the Court has repeatedly ruled that listeners may not be insulated from ideas that they might find offensive e.g. Carey v. Population Servs. Int'l. 431 U.S. 678, 701 (1977); Cohen v. California. 403 U.S. 15, 21 (1971). Censorship of pornography has been allowed even without a showing of harmfulness in the interest of protecting the sensibilities of unwilling recipients. Miller v. California. 413 U.S. 15, 19 (1973).
61 See note 24 infra.
62 See text accompanying notes 121-216 infra.
television broadcasters are protected by the first amendment, although it is the first amendment rights of listeners that are paramount. Now that the Court has recognized that commercial speech is entitled to constitutional protection, the first amendment rights of broadcasters, too, are implicated whenever their power to air any particular advertisement is regulated.

It is true that television broadcasting traditionally has been regulated more closely than have other forms of speech, based on an argument of spectrum scarcity because access to publicly owned airwaves is limited to licensees, the government has been allowed to oversee broadcast content to ensure that a variety of viewpoints is presented. When regulating broadcasting, however, the Federal Communications Commission must tread a tightrope between its role as an overseer and its duty to respect the first amendment rights of broadcasters. The FCC is prohibited by statute from interfering

64 Red Lion Broadcasting Co. v. FCC. 395 U.S. at 390.
66 Butz v. Capital Broadcasting Co. v. Mitchell, 333 F. Supp. 582 (D.D.C. 1971), aff'd mem. sub nom. Capital Broadcasting Co. v. Acting Attorney Gen., 405 U.S. 1000 (1972). In Capital Broadcasting, the court held that the first amendment interests of broadcasters in airing commercial advertisements were not sufficient to override a congressional ban on cigarette advertising through the electronic media. The court suggested that broadcasters were merely "conduits for advertisers' speech that their interest in commercials was entirely economic and therefore did not give rise to substantial first amendment concerns." Id. at 584-85.

However, Capital Broadcasting was decided before the Supreme Court extended first amendment protection to commercial speech. See text accompanying notes 29-39 supra. Moreover, as Judge Skelley Wright argued in dissent, the Capital Broadcasting decision was seemingly inconsistent with earlier cases which had held that newspapers and film distributors could assert first amendment rights in protecting their media as forums for controversial speech. 333 F. Supp. at 591 n. 25 (Wright, J., dissenting); see New York Times Co. v. Sullivan, 376 U.S. 254, 265-66 (1964) (newspapers); Joseph Burstyn, Inc. v. Wilson, 343 U.S. 495, 501-02 (1952) (film distributors).


The delicate balance required in broadcast regulation derives from the dichotomous nature of the broadcast media on the one hand, the airwaves are a public forum in which the interests
with the right of free speech on the airwaves, and, as federal licensees, broadcasters have primary discretion to decide what will be broadcast.

Thus, while spectrum scarcity has been used to justify an affirmative obligation to present balanced programming, it does not justify an outright ban on forms of broadcast speech. For example, in *Red Lion Broadcasting Co. v. FCC*, the Court endorsed the FCC's "fairness doctrine," which requires that equal airtime be allocated to proponents of opposing views on certain public issues, but cautioned that "the Commission's refusal to permit the broadcaster to carry a particular program . . . would raise more serious First Amendment issues." More recently, the Supreme Court refused to find that the fairness doctrine required broadcasters to carry paid political advertisements. The Court reasoned that to require editorial announcements would undercut the first amendment rights of broadcasters to determine programming content.


47 U.S.C. § 326 (1976) provides in pertinent part that "no regulation or condition shall be promulgated or fixed by the Commission which shall interfere with the right of free speech by means of radio communication".

*Columbia Broadcasting Sys., Inc. v. Democratic Nat'l Comm.* 412 U.S. at 116. The FCC has acknowledged that "the ascertainment of the needed elements of the broadcast matter to be provided by a particular licensee for the audience he is obligated to serve remains primarily the function of the licensee. His honest and prudent judgments will be accorded great weight by the Commission. Indeed, any other course would tend to substitute the judgment of the Commission for that of the licensee."


Id. at 375-86.

Id. at 396.


"Id. at 124. In a section not joined by the majority of the Court, Chief Justice Burger likened the role of broadcasters under the first amendment to that of trustees whose principal responsibility is to provide the public with balanced coverage of events and ideas, but who are given broad discretion to satisfy that responsibility as they see fit, subject only to general supervision by the Federal government as licensor. Id. at 118-20 (Burger, C.J., announcing the judgment of the Court) (joined by Stewart & Rehnquist JJ.)."

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those best able to finance editorial advertisement would monopolize and thereby undermine any fairness system. Spectrum scarcity, then, has been seen as a logical basis for some intrusion on the rights of broadcasters—namely, the imposition of a general requirement of fairness. But the special characteristics of the broadcast media do not justify the complete abrogation of the free speech rights of broadcasters through a ban on children’s advertising.

In addition to broadcasters’ first amendment interest in providing a forum for the exchange of commercial information, the FTC’s proposed ban would have an impact on substantive programming decisions that poses serious constitutional problems. The acknowledged purpose in federal regulation of broadcasting is the protection of the public interest, not the maximization of corporate profits. Nevertheless, the FCC also recognizes that advertising is the basis for the commercial broadcasting system and, as such, it provides an economic incentive for quality “cultural” programming as well as the full variety of “commercial” broadcasting. The elimination of sponsorship might lead broadcasters to drop children’s programming in favor of revenue-producing programming. The FCC recognized this.

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77 Id. at 123
80 Children’s Television Report, supra note 3, at 39399, 50 F.C.C. 2d at 11. see id. at 39399 n 11, 50 F.C.C. 2d at 11 n 11. 1960 Programming Inquiry, supra note 70, at 7285, 44 F.C.C. at 2315 (recognizing the importance of advertising to public interest broadcasting, but finding no reason to distinguish non-commercial programs in evaluating station performance)
81 Children’s Television Report, supra note 3, at 39398-99, 50 F.C.C. 2d at 8-11. Under the FTC staff’s proposal. any program attracting an audience including a significant proportion of small children would be prohibited from carrying commercials. FTC Staff Report, supra note 9, at 10-11. Accordingly, in order to maximize profits, free-operating broadcasters would design programming in order to avoid attracting young audiences. Licensees admit that the removal of advertising from children’s television would result in decreased spending on, and declining quality of, programs aimed at children. In a statement to the FCC, the American Broadcasting Co. wrote:

A total ban or sharp curtailment of commercial advertising is self-defeating. The production of television programming is expensive. The removal or drastic reduction of advertising support would inevitably result in producers, directors, writers and talent withdrawing to devote their time and energies to more lucrative undertakings. Licensees in turn would be forced to select the least expensive program product for broadcast. The ultimate result would be an increase in low cost productions and a decrease in quality programming.
possibility in 1974 when it rejected the proposal of Action for Children's Television (ACT) to ban advertising from children's programming, the Commission concluded that "[b]anning the sponsorship of programs designed for children could have a very damaging effect on the amount and quality of such programming." The 1978 FTC Staff Report acknowledges the fear of the FCC, but it does not explore the possible ramifications of its decision. To ensure the quality of children's programming without the economic incentive of advertising, ACT's 1970 petition had recommended regulations requiring broadcasters to devote time to children's programming. Although the FCC refused to set such programming requirements, it noted that such "rules would, in all probability, have been necessary had we decided to adopt ACT's proposal to ban advertising from children's programs." The issue of mandatory children's programming has not been raised expressly in the current FTC rulemaking, but must be considered in light of the serious first amendment concerns raised. The FCC does have statutory authority to oversee "general program


FTC Staff Report, supra note 3, at 39399, 50 F.C.C. 2d at 11

FTC Staff Report, supra note 9, at 338-41. The FTC staff deferred comment on this suggestion and announced its intention to elicit comment from the FCC in the course of rulemaking proceedings. The staff did recognize, however, that the FCC could not sanction deceptive or unfair advertising, whatever the economic effects on the broadcaster, and the staff noted that under the 1934 Communications Act 47 U.S.C. § 309(a) (1970), as interpreted in the 1974 Children's Television Report, supra note 3, 50 F.C.C. 2d 1, the broadcaster was required to provide programming for children as a condition of its broadcasting license. As a result, the broadcaster could not completely eliminate children's programming for lack of commercial support. FTC Staff Report, supra, at 338-41

ACT proposed a regulation which would require broadcasters to provide no less than 14 hours of children's programs per week, and would require age-specific programming during specified hours. In requesting a mandated minimum number of hours for children's broadcasting, ACT's stated intention was to promote "more programs, more diversity, and a broader range of choice for the child audience." Rep. Comments of Action for Children's Television at 20. Action for Children's Television, F.C.C. Docket No. 19142 (filed June 2, 1978). In response to ACT's petition, the FCC announced that it would carefully consider whether licensees were making a good faith effort to air material for children. Children's Television Report, supra at 39397-98, 50 F.C.C. 2d at 6-7

The courts have acknowledged that proposed rules must not intrude too deeply into the realm of licensee editorial judgment. See, e.g., Action for Children's Television v. FCC, 564 F.2d 458, 490-91 (D.C. Cir. 1977), Straus Communications, Inc. v. FCC, 530 F.2d 1001, 1008, 1010-11 (D.C. Cir. 1975); Accuracy in Media, Inc. v. FCC, 521 F.2d 288, 296-97 (D.C. Cir. 1975); cert. denied, 425 U.S. 934 (1976).
CHILDREN’S ADVERTISING

format and the kinds of programs broadcast by licensees," 87 and has included children’s programming among the “major elements usually necessary to meet the public interest, needs and desires of the community.” 88 But to require a specified number of hours of non-commercial children’s television would disrupt the uneasy balance between the agency’s general affirmative duties and its recognition of the constitutional dangers inherent in government intervention in specific programming decisions. 89 The only means that could be employed to ensure some level of quality in children’s broadcasting would be the establishment of the government as an arbiter of quality. The FCC would, in effect, become a member of each station’s programming department, with ultimate responsibility for programming decisions. Such a policy would represent a far greater intrusion on the free speech rights of broadcasters than has ever been sanctioned by the courts. 90

Thus, several first amendment concerns militate against a ban on advertising directed at children: the interest of society in legal and

87 Children’s Television Report, supra note 3, at 39396, 50 F.C.C.2d at 3 (quoting Red Lion Broadcasting Co v. FCC, 395 U.S. 367, 395 (1969)). Since its inception in 1929 as the Federal Radio Commission, the Commission has stressed that programming must be varied in order to properly serve the public interest. Great Lakes Broadcasting Co. v. F.R.C. Ann. Rep. 32, 34 (1929). See id. for other grounds, 37 F.2d 995, cert. denied, 281 U.S. 706 (1930). However, the FCC has added that its designation of program categories (e.g., educational programming, political broadcasts, public affairs) is not intended to be a rigid schedule, but rather “the general character of programming to which licensees must conform in order to fulfill their public service responsibility.” Children’s Television Report, supra, at 39396-97, 50 F .C.C.2d at 4.

In dictum, the Supreme Court has endorsed the FCC’s policy as consistent with its authority to grant licenses in the public interest. Red Lion Broadcasting Co v. FCC, 395 U.S. 367, 393-95 (1969). The Red Lion majority wrote that the crucial interest in broadcast regulation is “the right of the public to receive suitable access to social, political, esthetic, moral and other ideas and experiences.” Id. at 390. In Columbia Broadcasting Sys., Inc v. Democratic Nat’l Comm., 412 U.S. 94 (1973), the Court stressed that in recognition of broadcasters’ first amendment rights FCC supervision should be limited to consideration of “whether a licensee’s overall performance indicates a sustained good-faith effort to meet the public interest.” Id. at 127. See generally Note, Regulation of Program Content by the FCC, 77 HARV. L. REV. 701, 704-06, 716 (1964). Note, The Listener’s Right to Hear in Broadcasting, 22 STAN. L. REV. 863, 868-81 (1970).

88 1960 Programming Inquiry, supra note 70, at 7295. 44 F.C.C. at 2314. The FCC has listed 13 other elements of programming necessary to serve the public interest: the opportunity for local self expression, the development and use of local talent, religious programs, educational programs, public affairs programs, editorialization by licensees, political broadcasts, agricultural programs, news programs, weather and market reports, sports programs, service to minority groups, and entertainment programming. Id., 44 F.C.C. at 2314


90 See Simmons, Commercial Advertising and the Fairness Doctrine: The New F.C.C. Policy in Perspective, 75 COLUM. L. REV. 1103, 1110 (1975). (making a similar argument against the application of the fairness doctrine to commercial advertisements.)
truthful advertising; the right of children to share in the first amendment freedoms of adults unless a compelling reason to restrict that right can be established; the right of advertisers to promote legal transactions truthfully, and the right of broadcasters to determine what advertising will be sent over the airwaves and to exert primary control over programming as part of a system which relies upon commercial revenues to motivate licensees.

The assertion of a presumptive right to broadcast children's advertising, however, by no means bars the FTC from regulating televised commercials directed at young audiences. If it can be shown that such advertising is deceptive, or that children are harmed by television commercials, then the balance might tip in favor of regulation. The presumption of constitutional protection should place a burden on the FTC to show that the proposed regulations are necessary to "cleanse" the airwaves.

C Time, Place, and Manner Restrictions

In a separate attempt to circumvent the first amendment protections accorded commercial speech in Virginia Pharmacy, the FTC Staff Report argued that the proposed ban should be characterized as a limited "time, place, and manner restriction." Although the regulation challenged in Virginia Pharmacy did not itself fit within this classification, the Court did note that it frequently had allowed such restrictions to be placed on otherwise protected speech provided that they served significant governmental interests and were narrowly tailored to further those interests. In a later case, Justice Powell expressed approval of such restrictions in the context of "pure" commercial speech, noting that "carefully tailored restrictions may be especially appropriate when advertising is accomplished by means of the electronic media." 94

92 FTC Staff Report supra note 9, at 296-95.
94 Carey v Population Servs Int'l, 431 U S 678, 712 n 6 (1977) (Powell, J., concurring in part). Other Justices apparently shared Justice Powell's view that such a restriction might be
The Court has cautioned that such restrictions will be allowed to outweigh first amendment protection "provided that they are justified without reference to the content of the regulated speech." Furthermore, the degree to which time, place, and manner restrictions intrude on the protected speech must be evaluated: the Supreme Court has refused to permit the imposition of time, place, and manner restrictions which totally deny access to the marketplace.

The FTC Staff Report does not detail the time and place restrictions to be imposed on broadcasters under the proposed rulemaking. Presumably, however, effective regulation would ban commercials during the late afternoon and early evening hours, when more than half of the television programs watched by small children are broadcast. But large numbers of older children and adults are also present in the viewing audience during this period. An effective

permissible, even when based on content. Justice Stevens wrote: "In the area of commercial speech, the offensive character of the communication is a factor which may affect the time, place, or manner in which it may be expressed." Id. at 716-17 (Stevens, J., concurring in part).

Virginia State Bd of Pharrmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. at 771 (emphasis added). The impact of the Court's language requiring that time, place, and manner restrictions be content-neutral is by no mean clear. The FTC argued that the Supreme Court has expressed a willingness to impose time, place, and manner restrictions that do take into account the content of the speech to be regulated. FTC Staff Report, supra note 9, at 290-95. In FCC v. Pacifica Foundation, 438 U.S. 726 (1978), the Court found that the content of certain speech justified its restriction to time periods when children would not be present in the audience. Id. at 749-51. Justice Stevens, speaking for a plurality of the Court, wrote broadly about classifications of speech based on content, concluding: "It is undisputed that the content of Pacifica's broadcast was 'vulgar,' 'offensive,' and 'shocking.'" Id. at 747. Justice Stevens was careful to distinguish content-based regulation of indecent language, which he found permissible, from regulation based on the ideas or beliefs that might have been expressed, which he found impermissible. Id. at 744-48. Accord. Young v. American Mini Theaters, Inc., 427 U.S. 50, 70-71 (1976) (plurality opinion), see id. at 86 (Stewart, J., dissenting) (indicating approval of content-based time, place, and manner restrictions in the limited context of a captive or juvenile audience).

In relying on these cases, however, the FTC Staff failed to note that they involved sexually explicit materials, which, unlike other forms of speech, have traditionally been subject to regulation on the ground of offensiveness. See note 60 supra, text accompanying notes 187-95 infra.

In Young v. American Mini Theaters, 427 U.S. 50 (1976), a sharply divided Court upheld a zoning ordinance restricting the location of 'adult' movie theaters but was careful to distinguish those cases in which a restriction on placement would totally deny access to the market to distributors or exhibitors of adult films. Id. at 82.

Noting that children under eight are almost never a majority of the audience. FTC Staff Report, supra note 9, at 329, the staff recommended that restrictions be of particular effect when younger children constitute more than X percent of the audience, and of lesser effect when less than X percent, id. at 330.

Fifty-one percent of the television watched by children under the age of six is broadcast between 4:30 p.m. and 11 p.m., when 61% of the audience at large is also watching. The number of children under six in the viewing audience "peaks" at 8 p.m., when over 40% of the small children who watch television are in the viewing audience. ASSF RESEARCH, supra.
ban on advertising broadcast to small children thus would also affect programming broadcast to viewers who are capable of evaluating commercial messages. In effect, then, the proposed ban would reach beyond the scope of the proffered justification of preventing the undue influencing of young children. The impact of the second staff proposal—a ban on ads for highly sugared foods seen by older children—is even more striking: thirty-six percent of the programming watched by children between the ages of six and eleven is shown during the evening hours.\(^\text{99}\) Twelve of the fifteen television programs most popular among older children are shown during "prime time."\(^\text{100}\) Twenty-five percent of the older children who watch television are still in the viewing audience as late as 10 p.m.\(^\text{101}\) In order to be effective, then, the FTC's proposal would have to approach an almost complete ban on television advertising for sugared products, an impermissible intrusion on the advertiser's constitutional rights.\(^\text{102}\) It would be impossible, therefore, for the FTC to draft time restrictions that would eliminate advertising to younger children without also restricting the flow of commercial messages to the rest of the market. Similarly, sugared foods could rarely be advertised on television at all if they could not be directed at older children. Finally, the proposed ban on television advertising for highly sugared foods also appears to violate the proviso that time, place, and manner restrictions be content-neutral,\(^\text{103}\) since it is based on the FTC's judgment.

Note 20 at 14-15, 17 The A. C. Nielsen Co.'s, whose statistics were used in the NSF report, subdivides the child audience into two groups—children aged 2-5 and children aged 6-11.\(^\text{Id.}\) at 12. Accordingly, the data for "small children" do not include the entire target group that would be affected by the proposed ban (children under eight). This is especially significant in light of other NSF data which suggest that six- and seven-year-olds are more likely than younger children to watch prime-time programs.\(^\text{Id.}\) at 18.\(^\text{99}\) Id. at 15-19 n. 8.

\(^\text{100}\) Id. at 19.

\(^\text{101}\) Id. at 13, 17.

\(^\text{102}\) In a situation analogous to the proposed ban, the Supreme Court held that Michigan's efforts to bar all sales of books "tending to the corruption of the morals of youth" violated due process because the regulation was not reasonably restricted to the evil the statute was designed to remedy. Butler v. Michigan, 352 U.S. 380, 381 (1957). The Court said that to purge the bookstores of material "not too rugged for grown men and women" in order to shield juveniles was to "burn the house to roast the pig."\(^\text{Id.}\) at 383. It might thus be argued that reducing the amount and variety of commercials broadcast to largely adult audiences in order to protect the sensibilities of children similarly violates the Constitution.\(^\text{Butler may be distinguished, however, while a less restrictive means of regulation—simply barring the sale of such materials to minors—was available to the state in Butler, the FTC cannot restrict small children's access to television in the early evening hours. See FCC v. Pacifica Foundation, 438 U.S. 726, 746-51 (1978).}
of the value of the product offered, and not the techniques employed in, or the placement of, the regulated advertisements. In short, the FTC's proposal is not the "carefully tailored" restriction called for by Justice Powell, but rather a blunderbuss which could broadly restrict all television advertising.

II

FTC Authority and the First Amendment

The Virginia Pharmacy decision and the cases which have followed it explicitly state that first amendment protection of commercial speech does not preclude regulation of false or misleading advertising. Such a conclusion is consistent with a balancing test approach to regulation: if false or misleading advertising has no first amendment value because the distribution of untruthful or confusing product information does nothing to promote informed decision-making, fair competition, or improved distribution of resources, then government regulations aimed at eliminating deceptive advertising should withstand a test which "assess[es] the First Amendment interest at stake and weigh[s] it against the public interest allegedly served by the regulation." Some untruthful, noncommercial speech may be protected by the free speech and free press doctrines, because the exclusion of all false speech from first amendment coverage would have a chilling effect on speakers. The Supreme Court has noted, however, that this consideration is not as compelling in the case of advertisers: since commercial speech is motivated by profits, there is less likelihood that regulations will chill truthful, protected advertising, and since advertisers, unlike other speakers, can

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104 See FTC Staff Report, supra note 9, at 122-56.
more readily substantiate their claims, implementing the regulations imposes no unreasonable burden.\textsuperscript{110}

What is unclear, however, is the breadth of the authority the regulators may draw from Supreme Court dicta. Because no Supreme Court commercial speech case since Virginia Pharmacy has involved federal regulation, the relationship between the FTC's statutory authority to regulate advertising and the dictates of the first amendment has not yet been established. Section 5 of the Federal Trade Commission Act empowers the FTC to define and limit "unfair or deceptive acts or practices in or affecting commerce."\textsuperscript{111} Under this broad mandate,\textsuperscript{112} the FTC has long exercised its power to proscribe untruthful and misleading advertising.\textsuperscript{113} The FTC has been permitted to characterize advertising as misleading even absent any actual cases of deception, rather, the test is whether a given advertisement is likely to deceive.\textsuperscript{114} Furthermore, it is not necessary for the FTC to find that the proscribed statement is likely to deceive a majority of consumers or even the average consumer. The Commission may prohibit an advertisement which would mislead "an appreciable or measurable segment of the public."\textsuperscript{115} To the extent that the Virginia Pharmacy decision allows federal regulation of misleading or untruthful advertising, then, the currently recognized scope of FTC statutory authority would also seem to survive first amendment scrutiny.\textsuperscript{116}


\textsuperscript{112} Both the Congress and the courts have stressed that the powers granted to the FTC were intentionally nonspecific in order to give the agency broad authority to ferret out and eliminate "unfair and deceptive" business practices in a manner that would not be possible under a clearer and more restrictive statute. S REP. NO. 597, 63d Cong., 2d Sess. 33 (1914), H.R. CONF. REP. NO. 1142, 63d Cong., 2d Sess. 19 (1914). See FTC v. Sperry & Hutchinson Co., 405 U.S. 233, 239-44 (1972), FTC v. R. F. Keppel & Bros., 291 U.S. 304, 310-14 (1934).


\textsuperscript{115} Fed. v. FTC, 285 F. 2d 879, 892 n.19 (9th Cir. 1960), see Aronberg v. FTC, 132 F.2d 165, 167 (7th Cir. 1942) (FTC standards are designed to protect "the ignorant, the unthinking and the credulous"). Bunnus Watch Co., 64 F.T.C. 1018, 1045 (1964) (Advertising held deceptive despite a poll that showed that only 14% of the audience was deceived), aff'd, 352 F.2d 313 (8th Cir. 1965), cert. denied, 384 U.S. 929 (1966).

\textsuperscript{116} This is not to say that Virginia Pharmacy will have no impact on FTC regulation. Given the newly recognized constitutional protection of commercial advertising, the FTC will bear a
CHILDREN'S ADVERTISING

The FTC has also sought to proscribe advertising that is "unfair" although neither untruthful nor deceptive. For example, in 1964 the Commission issued its "Cigarette Rule," which proposed regulations that would require that cigarette packaging and advertisements carry warnings highlighting the hazards of smoking. The FTC justified its regulations by claiming that "a method of selling violates Section 5 if it is exploitative or inequitable and if, in addition to being morally objectionable, it is seriously detrimental to consumers or others." In 1972, the Supreme Court, in dictum, approved the FTC's criteria for proscribing as "unfair" advertisements that may not be deceptive. However, the Supreme Court has never directly held that clear and truthful advertisements may be banned because of their alleged unfairness. It is arguable that the unfairness standard imposes a heavier burden of proving that a disruption of commercial communication is justified. See text accompanying notes 150-54 infra. Moreover, the courts have held that the FTC restrictions must have the least possible impact on protected speech. See text accompanying note 44 supra. These limiting factors should result in increased freedom for advertisers. See Coase, Advertising and Free Speech, 6 J. LEGAL STUD. 1, 33 (1977). But see Note, Yes, FTC, There is a Virginia Pharmarcy, Virginia Citizens Consumer Council, Inc. on the Federal Trade Commission's Regulation of Misleading Advertising, 57 B. U. L. REV. 833, 852 (1977) (arguing that "only advertising that a reasonable person could interpret as making a false assertion of material fact should be subject to regulation," and that the limiting dictum of Virginia Pharmacy suggesting that regulation of false or misleading advertising is permissible should be ignored).


118 Cigarette Rule, supra note 117, at 8355.

119 FTC v. Sperry & Hutchinson Co., 405 U.S. 233, 244 n.5 (1972), see Thain, supra note 4, at 659.

120 The Elman Letter, supra note 46, suggests that although the Supreme Court has not specifically allowed a ban on truthful advertising due to unfairness, nevertheless it does not intend to limit the FTC's authority to stop "unfair advertising" at 2-3. Moreover, the Court will have to decide what is the scope of unfair within the context of the FTC Act and the constraints imposed by the First Amendment. Id. at 3.

In 1978, the Supreme Court upheld a ban on direct solicitation by attorneys, despite the fact that such advertising was not necessarily deceptive or misleading. Ohio Bell vs. Ohio State Bar Ass'n, 436 U.S. 447, 464-68 (1978). However, the Court gave great weight to the argument that such solicitation poses a unique opportunity for deception because it cannot be supervised by bar officials. Id.

The Cigarette Rule was similarly based on considerations of "unfairness," however the rule was drafted before the Court recognized that first amendment protections extend to commercial speech. See note 164 infra.
used by the FTC to justify its proposed rulemaking is overly broad in the context of first amendment protection, and therefore exceeds the constitutional limits of FTC authority.

A. Deceptiveness

1. Small Children and Television Commercials

Each of the FTC staff’s proposed rules is supported by a separate argument concerning deceptiveness. The first rule, calling for the banning of all advertisements “directed to, or seen by, audiences composed of a significant proportion of children,” seeks to prevent deception caused by the exploitation of those listeners too young to understand and evaluate commercial messages. Under this line of reasoning, if small children are incapable of understanding and evaluating advertisements, then such messages can hardly be said to contribute to informed decisionmaking. In addition, since parents, and not children, are really the principal purchasers, it is argued that advertising to children is really a means of selling to parents: advertisers bypass parents’ intellectual defenses to the commercials themselves and substitute miniature screaming salesmen, parroting television commercials.

The FTC staff recommendation was based on research findings summarized in the FTC’s rejection of an earlier proposed ban on televised “premium” advertising for children:

[The literature tends to support the conclusions that young children (1) fail to understand the nature and profit-making purpose of television commercials; (2) tend to trust and believe television advertising indiscriminately; (3) tend to recall only simple, concrete elements of commercials; (4) have difficulty distinguishing commercials from programs, and (5) tend to want whatever products are advertised on television.]

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121 Children’s Advertising Proposals, supra note 1, at 17060
122 FTC Staff Report, supra note 9, at 264-67.
123 See NSF RESEARCH, supra note 20, at 138-43; Note, Little Ears, supra note 20, at 1151; text accompanying notes 194-95 infra.
124 For example, the FTC Staff Report, supra note 9, argues that children’s requests for given brands of cereals and snack foods are frequently granted by parents Id. at 96-99. This contention is supported by studies discussed in the NSF RESEARCH, supra note 20, at v. 103-04. However, the NSF report also notes that no study of television advertising to children has yet determined its impact on the overall nutritional content of children’s diets. Id. at v. 108
125 Premium Report, supra note 4, at 15070 (footnotes omitted); see NSF RESEARCH, supra note 20, at 25, 27-28; FTC Staff Report, supra note 9, at 82-84, 221-28.
The FTC expressly cautioned, however, that the research results did not justify the conclusion that advertised "premiums," let alone all advertising directed at children, were inherently deceptive.

The FTC staff, in making its proposed regulations, relied on the FTC's authority to regulate deceptive advertising. This authority was recognized as early as 1934, when in FTC v. R.F. Keppel & Brothersthe Supreme Court approved the FTC's ban on an advertising technique that took advantage of children's naiveté by offering inferior candy at inflated prices through the use of an enticing packaging device. More recently, the FTC has used its regulatory powers to prohibit toy commercials which used sophisticated camera...
techniques to deceive children about a product's "lifelike" qualities and has ruled that certain Wonder Bread advertisements were false and misleading because they induced small children to believe that Wonder Bread produced extraordinary growth.

The FTC staff drew additional authority for the scope of its regulatory power from a provision of the Federal Communications Act which requires television and radio stations to clearly identify paid advertisements. The FCC had explained that this statute was intended to prohibit practices that conflicted with the public interest responsibilities of licensees: "an advertiser would have an unfair advantage over listeners if they could not differentiate between the program and the commercial message, and were, therefore, unable to take its paid status into consideration in assessing the message." If adults need protection from advertising which blurs the distinction between programming and commerce, the FTC staff argued, then children, who do not understand deception, should be protected from their own conceptual shortcomings.

Citations to precedent and a superficial application of the Supreme Court's balancing test, however, merely mask the scope of the FTC's proposed action. Primarily, the situations in which FTC regulation was sustained all involved advertising techniques which concealed the purpose of commercial messages or the deficiencies of products. Limitations on deceptive methods are wholly consistent with Virginia Pharmacy; by clarifying advertisements they foster communication of commercial information. The FTC's proposal, on the other hand, would not enhance communication, but rather eliminate it. Instead of regulating in the least intrusive manner, the FTC staff based on the basis of minimal evidence, proposed the broadest possible intrusion on the distribution of commercial information to children.

CHILDREN'S ADVERTISING

2. Implied Deception and the Hazards of Sugar

The FTC's second proposed ban, on commercials for highly sugared foods directed at children aged eight to eleven, also represents an unconstitutional extension of the FTC's statutory authority to regulate deceptive commercial practices. The staff argued that children's advertising is deceptive if it does not reveal all of the adverse information about the product—a type of "implied deception." Implied commercials for sugared foods are alleged to be deceptive not because they make positive statements claiming that eating sugar is healthful, but because they suggest that eating sugar is pleasant without mentioning its harmful side effects. This proposition threatens all advertisers, however, because it is not limited to children's advertising; the FTC's argument about sugared cereals could require all advertising to become a catalogue of consumer information, its selling purpose completely obscured. Furthermore, the FTC's proposal...
presents an expansion of currently recognized FTC authority. The courts have held that the FTC has only limited authority to find that advertisements are deceptive because of what they fail to say; in general, findings of alleged deception are upheld only when the omission renders the advertising claims untruthful.

In *National Commission on Egg Nutrition v. FTC*, the Seventh Circuit upheld an FTC cease and desist order which barred an egg producers' trade group (NCEN) from incorrectly alleging in its advertisements that there is no scientific evidence linking eggs to heart disease. The NCEN decision is consistent with the *Virginia Pharmacy* policy of careful line-drawing in regulation involving first amendment rights of advertisers. Advertisements may be found deceptive—and therefore constitutionally and statutorily subject to FTC sanctions—when they misrepresent some objective and material fact. NCEN's advertisements could be regulated, therefore, to the extent that they "categorically and falsely denied the existence of evidence that in fact existed." The extension of first amendment protection to advertising under *Virginia Pharmacy* would be worthless if the FTC were free to prescribe advertising simply because the advertisement is effective and the FTC finds the product it offers less than perfect. If, as the Seventh Circuit held in NCEN, the first amendment limits the FTC's power to order balancing statements to those instances in which a balancing statement is necessary to prevent [future] deception...

775 (1977) Under this scheme the use of the slogan "Coke adds Life" would be illegal, and the statement that "Pet Milk makes you happy," accompanied by the gleeful sounds of joyful children, probably would make that advertisement unfair since actual use of milk is substantially unlikely to generate similar displays of emotion. *Id.* at 776. It is difficult to distinguish this extreme view from the position taken by the FTC staff. *See also* Note, Psychological Advertising: A New Area of FTC Regulation, 1972 Wis. L. REV. 1097.

134 *E.g.*, FTC v. Simeon Management Corp., 532 F.2d 708, 715-16 (9th Cir. 1976) (weight reduction clinics not required to disclose that drugs utilized in treatment were not approved by the FDA). *Albetti v. FTC*, 182 F.2d 36, 39-40 (D.C. Cir. 1950) (advertisers not forced to disclose the limitations of an iron supplement).

135 *Id.* at 157 (7th Cir. 1977), cert. denied, 99 S. Ct. 86 (1978).

136 *Id.* at 164.


138 *Id.* at 163. The NCEN argued that its advertisements constituted the expression of the group's opinion on a controversial public issue. Such an opinion, it argued, had "higher" constitutional value than mere commercial speech and therefore was more resistant to regulation. *Id.* at 162-63. The court rejected this argument, finding that the advertisements were "made for the purpose of persuading the people who read them to buy eggs." *Id.* at 163.
or correct the effects of past deception," then it must be similarly unconstitutional to bar advertisers from merely representing their products in a favorable light.

3. Overly Broad Regulation

Although the extension of first amendment rights to commercial speakers does not protect deceptive advertising, courts have held, after Virginia Pharmacy, that regulations of deceptive speech must be narrowly drafted and closely examined. Prior to Virginia Pharmacy, the FTC had broad authority to reach conclusions about the effects of advertising and the propriety of remedies, and courts could upset FTC orders only if they were "unsupported by substantial evidence" or "arbitrary, capricious, [or] an abuse of discretion." The extension of constitutional protection to advertising has raised the standard of review, however, allowing the FTC to impose prior restraints on advertising only when they are "reasonably necessary to accomplish the remedial objective of preventing the violation."

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147 Id. at 164 (citations omitted).
148 See text accompanying notes 106-07 supra.
149 See Standard Oil Co. of Cal. v. FTC, 577 F.2d 653, 660-63 (9th Cir. 1978), Beneficial Corp. v. FTC, 543 F.2d 611, 618-20 (3d Cir. 1976), cert. denied, 430 U.S. 983 (1977).
150 See Bigelow v. Virginia, 421 U.S. 809, 815-19 (1975) (indicating that the statute struck down on other grounds might also have been subject to an overbreadth attack).
151 Although the extension of constitutional protection to advertising has raised the standard of review, however, allowing the FTC to impose prior restraints on advertising only when they are "reasonably necessary to accomplish the remedial objective of preventing the violation."
152 See text accompanying notes 106-07 supra.
A restriction on advertising will be upheld only to the extent that it effectively cures deceptiveness. Given the evidence that methods of advertising to children are not deceptive, and that the deceptiveness deemed "inherent" in advertising directed at children may be eliminated by less restrictive means, it is apparent that the first amendment demands a case-by-case analysis of children's advertisements and does not permit sweeping regulation of an entire class of advertising.

The FTC's first proposal assumes that all advertising directed at children aged eight to eleven is necessarily misleading, and that no regulation short of an outright ban can cure its deceptiveness. The National Science Foundation (NSF), however, suggests that certain techniques, such as separation devices which would clearly differentiate commercials from programming, the requirement of simplified language to communicate nutritional information, or the use of more effectively posed disclaimers, might cure much of the alleged deceptiveness of advertising directed at small children.

Problems of overly broad application similarly plague the second proposal, a total ban on advertising of highly sugared products. As argued above, "implied deception" is not a constitutionally acceptable basis of regulation. But even if the FTC's implied deception argument were to support some regulation of deceptive advertisements for sugared foods, it would hardly justify the broad ban suggested by the FTC's second proposed regulation. This proposal fails to consider the deceptiveness of individual methods and advertisements and instead concludes that all advertising methods which are now...
employed or might potentially be used to sell highly sugared foods are incurably deceptive.\textsuperscript{158} The better remedy would be to promulgate regulations to correct each allegedly deceptive practice.\textsuperscript{159}

The available research does not support the broad reach of the proposed regulation, on the contrary, the NSF has noted that "there is . . . preliminary evidence indicating that information about the nutritional content and value of food products can be effectively communicated to children . . . within commercials,"\textsuperscript{160} and has recommended further research to discover the most effective means of teaching children about the nutritional consequences of their diets.\textsuperscript{161} In proposing the broad ban, the FTC staff relied on an argument it had made to support its 1967 proposals for regulation of cigarette advertising:\textsuperscript{162} as in the case of cigarette commercials, the staff argued, the cumulative effect of the barrage of sugared food advertising had been to establish "a barrier to adequate knowledge and appreciation of the health hazards."\textsuperscript{163} The FTC broadly regulated cigarette advertising as a class but it did not ban cigarette advertising. Instead, it proposed health warnings to counteract the

\textsuperscript{158} See id. at 332. But see Premium Report, supra note 4, at 15072 (FTC resolved to proceed against advertising directed at children on a case-by-case basis).

\textsuperscript{159} The FTC has frequently invoked, and the courts have approved, the remedy of affirmative disclosure to correct deceptive advertising. E.g., Ward Labs., Inc v. FTC, 276 F.2d 952 (2d Cir.) (advertiser required to disclose that baldness remedy was effective for only one relative, although stress was not a form of baldness), cert. denied, 364 U.S. 827 (1960); Firestone Tire & Rubber Co. v. FTC, 256 F.2d 246 (5th Cir.) (advertiser required to mention effect of various operating conditions on tire), cert. denied, 377 U.S. 950 (1966).

\textsuperscript{160} NSF RESEARCH, supra note 20, at 107. See id. at 104-05. Evidence in the FTC Staff Report revealed that the techniques employed by television commercials might be used to educate children. Report cites Joan Ganz Cooney, President of the Children's Television Workshop, who explained that Sesame Street and The Electric Company, were designed to teach commercials, in order to successfully educate children. FTC Staff Report, supra note 9, at 79 n.96.

\textsuperscript{161} NSF RESEARCH, supra note 20, at 108. More strikingly, though, the proposed regulation seems to overlook the fact that parents and schools, not television commercials, should play the primary role in teaching children what and when to eat. Studies have suggested that if parents have more authority about nutrition, they would supervise their children's eating habits more closely. See Glancey-Reburn, Hayes & Neill, Children's Behavioral Responses to TV Food Advertisements, 6 J. Nutrition Educ. 93-98 (1974) (research revealed that children of mothers who had knowledge of the validity of nutritional claims to such food advertisements were less interested in the advertised foods); see NSF RESEARCH, supra, at 142.

\textsuperscript{162} FTC Staff Report, supra note 9, at 173 (explaining Cigarette Rule, supra note 117, at 8357).

\textsuperscript{163} Id. at 173-74.
cumulative harm of industry advertisements. The present proposal to ban television advertisements for highly sugared products goes far beyond this measured means of regulation.

Finally, the overbreadth of the FTC's ban on advertisement of sugared foods is revealed by its third proposal—the requirement of "nutritional and/or health disclosures" to balance advertisements for less-highly sugared foods. If the less intrusive remedy of disclosure will cure the alleged deceptiveness of advertisements for products whose sugar content falls below some cut-off point, then the argument that no amount of disclosure could cure the alleged deceptiveness of commercials for products with slightly more sugar is difficult to accept.

B. Unfairness

In 1972, the Supreme Court cited with approval the "Cigarette Rule" criteria developed by the FTC to proscribe business and advertising practices which, although not "false and deceptive," were "unfair":

"(1) whether the practice, without necessarily having been previously considered unlawful, is within at least the penumbra of some common-law, statutory, or other established concept of unfairness; (2) whether it is immoral, unethical, oppressive, or unscrupulous; (3) whether it causes substantial injury to consumers (or competitors or other businessmen)."

The FTC and FCC orders mandated public health advertising and warnings to balance advertisements for cigarettes. Following the ruling in Banzhaf, cigarette smoking declined nationally for the first time. Fearful of invoking antitrust liability, cigarette manufacturers could not unilaterally stop broadcasting cigarette commercials, and thereby eliminate the widespread "balancing" public health announcements. However, the industry's lobbyists did prevail upon Congress to ban cigarette advertising on radio and television, and thereby cut down on the effective antismoking advertising. See Capital Broadcasting Co v. Mitchell, 333 F Supp. 582, 587-90 (D.D.C. 1971) (flagging J. dissenting), aff'd mem. sub nom Capital Broadcasting Co. v. Acting Attorney Gen., 405 U.S. 1000 (1972).


165 Children's Advertising Proposals, supra note 1, at 17969.

Neither the FTC nor the Supreme Court has determined whether all three of these factors must be present to support a finding of unfairness. Both Congress and the Court have stressed, however, that unfairness is a flexible concept, and that the FTC may serve "like a court of equity" in weighing business practices against the public interest.

However, the FTC staff may have exceeded this "equitable authority" by claiming that even if children's advertisements are not deemed to be deceptive, they should be banned under the FTC's authority to halt unfair business practices. As will be shown, advertisements directed at young children may not be proscribed constitutionally, under either the unfairness criterion or the unscrupulousness criterion absent a showing of serious harm to consumers. Furthermore, the threat to health allegedly present in advertisements for sugared products is not great enough to justify the broad sanction proposed in the FTC Staff Report.

1. Children's Commercials and Unfairness

To justify its first proposal—to ban all commercials on programs seen by young audiences—the FTC staff asserted that, under the Cigarette Rule criteria, television advertising directed at young children may be proscribed as unfair even if it is not deceptive. The staff argued that a marketing practice which enables adult advertisers to employ vast financial resources and clearly superior knowledge to exploit the gullibility and perceptual deficiencies of small children is "immoral, unethical, oppressive or unscrupulous," and therefore comes within the FTC's statutory power to regulate. For authority, the staff relied off the common law doctrines of voidability of minor's contracts and attractive nuisance, which provide that...
children may not be lured into commercial transactions or potentially harmful situations.\textsuperscript{176}

In cases subsequent to the 1964 cigarette rulemaking, the FTC has indicated that under the proper circumstances, it might accept its staff’s “unfairness” argument as a basis for stopping certain forms of advertising to children. For example, in \textit{ITT Continental Baking Co.}\textsuperscript{177} the FTC complaint suggested that Wonder Bread advertisements might be unfair because they led children to believe that Wonder Bread had extraordinary growth producing qualities.\textsuperscript{178} The Commission declined to rule on the unfairness issue, however, striking down the advertisements on the alternate ground that they were false and misleading.\textsuperscript{179} The FTC has never used unfairness alone as a ground for banning truthful advertising, and has given serious consideration to unfairness only when the third Cigarette Rule criterion—a threat of substantial injury to consumers—has been present.\textsuperscript{180} For example, in a situation analogous to the current rulemaking, the FTC approved a consent agreement barring as unfair and deceptive the advertising of vitamins to children.\textsuperscript{181} Significantly, the FTC’s ruling on vitamin advertising was based in large part on the fear that such advertisements posed a serious health threat because they encouraged children, too young to understand the dangers of overdose, to take medications.\textsuperscript{182} In the current rulemaking,

\textsuperscript{176} See \textit{id.} at 206-18.
\textsuperscript{177} 83 \textit{F.T.C.} 865, modified, 83 \textit{F.T.C.} 1105 (1973), modified and enforced, 532 \textit{F.2d} 207 (2d Cir 1976).
\textsuperscript{178} \textit{id.} at 960-61.
\textsuperscript{179} \textit{id.} at 963-64.
\textsuperscript{180} The use of unfairness as a basis for the protection of vulnerable groups such as children has been criticized as paternalistic. Moreover, “standards for what constitutes ‘exploitation’ of ‘vulnerable’ groups will be exceptionally elusive.” Pitofsky, \textit{Beyond Nader: Consumer Protection and the Regulation of Advertising}, 90 \textit{Harv. L. Rev.} 661, 684 (1977).
\textsuperscript{181} See Memorandum to Commission: Television Vitamin Advertising Addressed to Children, at 20 (filed Feb 22, 1972); Thain, \textit{supra} note 4, at 664 (noting that “the FTC has steadfastly refused to explore and implement the full scope of its authority to impose blanket prohibitions against certain kinds of advertising . . . under the ‘unfairness’ rubric”); Reed & Coalson, \textit{supra} note 140, at 781-82 (1977) (acknowledging that the FTC has authority to regulate advertising that is unfair to consumers, but that it has focused instead on regulation of advertising that is deceptive).
\textsuperscript{182} Hudson Pharmaceutical Corp., 89 \textit{F.T.C.} 82, 86, 87-88 (1977).
\textsuperscript{183} See \textit{id.} at 86. In subsequent cases, the “unfairness” standard has been used as a basis for FTC action against advertising that threatened an immediate and substantial injury to children’s health. \textit{E.g.}, \textit{Uncle Ben’s, Inc.}, 89 \textit{F.T.C.} 131, 132-33 (1977) (advertisements depicting unsupervised children cooking rice discontinued); \textit{General Foods Corp.}, 86 \textit{F.T.C.} 831, 838 (1975) (advertisements implying to children the safety of eating wild berries and plants banned); \textit{Philip Morris, Inc.}, 82 \textit{F.T.C.} 16, 17 (1973) (distribution of sample razor blades in newspapers halted as posing immediate hazard, particularly to young children). The Cigarette Rule, from which
however, the FTC staff has not claimed that all advertisements directed at small children pose an immediate or serious threat to their audience. The FTC's unwillingness to rely solely on the first two elements of its three-pronged "unfairness" test, absent a showing of harm, is explicable in light of the first amendment concerns raised by Virginia Pharmacy: without harm to consumers or competitors, reliance on the two remaining criteria—whether the advertisements are within the penumbra of a common law doctrine or are unscrupulous—is equivalent to saying that advertisements may be banned if they are offensive. And while a finding of offensiveness may seem

the unfairness standards have been derived, also involved a known and substantial health hazard. See Cigarette Rule, supra note 117, at 8353-54, text accompanying note 209 infra. Finding of substantial physical or economic injury to consumers has been the key element used by the staff to justify each of the FTC's proposed rulemakings based on the unfairness doctrine. E.g., Staff Statement of Fact, Law and Policy in Support of the Proposed Rule and in Support of Alternative Disclosure in Food Advertising, 39 Fed. Reg. 39852, 39858 (1974) (failure to disclose nutritional information is an unfair practice because "while nutritionally sound food choices do not ordinarily pose an imminent danger to health, they quite clearly do affect health adversely if they are habitual"). Posting of Minimum Octane Numbers on Gasoline Dispensing Pumps, 36 Fed. Reg. 23871, 23875-77 (1972) (failure to disclose octane ratings induced consumers to pay higher prices and to risk damage to their cars by buying higher octane gasoline than they needed), Trade Regulation Rule, Care Labeling of Textile Wearing Apparel, 36 Fed. Reg. 23883, 23889 (1972) (failure to disclose care information resulted in undue economic injury).

One commentator has suggested that the finding of a substantial injury to consumers should be a necessary element of any "unfairness" standard, for without such a requirement the doctrine would become too indefinite and expansive. See Schwartz, supra note 167, at 27-28. In dealing with the alleged "substantial injury" to children, the FTC Staff Report discussed only conclusions about the harmful aspects of eating sugared foods. FTC Staff Report, supra note 9, at 190-94. The staff further alleged that television damages the parent-child relationship by fostering conflict id. at 195-203. These alleged injuries, however, are not as serious as those threatened by the potential of vitamin overdose, by razor blades placed in Sunday newspapers or by poisonous roots—the injuries in which the FTC has banned advertisements as endangering the health of children. See note 182 supra. Indeed, the NSF has noted that there is no evidence that directly links televised advertising of sugared products to deficiencies in children's nutritional health. NSF Research, supra note 20, at v. And the NSF has suggested that research may show that the interactions between parents and children induced by television commercials have a beneficial impact on child development. id. at 130-31. 142.

182 The notion of unfairness absent deception or a proven economic or physical hazard is not unknown. In Pfizer, Inc., 81 F.T.C. 23 (1972), the Commission wrote that it was an unfair practice for an advertiser who made a claim for a product without having a "reasonable basis" for such claim id. at 62-64. Although the charge against Pfizer was dismissed because the evidence was inconclusive, id. at 73, the FTC nevertheless established the "reasonable basis doctrine" under which it now requires support for all product claims. Id. at 64. The issue is not whether the advertisement misrepresents the performance of the product, but whether the advertiser's actions are reasonable, and the evidence upon which such actions were based is adequate. Factors to be considered in evaluating reasonableness include (1) type and specificity of the claim made, (2) type of product advertised, (3) consequences of a false claim, (4) degree of reliance by consumers, and (5) type and accessibility of evidence. Id. For a detailed discussion of
to be an acceptable basis for prescribing speech under the FTC's current statutory authority.\textsuperscript{185} the Supreme Court has established that offensiveness alone is not a constitutionally permissible basis for banning commercial speech.\textsuperscript{186}

Some authority for banning "offensive" advertising directed at children might be drawn from the Supreme Court's recent decision in \textit{FCC v. Pacifica Foundation}.\textsuperscript{187} The Court held that offensive words may constitutionally be banned from the airwaves when it is likely that children are present in the audience.\textsuperscript{188} The Court rejected Pacifica's argument that the airwaves may not be censored absent a showing that the speech is obscene or harmful to children, deciding instead that "when the Commission finds that a pig has entered the parlor, the exercise of its regulatory power does not depend on proof that the pig is obscene."\textsuperscript{189} Since broadcasters receive the least first amendment protection, especially when the speech being broadcast is offensive, the government may regulate such speech on the airwaves to protect the sensitivities of children.\textsuperscript{190}

\textsuperscript{185} As noted in the FTC advertisement substantiation program, see Note, \textit{The FTC Ad Substantiation Program}, 61 Geo. L.J. 1427 (1973). The Pfizer doctrine has been criticized as unfair to advertisers because, under its expansive scope, they may be forced to conduct testing to substantiate truthful and nonoffensive claims in instances in which the cost of testing may far surpass any benefit to society. Pfizer, supra note 179, at 683, see Reich \textit{Consumer Protection and the First Amendment A Dilemma for the FTC}, 61 Minn. L. Rev. 705, 728-29 (1977).

\textsuperscript{186} Federal Trade Commission Act \S 5. 15 U.S.C. \S 45 (1976); see text accompanying note 172-73 supra.


\textsuperscript{188} 438 U.S. 726 (1978).

\textsuperscript{189} \textit{Id. at} 749-50.


\textsuperscript{191} 438 U.S. at 750-51.
The broad language of *Pacifica* does not justify a ban on "offensive" advertising to children, however. In the case of pornography and indecent language, the claim of the regulators is that it is the content of the speech which is harmful to young audiences; but, in the case of children's advertising, there is no proof that the speech itself is injurious to children. Instead, it is asserted that unfair advertisements will induce children to demand and consume products that are not in the child's best interest. But parents are stationed between their children and the alleged harm. The speech itself is not harmful, but merely communicates to children information that their parents are free to either act upon or ignore. In this situation, there is no justification for the government to step in.

Some support for FTC authority to ban truthful advertisements under its "unfairness" power may be found in *Ohralk v. Ohio State Bar Association*, a recent Supreme Court decision upholding a state ban on in-person solicitation by attorneys. In *Ohralk*, the Court recognized that such solicitation may be, an effective means of distributing information about available legal services, but...
nevertheless concluded that the method was especially susceptible to
abuse. The likelihood that attorneys would use such solicitation to
mislead their prospective clients, and the possible serious ramifications of these actions, justified banning the method itself.31

Advertising directed at young children is, to some extent, similar
to the solicitation into Ohralik, like the attorney who uses his superior
knowledge and persuasive powers to browbeat an accident victim who
may not be in full control of his powers of reason, the advertiser
can be construed as the home through an electronic device to entice children
whose reasoning powers may also be limited.32 The case against children's advertising is not sufficiently like the case against Albert
Ohralik, however, to justify a broad ban. Children under the age of
eight are not the decisionmakers, it is their parents who decide what
will and will not be bought.

2. The Advertisement of Sugared Products

Unlike its first proposal, the FTC's second proposal, to ban all
advertising of sugared foods seen by children,33 did allege actual
substantial harm to consumers. Since sugared food consumption
poses the most serious dental health risk, the FTC staff claimed
that a ban on advertising of these products would be justified under
the third Cigarette Rule criterion.34 Much of the Staff Report

31 Id. at 460-62. In a more recent case, the Court upheld a ban on optometrists' use of trade
names, a form of commercial speech, because of the significant possibility that such a practice
would be used to deceive customers about the quality of services Friedman v. Rogers, 99 S.C.
32 The FTC staff suggests that the alleged unfairness of advertising directed to children may
be exacerbated by the use of television—an electronic medium especially suited to hold the
attention of young audiences. FTC Staff Report, supra note 9, at 83-85. See R. Shusterman
33 FTC Staff Report, supra note 9, at 11
34 Id.
35 Id. at 190-94. See text accompanying note 106 supra. It is arguable that even if the alleged
danger of sugar consumption present a sufficient basis for someone to regulate the advertising
of sugared products, they do not justify FTC regulation. The FTC has no apparent authority to
regulate either the consumption of sugar or the amount of sugar that may be allowed to food
products. The authority to regulate adulterated or misbranded food is vested in the Food and
infra. And Congress, in its discretion, may set a national policy regarding sugar consumption.
Accordingly, the FTC's effort to turn its own judgment about sugared foods into a national
policy against sugar consumption seems to exceed its statutory authority, first amendment con-
on advertising for legal abortions was beyond the scope of the state's direct authority to influence
the behavior of its citizens, and was therefore entitled to little weight in a constitutional balanc-
ing test).
CHILDREN'S ADVERTISING

focuses on medical evidence that the consumption of sugared products promotes tooth decay and, when it reaches the point of excess, obesity and diabetes. But several problems are raised by this argument. Certainly the government has the power to regulate the sale and distribution of products that pose a health threat. It is unclear, however, how great a threat and how serious an injury must be present to justify a ban on speech.

The FTC staff found considerable support in Congress' 1969 ban of broadcast advertising for cigarettes, upheld in Capital Broadcasting Co. v. Mitchell. However, even if a congressional ban on broadcast advertising for cigarettes was warranted, it does not follow that the FTC may similarly ban commercials for sugared products. As the FTC itself argued when it passed the Cigarette Rule, the ban on cigarette advertising does not justify similar action against sugar, because the long-term harmful effects of sugar consumption result only from abusive overeating, while cigarettes are habit-forming drugs which pose an intolerable threat to health even when used in moderation. Thus, it is clear, in the context of the constitutional balancing test, that the threat posed by cigarettes justifies a higher degree of interference with protected rights than do the alleged dangers of sugar consumption. The state interest in pro-

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104 FTC Staff Report, supra note 9, at 105-56
105 Id. at 268-71
108 Id. at 584
109 Cigarette Rule, supra note 117, at 8361-62. To dispute the assertion that the Cigarette Rule might be unduly expanded to require affirmative disclosures in advertising for a number of consumer products, the FTC argued that the documented evidence clearly linking smoking to heart disease and cancer differentiated cigarettes from other consumer products, including sugared foods. For purposes of the unfairness doctrine, id. at 8361-63. The FTC did not intend that if some day become established that consumption of any of these foods (including sugared products) is as dangerous as cigarette smoking, remedial action by the Trade Commission, the Department of Agriculture, or some other agency might be appropriate. Id. at 8362.
110 The FTC staff now argues that changing scientific views about sugar and its long-term impact on health vitiate the differentiation the Commission made in the Cigarette Rule. FTC Staff Report, supra note 9, at 174-75. However, the Department of Agriculture (USDA), which is responsible for safeguarding the health and well-being of the Nation's children in federally funded food programs, 42 U.S.C. § 1771 (1976), does not agree with the FTC that the case against sugar is so clear-cut. The USDA declined to ban sugared cereals from distribution in its "Special Supplemental Food Program for Women, Infants and Children," pending additional investigation, concluding that "there is some disagreement in the scientific literature regarding the correlation between various sugars and health problems." 42 Fed. Reg. 43210, 43212 (1977).
Protecting the public from treatable dental cavities is hardly as compelling as the need to control cancer.

The availability of other, less intrusive means of controlling sugar consumption also dictates against the constitutionality of the proposed ban. In Virginia Pharmacy, the Court recognized the legitimacy of the state's interest in holding pharmacists to high professional standards,210 but nevertheless concluded that a ban on advertising was not an acceptable means to effect that interest: "Virginia is free to require whatever professional standards it wishes of its pharmacists; it may subsidize them or protect them from competition in other ways.

But it may not do so by keeping the public in ignorance of the entirely lawful terms that competing pharmacists are offering."211. In the present situation, the government may also have other less restrictive options if it elects to conduct a war against sugar. One critic has suggested that sugar could be removed from the Food and Drug Administration's list of foods "Generally Recognized as Safe,"212 and that Congress could stop "subsidizing" sugar production, stop funding any school breakfast or lunch program that serves highly-sugared cereals, take candy out of school lunchroom vending machines, make highly sugared products ineligible for food stamp purchases, and, most directly, simply limit the sugar content of breakfast cereals and snack foods.213

The FTC Staff Report argued that the mandate of Virginia Pharmacy to use means of control other than complete suppression of commercial speech should not be applied to the proposed rulemaking on sugar because sugared product advertising is directed at children, whose reasoning powers are limited and who therefore have no interest recognized by the commercial speech doctrine.214 But the FTC cannot rationally distinguish Virginia Pharmacy on the basis of the difference between adult and child audiences: the ban on advertising for highly sugared products is not focused on commercials directed at very young children, whose conceptual and perceptual
difficulties were discussed above, but on those directed at older children, who, according to the FTC staff’s own report, do understand the selling purpose of commercials and are more likely to be skeptical of advertised messages.

What emerges, then, is a difficult balance. On one side is the FTC’s duty to protect consumers from unfair business practices or physical harm; but against this duty must be weighed the first amendment rights of advertisers to disseminate commercial information. To the extent that the ill effects of unfair practices are shown, the Commission should be free to regulate unfairly manipulative advertising practices, and perhaps ban them altogether, when the potential hazards are so great and so likely to occur that an individualized consideration of particular commercials would be ineffective. That case, however, has not been made against children’s advertising. The FTC’s assertion that all advertisements directed at small children are unfair or unhealthful is certainly contrary to the policy of careful line-drawing required by the constitutional doctrine which prohibits the silencing of protected speech merely because it offends the sensibilities of some members of society.

CONCLUSION

Unpopular speech frequently poses difficult first amendment questions, and children’s advertising is no exception. Each side of the debate is charged with emotional issues that make any constitutional balance difficult to strike. The FTC’s popular crusade against children’s advertising is filled with assertions that would expand the Commission’s power to promulgate content-based regulations of advertising. In an effort to protect children, the Commission has drafted a report which, if accepted, would enable it to broadly interfere with commercial speech on several fronts in an unprecedented manner. Such an expansion, in the form of a broad assault on an entire class of speech, cannot be upheld if the constitutional protection recently extended to commercial speech is to remain meaningful.

This does not mean that the FTC is powerless to regulate advertising directed at young audiences. The FTC has longstanding authority to control advertising techniques that prey on and mislead the

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215 See text accompanying notes 121-25 supra.
216 FTC Staff Report, supra note 11, at 78-91 (indicating that children’s ability to differentiate between programming and commercials, and to understand the selling purpose of advertising, increases with age), see NSF RESEARCH, supra note 20, at 27-32.
public by deceptive assertions and omissions. The commercial speech cases make it clear, however, that the role of regulators is to preserve communication in the marketplace, and to ensure that advertisements are clear and truthful. Any regulations premised on the assumption that the proper detergent for cleansing the flow of commercial speech is silence violate both the letter and the underlying policy of the commercial speech doctrine.
The Current Status
Of Comparative Advertising

STEPHEN W. BROWN
DONALD W. JACKSON, JR.

Advertisers warn us not to confuse the Ford Granada with a Mercedes-Benz and they ask us to compare the shave of the Remington razor with that of any razor blade. These are examples of comparative advertising—the practice of naming a competing product in an advertisement and making a direct comparison.

Comparative advertising has touched off considerable controversy in the advertising industry. Some leaders vigorously support the practice while others condemn it. Victor Bloede, Chairman of Benton and Bowles, says "There is nothing wrong with sliming' names. It is neither illegal nor immoral. And it isn't even fattening. " Tracy Western, Director of the FTC Bureau of Consumer Protection, commented on the charge that comparison advertising is confusing. He feels "confusion is a higher state of knowledge than ignorance." Stanley I. Tennenbaum, Chairman of Ken- nedy and Ehardt, views comparative advertising as "advertising's own brand of consumerism."

Strong opposition to these favorable opinions has also developed, however. One of the most outspoken critics is Andrew G. Kershaw, Chairman of the Board of Ogilvy and Mather. He views the comparisons as extremely damaging to advertising's credibility and possibly destructive to the free enterprise system due to the loss of respect for business. Jack Roberts, also of Ogilvy and Mather, warns that comparative advertising may turn business into a "carnival brand name shooting gallery."

Although many firms have always used comparative messages in their personal selling efforts, the practice of using comparative messages in advertising is relatively new. The purpose of this article is to explore the area of comparative advertising with special attention to the regulatory environment, the use of this form of advertising, the strategies used to compare products, and the effectiveness of the technique.

ENABLING CONDITIONS

Comparative advertising has been used for many years. In the early 1950s, for example, Plymouth challenged the consumer to compare their car with the "big 3." However, prior to the 1970s, many advertisers shied away from comparative advertising despite the absence of any regulations against it. Perhaps this was due to an unwritten code of honor within the advertising industry.
ARIZONA BUSINESS

The AAAA issued a "Policy Statement and Guidelines for Comparative Advertising," in April 1974. Basically, the provisions required that (1) The advertisement should inform and not discredit others. (2) The advertisement should name only significant competitive product features. (3) The advertisement should not discredit others. (4) The advertisement should not bias results. (5) All claims must be supported, and full results must be reported as to not lead consumers to improper conclusions based on partial and biased results.

In addition to the AAAA Policy Statements, a Television Code was developed that has allowed comparative advertising since January 1974, as long as the comparisons are fair. A Radio Code has also been developed, which asks that comparisons be "confined to specific facts rather than generalizations or conclusions." ABC has written its own set of Comparative Advertising Guidelines that are similar to the AAAA Policy Statements. The print media has no current regulations in this area.

Regulations

Regulating comparative advertising is still very difficult despite these recent advances. Before a commercial can be shown on any network, it must be reviewed by that network's own clearance staff for taste and ac-

For advertising. Their 1962 revised Standards of Practice recognized that "keen and vigorous competition, honestly conducted, is necessary to the growth of American business" and that advertising is part of this. It also mentions the potential for weakened public confidence should unfair competitive practices begin. The Creative Code, which is enforced by the AAAA and several other organizations and industries, includes a statement against "comparisons which unfairly disparage a competitive product or service." Until recently, CBS and ABC felt that just naming names constituted disparagement.

The AAAA was deeply concerned with comparative advertising and has had numerous committees study the subject. Policy statements were published in 1966, 1967, 1968, and all of them tended to discourage comparison advertising. It was not until 1974 that their position changed.

Statement of Policy

In 1974, the Federal Trade Commission (FTC) began taking steps to encourage comparative advertising, hoping to provide more tangible product information to consumers and also to open up a new range of creative marketing strategies. The FTC staff suggested that consumers might be able to make better product choices by knowing the identity of the competing brands and that this would also benefit the consumer. Comparative advertisements on all networks in late 1974. Robert M. Paddock, Director of Consumer Protection, led an 11-member group in writing a series of letters explaining the situation and asking that CBS and NBC accept comparative advertisements on their networks. NBC already allowed comparative advertisements, but few were shown. That was because of the restrictions on advertisers making a comparative advertisement against NBC's and another non-comparative advertisement. Comparisons may be shown on ABC at 7 p.m. and 11 p.m. The FTC suggested that by allowing comparative advertising would become similar to Consumer Reports in the offering of comparative product information.

There were also concerns that unless non-comparative advertisements might be considered a restraint of trade. It was not allowed to hold feelings about their presence, because the FTC had no authority to introduce new products into the market; because the use of brand X and helped competitors open new opportunities, instead of the consumer, the FTC had to consider that comparisons did not change the sales of the products. In short, these helped open up new era of corporate advertising, resulting from comparative advertising programs. This encouragement for comparisons was not without controversy, however. The American Association of Advertising Agencies (AAAA) has attempted to keep advertising standards high in order to build industries.
of this last type is a recent deodorant advertisement in which a woman says "I'm throwing out my old Secret. New Secret!" Products produced by the same company. An example of this last type is a recent deodorant advertisement where a woman says "I'm throwing out my old Secret. New Secret!"

Television Advertising

When the broad definition was used, the study found that 22 percent of observed television advertisements could be classified as comparative in nature.

COMPARATIVE ADVERTISING

That percentage goes down to 4.6 percent. However, when only strictly comparative advertisements are counted, these account for only about 1 percent of total advertising time. Thus, the controversy about comparative advertising is not limited to a relatively small amount of advertising.

The researchers were also interested in whether any products were most often associated with comparative advertising. They found that over-the-counter drugs were the most commonly compared items. Some of the products include aspirin, cold tablets, allergy pills, and sleeping aids. Several other products found to be moderately associated with comparative advertisements were "household products, food, consumer durables, and personal care products."

Another question investigated by the study was the nature of the comparisons. It was found that 80 percent of the time, quality was compared; price was compared only 12 percent of the time. It was suggested that this may be due to the fact that price is more difficult to control and in dollars basic fluctuations and thus may not be suitable for national media.

MAGAZINE ADVERTISING

Comparison advertising in magazine articles was observed in another study by Jackson, Brown, and Harmon. The basic question asked was again in regard to nature and frequency. Comparison advertising was also investigated in conjunction with the type of magazine in which it was found.

Four different types of magazines were used in the study, covering areas of general editorial (Reader's Digest), women's (Ladies' Home Journal) and business (Newsmaker). A range of fifteen years was covered by observing magazines in 1960, 1965, 1970 and 1975. Definitions used in the study were very similar to those used in Brown and Jackson's study of television comparison advertising.

The frequency of comparative messages represents only 8 percent of the advertisements using the broad definition. If the strictly comparative meaning is used, the percentage falls to 1.2 percent. When these results are related to the frequency of comparative television advertisements, the low percentages are not too surprising. Over time, the frequency has increased moderately. In 1960 the number of total comparative advertisements was 0.2 percent; by 1975 it had increased to 0.8 percent. The implied category stayed fairly level over the years at approximately 0.7 percent, while strictly comparative advertisements increased from 0.4 percent in 1960 to approximately 3 percent in 1975.
In summary, thereby teasing the competitor's ad and sales, the consumer might not be able to identify the design be made available to anyone who wants order to deem them significant. Should the results and ur of test results How conclusive must the tests be in light of the results? Also, the consumer might not be able to identify which product is being promoted in a comparative advertisement. This could cause a domino effect, thereby increasing the competitor's sales.

EFFECTIVENESS

The effectiveness of comparative advertising is important both to the public and to the advertiser. Several
questions still need to be answered about comparative advertising.

Are comparative advertisements more informative, or are people just more likely to believe them simply because a comparison was made? Does comparison advertising lead to a clearer brand image, or can it backfire? Do the consumers’ prior beliefs make a difference in comparison advertising effectiveness? If they already prefer a competitor’s brand, what are the chances of swaying them over to the sponsor’s brand? Should seeing their preferred brand in a comparison have a negative effect on their attitude toward the sponsor’s product? Finally, does comparison advertising actually increase sales more than noncomparative advertising? Although several studies have been performed, the answers to these questions are not yet clear.

Generally, studies have shown no real differences between comparative and noncomparative advertising. Furthermore, when interactions with other variables are not considered, comparative advertisements are no better or worse than single product advertisements.

Brand Recall and Loyalty

The ability of an advertisement to leave the viewer with a solid memory of the product is usually referred to as brand recall. In a study by Levine, respondents were exposed to a number of sets of commercials containing various mixes of comparative and noncomparative advertisements. After each set, they were asked to recall as many brands as possible. Generally, identification of brands was not dependent on type of advertisement. In one case where differences did exist, comparatively advertised brands were recalled less often. In contrast, Prasad measured claim recall and found that subjects had a much higher memory of claims when comparative advertisements were viewed. Perhaps, as Maxie’s work indicates, this is because comparative advertisements are more active, aggressive, and interesting, thus causing higher awareness.

When another brand is mentioned, the possibility always exists of misidentification of the sponsored brand. Levine’s study supports this idea. Women exposed to comparative advertisements were significantly more likely to identify one of the competitive named brands as the sponsor brand than women exposed to noncomparative advertisements. This could lead to a higher awareness of the competitor’s product than of the sponsored product.

If the consumer already prefers a brand, comparative advertising against it may cause negative attitudes toward the sponsored brand. Golden found that brand loyalty was very important when explaining the variance in purchase intentions. It was found that the “degree of brand loyalty toward the sponsoring brand positively affects respondents’ purchase intentions.” Among subjects who had a prior preference for Kodak, Prasad found more negative attitudes toward a competitor brand regarding claim credibility than among subjects who did not have a prior preference for Kodak. He then recommends that advertisers be extremely careful in adequately substantiate all claims in order to boost public confidence in their advertisements.

Informativeness Value

Since information value was a prime reason for lifting the taboo on comparative advertising, it would be hoped that comparative advertisements are more informative than noncomparative advertisements. These direct comparisons give the consumer a specific standard with which to weigh purchase decisions between competing brands. Single product advertisements may not provide a basis for decision. A study by Pride, Lamb and Pletcher found that the effectiveness of comparative advertisements for producing feature awareness was not significantly different between the two types of advertisements. It was found, however, that moderately intense advertisements “create higher levels of perceived informativeness” than do low intensity advertisements.

Perusiveness

Along with informative value and brand recall, persuasiveness is a major concern to advertisers. Do comparison advertisements really persuade consumers to try a product? Again, Levine’s study finds no significant increase in brand choice when the product was comparatively advertised. Specific commercials were found to be more persuasive than others, but this did not depend on whether the ad was comparative or not. Levine did find that persuasive value of a commercial increased significantly if it was the only comparative one shown in a group of commercials. This suggests that novelty is a factor. As long as comparative advertisements remain a small part of total advertising, the persuasive value may be greater.

Studies basically show that negative attitudes are associated with comparative advertising. People are skeptical of advertisers’ claims because they do not believe that the tests are conducted fairly.

McDougall
Although there are a minority of respondents who do hold positive attitudes towards comparative advertising, there are those who do not. In this study, though, that Mett are a minority of respondents who did hold positive attitudes towards it. Some positive benefits can be derived from comparative advertising. If done fairly and honestly, the consumer may really benefit from the increased information allowing better buying decisions. Comparative advertising may also encourage innovation and fair competition, also benefiting the consumer.

On the negative side, possibility of deception always exists. Perhaps the biggest problem is the opportunity to use only selective data in the advertisements. Few advertisers would conduct test results that were negative toward their own product. Few design can be constructed so as to give the desired product an edge over the competitor. One solution to this problem is to create an independent test center that screens all comparative ad claims before they are released. This obviously would be very expensive. Another solution would be to have strict regulation and heavy penalties for deceptive ads and distorted test results. Another negative factor might be the possibility of consumer confusion caused by exposure to competing advertisements.

From the advertiser's viewpoint, comparative advertising may allow a small company to benefit from association with the industry leaders, may allow products benefits to be more clearly differentiated, and may force firms to be more progressive and innovative. On the negative side, there is the possibility of loss of credibility for the firm, a boomerang effect, and the questionable effectiveness of the technique.

When considering using comparative advertisements, a firm should follow Wilson's suggestions: First, nontrivial attributes must be compared. Second, well-documented evidence should be obtained on which to base all claims. Third, comparisons should be of a moderate intensity and among brands with which the advertiser directly competes. Finally, all measures should be taken to avoid sponsor misidentification. This includes displaying the sponsor's name prominently and early in the advertisement. If these cannot be met, the advertiser would do well, in light of available evidence, to follow a traditional type of advertisement.
COMPARATIVE ADVERTISING

NOTES


In recent years the Federal government has increased its role in ensuring that the American public's safety and health are not impaired by the introduction or use of toxic substances in consumer products. The U.S. Congress has enacted numerous laws to establish the control of and protection from toxic substances not only in consumer products but also in air and water. These laws have included protection from exposure to substances that may cause cancer (carcinogens).

Laws to regulate toxic substances have been difficult to implement due to their reliance on scientific evidence to determine whether or not, among other effects, a substance poses a carcinogenic risk to humans. Science is not a static discipline. Its dynamic nature forces policymakers to make decisions based on "the best available evidence," and each of the laws enacted has included guidelines based on the state of scientific knowledge at the time it was passed.

This inconsistent method of controlling exposure to hazardous substances has led to disparate and confusing methods to evaluate the risks of a substance's use in a variety of exposures. Some of the laws explicitly state how the "risks" associated with a substance must be weighed against the benefits derived from the use of that substance. The methods of testing, however, are left to the appropriate administrator to decide. Other laws allow regulators to determine only the risks associated with a substance: they allow no use of discretion by the regulators.

In the wake of public outcries over proposed regulation of such products as saccharin and nitrites, Federal regulators and the Congress are currently evaluating their policies and laws with regard to carcinogenic substances. The Federal agencies responsible for regulating toxic substances have moved to coordinate their criteria for determining the potential carcinogenic risk posed by a substance. The Congress has begun to explore alternatives to existing toxic substances laws.

Many issues have arisen in these efforts to set standards for testing and marketing products which contain substances with carcinogenic properties. These questions include: (1) Should Congress amend or repeal current laws requiring absolute safety in the marketing of consumer products? (2) Have these laws become outdated due to further advances in scientific knowledge? (3) Should Congress make policy judgments in regard to risks associated with consumer products, or are these decisions better handled by scientists? (4) Who should be responsible for determining an acceptable level of risk of exposure to carcinogens—Congress or the Federal agencies? (5) Is standardization of testing substances for carcinogenic properties feasible, given the controversies over differences in sources of exposure, appropriate routes of
administration, high-risk populations, extrapolation of experimental animal results to humans, and the inadequacies of epidemiological studies? These are some of the complex scientific and policy questions that need to be answered. The following articles have been selected to illustrate several viewpoints on these questions. More general articles are also included for use as points of departure and background.
Controlling Toxics

By Truman Temple

Exactly 100 years ago Peter Collier, the chief chemist at the U.S. Department of Agriculture’s Division of Chemistry, decided to do something about the rampant adulteration of foods in the United States. A hodgepodge of State laws provided scant protection. Collier saw the need for Federal action and drafted a bill to provide it.

During the next 25 years more than 100 bills were introduced in Congress to cope with the situation. A handful of measures were approved around the turn of the century dealing with the problem in piecemeal fashion, but the most significant action came in 1906 with enactment of the Pure Food and Drug Act and the Meat Inspection Act. These were the first important Federal laws in this country dealing with “toxic substances,” for they sought to prevent the distribution of consumer products that contained, for one reason or another, some very potent poisons. Prompted in part by illness and death among U.S. troops who had eaten contaminated meat during the Spanish-American War, and by a series of articles and books on abuses in the meat-processing and patent medicine industries, the laws enabled the government to proceed in Federal courts against adulterated food preservatives. They halted numerous abuses in interstate commerce.

They provided food processors with the incentive to seek better sanitation and sterilization. But the growth of many industries in the 20th century involving chemicals made it clear that other legislation would be needed and the Federal Government’s regulatory role broadened. The Federal Food, Drug and Cosmetic law was rewritten in 1938 and updated periodically. In addition, many other laws dealing with toxic substances were enacted. Ultimately, five major Federal agencies were involved in regulating some 15 different laws on the subject of toxic substances.

By the most active period for legislation was the decade in the 1970’s. Measures enacted by Congress during this period have been prompted by widespread public concern over environmental damage, by the consumer protection movement, for lawsuits, and by advances in medicine that revealed the need for preventative steps to shield the public from harmful chemicals. Rather than costly clean-up activity after the damage has been done, Part of this philosophy reflected a shift in emphasis within the medical profession in dealing with cancer. More physicians and research professionals felt that more emphasis should be placed on keeping dangerous chemicals out of man’s environment rather than on the “cure” approach. Outlining this view was the widely-circulated Surgeon General’s report that had linked cigarette smoking with lung cancer, heart disease, and other ailments.

The Environmental Protection Agency has played a prominent role in administering many of the new laws dealing with various aspects of toxic substances. TSCA’s creation in 1970. The most directly involved in the implementation of these laws, of course, is the the Toxic Substances Control Act (TSCA) and the Resource Conservation and Recovery Act both enacted in 1976. Others dealing with toxic substances are the Clean Air Act, the Clean Water Act, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) of 1972, and the Safe Drinking Water Act of 1974. (Control of toxics under the Clean Air Act is described elsewhere in this issue.)

One of the first problems that confronts someone grappling with this arena subject is: What is toxic? From a medical point of view, just about everything is toxic if taken in large enough quantities. As the 18th century physician, Paracelsus, has put it: “All things are poisons, for there is nothing without poisons qualities. It is only the dose which makes a thing poison.” It is because toxins can be so broadly defined and so pervasive in our advanced technology, that many agencies and laws are involved in controlling them. However, much of the focus in identifying and controlling toxic substances today is on those that may cause chronic and irreversible health effects, cancer, birth defects, and gene mutations.

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The Resource Conservation and Recovery Act deals with wastes when they are in the form of hazardous wastes being disposed of by society. The 1976 law directs EPA to identify hazardous wastes taking into account such factors as toxicity, persistence, degradability, potential for biodegradation, leachability, and toxicity. It provides for facilities treating, storing, and disposing of such wastes. EPA is developing comprehensive regulations for hazardous waste management, including guidelines for the development of State hazardous waste management programs. The Act also authorizes EPA and State officials to inspect facilities, copy records, and demand samples to enforce requirements.

The Clean Water Act controls the discharge of toxic pollutants into navigable waters by means of effluents. Under the 1972 Federal Water Pollution Control Act, EPA established national limits on the discharge of such pollutants in navigable waters. Under the Clean Water Act, any industry that discharges its wastes into a publicly-owned treatment plant must use treatment methods so efficient that it does not interfere with the plant's operation. A more detailed article on this subject appears on page 17 in this issue. EPA published a list of 85 toxic pollutants last year and may add to the list as authorized by the law. Each toxic pollutant listed is subject to effluent limitations, using best available technology for clean-up.

Finally, the Safe Drinking Water Act of 1974 authorizes the protection of drinking water supplies from contamination by toxic substances through national drinking water standards. The Act calls for studies of contamination by cancer-causing chemicals, a task in which EPA is undertaking a major role. Federal regulation of toxic substances is not wholly the responsibility of EPA; in addition to the Food and Drug Administration, which administers the Federal Food Drug and Cosmetic Act, and the Federal Insecticide, Fungicide, and Rodenticide Act, there are several other agencies involved in this area. The Department of Labor's Occupational Safety and Health Administration (OSHA) has responsibilities for setting permissible levels of exposure for toxic substances in the workplace. It enforces these levels through workplace inspections and provides training and education concerning dangers posed by toxins to workers. The major law under which OSHA functions is the Occupational Safety and Health Act of 1970.

The Consumer Product Safety Commission is responsible for protecting the public from unreasonable risks of injury from consumer products, some of which may be chemical. The Commission derives its authority from the Consumer Product Safety Act of 1972, the Federal Hazardous Substances Act and the Poison Prevention Packaging Act of 1970. Some other laws less closely related to toxic substances. Also, the Food Safety and Quality Service, established by the Secretary of Agriculture in 1977, oversees the quality of meat, poultry, eggs, and egg products to ensure that they are safe to eat and properly labeled.

Other Federal agencies also have a hand in the way toxic substances are managed (see box). The Department of Transportation, for example, regulates the LEGISLATIVE AUTHORITIES AFFECTING THE LIFE CYCLE OF A CHEMICAL

Continued on page 19
**TV Documentary on Toxic Substances Available for Public Television**

The Southern Education Communications Association, under a grant from EPA's Office of Public Awareness, has produced a one-hour television documentary on toxic substances titled "Serpent Fruits."

SECA is a public education network of 160 stations in 50 southern states. The film was linked to the Public Broadcast System satellite in June and thereby made available to all public television satellites in the country for either simultaneous or later use.

"Serpent Fruits" documents the case histories of three individuals whose lives were dramatically affected by chemical poisoning. The first is a woman who was stricken with leukemia and had to have a hysterectomy at the age of 21 because her mother had used a drug called DES to prevent miscarriage during pregnancy.

The second describes the case of a young woman who suffered miscarriages, each within two months of the spraying of the herbicide 2,4,5-T near her residence in the Oregon forest. Over the years she had had four miscarriages. After use of this herbicide was suspended in that state she gave birth to a normal son.

The third history concerns a former employee of a plant that manufactured polybrominated biphenyls (PBBs) and who did not use a mask, coveralls, or other protective measures. Two years ago he had to leave work because he was too weak to stand up. In describing his failing health, he angrily reminds that his body contained too much PBBs if he were a Cow he would be shot by the State of Michigan.

The film also features discussions by scientists and industry representatives on the variability of applying animal test results to humans and the difficulty of balancing risks against benefits in society's attempts to regulate toxic substances.

The film was produced by the prize-winning firm of Richter McBride Productions, Inc., of New York. Writer-producer was Robert McBride. The television documentary was accompanied by the distribution in supermarket racks of a Women Voters' pamphlet entitled "A Toxic Substances Primer." A one-half-hour version of the documentary is being made available as a 16 mm film to schools and community organizations through Modern Talking Pictures Service, Inc., 3223 New Hyde Park Road, New Hyde Park, N.Y. 11040.

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**Federal Laws Dealing with Toxic Substances**

<table>
<thead>
<tr>
<th>Source</th>
<th>Responding Agency</th>
<th>Sources Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxic Substances Control Act</td>
<td>EPA</td>
<td>EPA regulations on manufacture and use of toxic substances</td>
</tr>
<tr>
<td>Class Air Act</td>
<td>EPA</td>
<td>EPA regulations on hazardous air pollutants</td>
</tr>
<tr>
<td>Federal Water Pollution Control Act</td>
<td>EPA</td>
<td>EPA regulations on water pollution</td>
</tr>
<tr>
<td>Safe Drinking Water Act</td>
<td>EPA</td>
<td>EPA regulations on drinking water contaminants</td>
</tr>
<tr>
<td>Federal Insecticide, Fungicide, and Rodenticide Act</td>
<td>EPA</td>
<td>EPA regulations on pesticides</td>
</tr>
<tr>
<td>Federal Insecticide, Fungicide, and Rodenticide Act</td>
<td>FDA</td>
<td>FDA regulations on food additives</td>
</tr>
<tr>
<td>Act of July 27, 1954 (Food, Drug, and Cosmetic Act)</td>
<td>FDA</td>
<td>FDA regulations on food, drugs, and cosmetics</td>
</tr>
<tr>
<td>Resource Conservation and Recovery Act</td>
<td>EPA</td>
<td>EPA regulations on hazardous waste</td>
</tr>
<tr>
<td>Marine Protection, Research, and Sanctuaries Act</td>
<td>EPA</td>
<td>EPA regulations on ocean dumping</td>
</tr>
<tr>
<td>Food, Drug, and Cosmetic Act</td>
<td>FDA</td>
<td>FDA regulations on food additives</td>
</tr>
<tr>
<td>Food additives amendment</td>
<td>FDA</td>
<td>FDA regulations on food additives</td>
</tr>
<tr>
<td>Color additives amendment</td>
<td>FDA</td>
<td>FDA regulations on color additives</td>
</tr>
<tr>
<td>New animal drug amendments</td>
<td>FDA</td>
<td>FDA regulations on new animal drugs</td>
</tr>
<tr>
<td>Muscle relaxant amendments</td>
<td>FDA</td>
<td>FDA regulations on muscle relaxants</td>
</tr>
<tr>
<td>Whitehouse Pest Control Products Act</td>
<td>USDA</td>
<td>USDA regulations on pest control products</td>
</tr>
<tr>
<td>Wholesome Poultry Products Act</td>
<td>USDA</td>
<td>USDA regulations on wholesome poultry products</td>
</tr>
<tr>
<td>Occupational Safety and Health Act</td>
<td>OSHA</td>
<td>OSHA regulations on workplace safety and health</td>
</tr>
<tr>
<td>Federal Hazardous Substances Act</td>
<td>CPSC</td>
<td>CPSC regulations on hazardous substances</td>
</tr>
<tr>
<td>Consumer Product Safety Act</td>
<td>CPSC</td>
<td>CPSC regulations on consumer products</td>
</tr>
<tr>
<td>Poison Prevention Packaging Act</td>
<td>CPSC</td>
<td>CPSC regulations on poisoning prevention packaging</td>
</tr>
<tr>
<td>Lead Based Paint Poison Prevention Act</td>
<td>CPSC</td>
<td>CPSC regulations on lead based paint poisoning prevention</td>
</tr>
<tr>
<td>Hazardous Materials Transportation Act</td>
<td>DOT (Maritime Transportation Bureau)</td>
<td>DOT (Maritime Transportation Bureau) regulations on hazardous materials and transportation</td>
</tr>
<tr>
<td>Federal Railroad Safety Act</td>
<td>DOT (Federal Railroad Administration)</td>
<td>DOT (Federal Railroad Administration) regulations on railroad safety</td>
</tr>
<tr>
<td>Pipeline Interstate Pressure Safety Act</td>
<td>DOT (Interstate Pipeline Safety)</td>
<td>DOT (Interstate Pipeline Safety) regulations on pipeline safety</td>
</tr>
<tr>
<td>Dangerous Cargo Act</td>
<td>DOT (Interstate Pipeline Safety)</td>
<td>DOT (Interstate Pipeline Safety) regulations on dangerous cargo</td>
</tr>
</tbody>
</table>

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**Sources**

- EPA (Environmental Protection Agency)
- FDA (Food and Drug Administration)
- CPSC (Consumer Product Safety Commission)
- DOT (Department of Transportation)
Controlling Toxics

Continued from page 15

Hazardous Materials Transportation Act

The many laws and regulatory agencies governing toxins have yielded concern both in industry and government over the complexities of administration. In response to this problem, a comprehensive agreement two years ago created the Interagency Regulatory Liaison Group (IRLG), which now shares the knowledge and resources of five Federal agencies working to control hazardous exposure to toxins throughout our society. The five agencies of EPA, OSHA, FDA, Consumer Product Safety Commission, and the Food Safety and Quality Service. The turmatron of this coordinating unit was redirected towards a process by President Carter to eliminate costly waste and duplication in government.

Through the IRLG, the five agencies are developing compatible testing procedures and a common approach to the problem of assessing cancer risks posed by toxic substances. When possible, they are coordinating their research as well as their efforts to keep the public informed about hazards to health and safety.

An example was the report "Hazardous Substances" issued late last year describing actions four of the agencies are taking to protect workers and the public from illness caused by pesticide manufacture and handling of 24 chemical compounds. Our cooperative efforts, explained Dr. Eve Bingham, Assistant Secretary of Labor for OSHA, mean that the government is now aware of what the right is doing about these compounds. Instead of duplicating one another's work or perhaps even subtracting one more unit, we are sharing information and results in issuing comprehensive standards, and conducting joint research studies to control the dangers from heavy metals and pesticides.

Another example of interagency coordination was brought about by the EPA, OSHA, and FDA in 1977 to protect farm workers and the general public from possible dangers of the pesticide dichlorodiphenyltrichloroethane (DDT). The agencies set emergency standards to limit body residue, proposed suspension of crop applications and other uses, and monitored food to make sure the public was not ingesting unsafe amounts of the substance. The IRLG carries out its coordination at the headquarters level in several ways. The heads of the agencies and other senior agency officials meet frequently, and a special senior official group oversees coordination efforts. Interagency work groups and task forces deal with specific issues and projects.

As Administrator Douglas Costle commented on the IRLG's operations, the result has been an effective team force which can develop testing standards and guidelines, conduct epidemiological studies, and risk assessment and share information. Our goal is to act as one entity in addressing important interagency issues.
An Overview of How the FDA Regulates Carcinogens Under the Federal Food, Drug, and Cosmetic Act

By EDWARD J. ALLERA

Mr. Allera is Associate Chief Counsel for Food, Food and Drug Administration, Department of Health, Education and Welfare.

I. INTRODUCTION

THE FOOD AND DRUG ADMINISTRATION (FDA) regulates three principal categories of products: food, drugs, and cosmetics; and the agency encounters and consequently regulates carcinogenic substances in each category and in the numerous subcategories of these products. As with the carcinogens, the statutory provisions by which the FDA regulates these substances are varied. The most noted is the "Delaney Anticancer Clause," but the Federal Food, Drug, and Cosmetic Act actually contains three Delaney Clauses. And these clauses apply only to three product subcategories: food additives, color additives, and new animal drugs. The Federal Food, Drug, and Cosmetic Act provides a scheme of premarket safety review by the FDA for these products. But the FDA regulates many products that are not subject to premarket review by the Agency that may contain a carcinogenic substance and that are not subject to a Delaney Clause, such as cosmetics, drugs subject to the over-the-counter (OTC) drug review, and food with added poisonous or deleterious substances such as aflatoxins. Conversely, it regulates one group that is subject to premarket approval but not a Delaney Clause—new human drugs.

Therefore, regulating carcinogens under the Federal Food, Drug, and Cosmetic Act is not simply a matter of concluding that a test...
compound is a carcinogen in test animals and, without more, banning
the substance from food, drugs, and cosmetics. Many more issues
must be considered and decisions made. To illustrate the intricacies
and the inconsistencies of dealing with carcinogens under the Act, I
will begin with a discussion of the Delaney Clauses and then proceed
to a discussion of the other criteria and procedures that the FDA uses
to regulate carcinogens in foods, drugs, and cosmetics.

II. LEGISLATIVE HISTORY OF
THE DELANEY CLAUSE

is a remedial statute designed to protect consumers and the public
from dangerous products, and one fundamental aspect of this public
protection function is to assure that all food additives, new drugs, new
animal drugs, and color additives\(^1\) are rigorously tested by their manu-
facturers and found to be safe by the FDA before the public is exposed
to these articles or to food containing them. The basic Act was passed
in 1938 without these provisions for premarket testing. Rather, it pro-
hibited the use of "any poisonous or deleterious substances in food
which may render it injurious to health" and prohibited recommending
a drug for any use for which it is "dangerous to health." As a result,
Congress has amended it several times, specifically to deal with the
issue of safety of food to man, and each amendment has had the same
underlying rationale, that is, to protect the public from the addition
of articles to food that have not been shown to be safe by appropriate
tests before they are marketed.

A. Food Additives Amendment

In 1958, Congress enacted the Food Additives Amendment (Public
Law No. 85-929) to protect consumers by requiring substances that are
intentionally added to food, or may reasonably be expected to become
components or otherwise affect the characteristics of food, to be shown
to be safe through rigorous scientific testing procedures. As the legis-
lative history of the Amendment demonstrates, one primary function
was to protect the health of consumers by requiring manufacturers of
food additives and food processors to test any potentially unsafe sub-
stances which are added to food.\(^2\)

Before the Amendment, the FDA's authority for action was limited
to Secs. 402(a)(1) and (2)(A) of the 1938 Act, where it has the burden
\(^1\)21 U. S. C. 321(p), (s), (t), and \(^2\)H. R. Rep. No. 2384, 85th Cong., 2d
of showing that an intentionally added food substance may be injurious to health. This required the Agency to test the poisonous or deleterious substance before taking action. Therefore, the Amendment shifted both the burden of testing and proof of safety to the proponent of the additive. When the Interstate and Foreign Commerce Committee reported the bill to the full House, the bill did not contain an anticancer clause, but it did contain a specific section, requiring the premarketing testing of food additives to demonstrate "safety," which is now known as the general safety provision.8 After the bill was reported out, Congressman Delaney suggested the addition of the anticancer proviso to the bill, and the following proviso was added to the bill as a Committee amendment on August 13, 1958:

Provided that no additive shall be deemed to be safe if found to induce cancer when ingested by man or animal, or if it is found, after tests that are appropriate for the evaluation of the safety of food additives to induce cancer in man or animals.

Reportedly to assure enactment of the legislation, the Committee and the Department of Health, Education, and Welfare (HEW) agreed to the amendment, but in a letter to the Chairman of the Committee, then Assistant Secretary Elliot L. Richardson noted that the amendment did not change the meaning of the bill. The letter also illustrates the interaction between the general safety and anticancer provisions of the bill and the broad scope that the Delaney anticancer Clause is to be given.

This Department is in complete accord with the intent of these suggestions—that no substance should be sanctioned for use in food that might produce cancer in man. H. R. 13254, as approved by your committee, will accomplish this intent, since it specifically instructs the Secretary not to issue a regulation permitting use of an additive in food if a fair evaluation of the data before the Secretary fails to establish that the proposed use of the additive will be safe. The scientific tests that are adequate to establish the safety of an additive will give information about the tendency of an additive to produce cancer when it is present in food. Any indication that the additive may thus be carcinogenic would, under the terms of the bill, restrain the Secretary from approving the proposed use of the additive unless and until further testing shows to the point of reasonable certainty that the additive would not produce cancer and thus would be safe under the proposed conditions of use. This would afford good, strong public health protection.

B. Color Additive Amendments

The Color Additive Amendments (Public Law No. 86-618) were added to the Federal Food, Drug, and Cosmetic Act in 1960. These

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*21 U.S.C. 348(c)(3)(A).*

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AN OVERVIEW
Amendments require sponsors of color additives to demonstrate the safety of these additives before they can be approved by the FDA for addition to food, drugs, and cosmetics in accordance with the provisions of Sec. 706 of the Act (21 U. S. C. 378). In addition, the Amendments added another Delaney Anticancer Clause to the Act which is found in Sec. 706(b)(5)(B) (21 U. S. C. 376(b)(5)(B)).

The legislative history of the Color Additive Amendments describes the Congressional and executive (Department of HEW) concern about the potential carcinogenicity of these color additives; nevertheless, the Secretary of HEW again explained that an express anticancer clause was unnecessary to prevent approval of carcinogenic or potentially carcinogenic color additives because the general safety and anticancer provisions of the bill provide the same scope of public protection. During the House hearings, the Secretary also recommended the modification of the existing anticancer clause in Sec. 409 of the Act (21 U. S. C. 348) for food additives and the proposed anticancer clause in the color additive bill to permit the use of carcinogens in animals so long as no residues appear in any edible portions of animals. The Secretary, however, added two explicit caveats. The FDA would prescribe the reasonable but sound criteria for analytical methods to assure that no residues of the compounds will occur in food derived from food-producing animals given additives, and the industry would retain the responsibility of developing adequate analytical methods for detecting residues and furnishing the assay methods to the government.

Therefore, as enacted, the safety provisions of the Color Additive Amendments are basically identical to the Food Additives Amendment. A color additive shall be deemed unsafe, within the meaning of the various sections of the Federal Food, Drug, and Cosmetic Act for use in food, drugs, and cosmetics unless the Commissioner has issued a regulation which states that the additive has been found to be suitable and safe for a particular use. The sponsor has the burden of establishing the additive's safety. Although the Commissioner can exercise his scientific judgment in determining whether safety has been proved, he is expressly precluded from listing any additive for any use that has been found to induce cancer in man or animals.

But the statute also contains a transitional provision that provides for the continued use of commercially established additives to the extent

\[\text{FOOD DRUG COSMETIC LAW JOURNAL—FEBRUARY, 1978}\]
consistent with the public health. The provision is transitional pending completion of the scientific investigations needed as a basis for making determinations on the safety of the additive for permanent approval. The provisional list was to expire on January 12, 1963, or such later date as the Commissioner determined necessary consistent with the objective of carrying to completion, in good faith and as soon as practicable, the investigations needed for making the safety determination. The Commissioner has extended that date several times over the past decade while concurrently establishing testing requirements and periodic reports to assure that there is an orderly test ongoing that will resolve the safety questions. Technically, the provisionally listed colors are not covered by a Delaney clause.

C. Drug Amendments of 1962

The livestock industry expressed increasing concern about the problems caused by the anticancer clause in the food additive provisions because the FDA had interpreted the Food Additives Amendment of 1958 to require continuation of approval for diethylstilbestrol (DES) for use in cattle and sheep, but to preclude new approvals of this drug. In 1962 Congress was also considering legislation, which later became the Drug Amendments of 1962 (Public Law No. 87-781), to strengthen the FDA's ability to regulate the drug industry, and the Senate version of the bill was passed without considering any amendments to the Delaney Clause. The House Committee on Interstate and Foreign Commerce, however, included the current modifications of the anticancer clauses in its report on the Drug Amendments of 1962, with the following explanation:

The committee amended the anticancer clause of the food additives amendment and the color additive amendment of the Federal Food, Drug, and Cosmetic Act by making this clause inapplicable to chemicals such as veterinary drugs when used in feed for food-producing animals if the Secretary finds (1) that under the conditions of use and feeding specified in the proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (2) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations) in any edible portion of the animal after slaughter or in any food such as milk or eggs yielded by or derived from the living animal.

Representative Sullivan objected to the proviso in the floor debate on the amendments and proposed a separate amendment to delete the

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Id at 206.

AN OVERVIEW
proviso from the bill because "they [the provisos to the Delaney clauses] weaken instead of strengthen consumer protection." She reminded the House that DES had been regarded as safe for use in poultry at one time because no residue was found in the meat; subsequently, that use had to be terminated when DES residues were found as a result of improved testing methods. But her amendment was defeated principally on the argument that, if DES were available for manufacture by those who obtained approvals prior to 1958, it should be made available for manufacture by everyone. 18

The Senate accepted the modifications to the Delaney Clauses in conference while preserving, as Senator Humphrey noted, the full vigor of consumer protection afforded by the Delaney Clause. 18

D. Animal Drug Amendments of 1968

Because the animal feed industry experienced an era of unprecedented growth and innovation beginning in the 1950's, that industry and the animal drug industry began an effort in the mid-1960's to consolidate the various provisions of the Federal Food, Drug, and Cosmetic Act governing the premarketing approval of drugs intended for use in animals, that is Secs. 409, 505, 507 (21 U. S. C. Secs. 348, 355, and 357) which culminated in the enactment of the Animal Drug Amendments of 1968 (Public Law No. 90-399). Neither the Committee reports on the bill nor the floor debates raised the issue of the Delaney Clause. Consequently, the Animal Drug Amendments passed without controversy and contained the following anticancer clause and proviso:

(H) such drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, induces cancer in man or animal, except that the following provisions of this subparagraph shall not apply with respect to such drug if the Secretary finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice (i) such drug will not adversely affect the animals for which it is intended, and (ii) no residue of such drug will be found by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (c), (d), and (h)), in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals; (Sec. 101(H) Public Law No. 90-399).

Again the legislative history indicates that the legislation in no way weakens the FDA's authority to regulate new animal drugs. 14

18 Supra note 10 at 206-207.
E. Conclusion

Thus, the Delaney Anticancer Clause has been added to the Federal Food, Drug, and Cosmetic Act three separate times, and the proviso to that clause has been enacted twice. Through all these re-enactments, the purpose of the clause has remained unchanged. Each article covered is to be rigorously tested for carcinogenic potential before it can be approved for use. Carcinogenic, or potentially carcinogenic food additives and color additives are not to be approved for human use, and no article can be approved for use in food-producing animals unless the Secretary designates an assay method which will assure that no carcinogenic residue of the article will be found in food derived from food-producing animals that are given the drug. Finally, the criteria and procedures used to designate the assay method must be sufficiently comprehensive to protect the unwary public from any significant risk of cancer from the undetected residues of any article.

Nevertheless, several problems exist under the Delaney Clause which exemplify the problems the FDA faces in regulating carcinogens under the other provisions of the Act. Foremost, of course, is the DES proviso. No matter how rigorous the FDA’s assay evaluation and approval process, it is a fundamental law of analytical science that for every assay there is some lowest concentration below which the assay will not yield an interpretable response. Other than ingestion tests, Congress has provided no guidance as to what constitutes appropriate tests for carcinogenesis, or what actually constitutes a carcinogenic response. These problems also exist for ingestion tests. Lastly, Congress has exhibited a continued fondness for familiar carcinogens versus new ones, e.g., under Secs. 201(s)(4), 402(a)(1), and 406 of the Act.

With this in mind, let us now look at how the FDA is regulating carcinogens. Because questions about regulating carcinogens arise in the three basic groups of products that the FDA regulates, I will focus on foods, drugs, and cosmetics for the sake of simplicity rather than approaching the review strictly by statutorily defined articles.

III. FOODS

A. Introduction

By far the most labyrinthian category is foods because it is subject to regulation under several statutory provisions with differing rationales, legal standards, and procedures. Essentially, the regulation...
lated food ingredients can be divided into three groups based on their sources:

1. Natural constituents, such as Vitamin C in orange juice;
2. Unavoidable contaminants, such as aflatoxin in corn;
3. Intentionally added substances that become or may be reasonably expected to become components of food due to their intended use, for example, saccharin, acrylonitrile monomers, DES.

**B. Natural Food Constituents**

The Delaney Clause is inapplicable to natural constituents of foods, even if they are found to cause cancer in test animals. Therefore, a food naturally containing a constituent that may be carcinogenic is not automatically banned by the Act, for example, safrole in nutmeg. These foods are regulated by Section 402(a)(1) of the Act. Such a food is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.

This section has been interpreted by the courts; and under these decisions the FDA must demonstrate that the amount of a naturally occurring poisonous substance is sufficient to render the food in which it appears potentially unsafe for consumption. A showing of a reasonable possibility of causing harm to some segment of consumers is sufficient to support a charge of adulteration, but the risk must be more than a speculative one. Thus, although the FDA might contend that any amount of such a nonadded, that is, constituent, carcinogen is unsafe for at least a smaller number of consumers, the case law and language suggests that the Agency must show a potential harm to a segment of consumers above the normal "background level of consumption."

Historically, the FDA enforces Sec. 402(a)(1) principally through seizure or other court action because there is no legal mechanism for requiring the distributor of such food to seek prior FDA approval of the safety of the food or its constituents. Nor does the statute provide a procedure for administratively withdrawing permission to market foods with these naturally unsafe constituents, although the

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*United States v. Lexington Mill & Elevator Co., 232 U. S. 399 (1914).*

FDA could use its rulemaking authority under Sec. 701(a) to administratively ban a food.

C. Unavoidable "added" food constituents

A second class of food constituents are those that, although not naturally occurring in the sense of being inherent, occur unavoidably in the harvesting or production of many foods, most of them agricultural commodities such as grains, fish, meat, or milk. The most prominent recent example is aflatoxin mold on peanuts and grains, well recognized as carcinogenic in both test animals and man. The FDA has recently completed a rulemaking procedure establishing a formal mechanism for regulating these constituents.17

Such unavoidable constituents are not subject to a Delaney Clause because the Food Additives Amendment is inapplicable to them for two reasons. First, although the FDA has treated such constituents as "added" within the meaning of Sec. 402(a)(1) of the Act, they cannot be approved at any level under Sec. 409 because they serve no functional purpose, and a food additive must be functional before it can be approved.18 Second, the FDA has assumed that Congress did not intend Sec. 409 to apply to constituents whose addition to food, at least at some levels, is unavoidable. As the legislative history of the Food Additives Amendment clearly demonstrates, it was enacted to regulate ingredients added to food intentionally and to constituents, such as packaging materials, that become part of food through intentional use for other purposes.19

The apparent absolute adulteration, under Sec. 402(a)(1) of the Act, of any food containing any amount of an "added" poisonous contaminant, such as aflatoxins, is modified by Sec. 402(a)(2)(A), which provides that a food shall be deemed to be adulterated: "If it bears or contains any added poisonous or added deleterious substance . . . which is unsafe within the meaning of section 406 . . . ."

Section 406 of the Act thus provides a basic framework within which the FDA can regulate toxic constituents, including carcinogenic chemicals, whose occurrence in some foods at some levels cannot be avoided, and the agency has established a mechanism to implement this provision.20

Essentially, the FDA is empowered to establish tolerances for unavoidable toxic contaminants of food, including contaminants that

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18 21 U.S. C. 348(c) (4) (B); 21 CFR Part 170.
may be carcinogenic, and Sec. 406 prescribes two basic criteria for the FDA to use when establishing such a tolerance: (1) the level whose consumption will not pose an unacceptable risk to public health, taking into account other ways in which consumers may be exposed to the contaminant, and (2) the extent to which occurrence of the contaminant cannot be avoided through good manufacturing practice. If good practice can achieve lower levels than public health considerations would otherwise dictate, the FDA will presumably establish a tolerance at the lower level.

A third criterion, even though not explicit in the Act, is implicit in the FDA’s ability to set tolerances—the measurability of the contaminant. Realistically, the FDA cannot enforce a tolerance that is below the level of detection or measurement of the best practicable method of analysis available.

The Act prescribes elaborate formal rulemaking procedures for establishing tolerances under Sec. 406. Partly because of the complexity of this procedure for establishing formal tolerances under Sec. 406, the FDA has established a system for prescribing so-called “action levels” for unavoidable, added contaminants in food by notice and these action levels are the levels of contamination which will cause the FDA to initiate court enforcement actions under Sec. 402(a)(1). The criteria establishing action levels and tolerances are basically the same, although the Agency will only establish an action when technological or other changes might affect the appropriateness of a tolerance in the foreseeable or near future.

D. Substances that may reasonably be expected to become components of food or affect the characteristics of food.

There are five basic types of substances in this category: food additives (both direct and indirect), substances that are generally recognized as safe by qualified experts (GRAS), prior sanctioned substances, color additives, and new animal drug residues. All are food ingredients, but not “food additives” as defined by the Federal Food, Drug, and Cosmetic Act. The latter four types have been carved out of the statutory definition. Only three (food additives, color additives, and new animal drugs) are subject to premarket review and approval by the FDA, and only two of those (food additives and color addi-
tives) are covered by the flat prohibition imposed by the Delaney Clause, although GRAS substances are indirectly. Carcinogenic new animal drugs may be added to food if they satisfy the DES proviso to the Delaney Clause.

1. Food additives

a. Direct food additives.

A food additive is:

any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended uses (21 U. S. C. 321(s)).

Before any such ingredient may lawfully be used, it must be the subject of an approved food additive regulation, and the FDA may not approve a food additive unless it satisfies two criteria. First, it must have been shown to be safe under the conditions of its intended use. This requires a demonstration that, with reasonable certainty, the additive will not have adverse effects on the health of consumers, and, second, it must also be shown to be functional, that is, a preservative must preserve when used at the levels intended. However, it is covered by the basic Delaney Clause which flatly prohibits the approval (or requires the withdrawal of any outstanding approval) of a food additive that has been shown to induce cancer in man, or, through appropriate tests, in animals. By statute, ingestion tests are always appropriate.

The procedure for approving or withdrawing approval of a food additive is as complex as that for the establishment of tolerances under Sec. 406. It is a variant of formal rulemaking.

b. Indirect food additives

A wide variety of materials are used in contact with food—such as food packaging and in equipment used to produce food—in such a fashion that small amounts may migrate to and become a part of the food. The Food Additives Amendment did not distinguish between ingredients used in making food and materials that migrate to

AN OVERVIEW

412
food from food-contact surfaces. The latter are colloquially known as indirect food additives.

The basic statutory criteria for approval are the same for indirect and direct food additives, and the procedures for obtaining, or withdrawing, approval are identical. The Delaney Clause therefore applies to indirect food additives, and effectively prohibits the use in applications that might migrate to food of any substance that has been shown to cause cancer in laboratory animals.

The FDA's most recent decision in this area is a case involving acrylonitrile copolymers used to fabricate beverage containers (42 Federal Register 48528). The Commissioner concluded that the acrylonitrile monomer may reasonably be expected to migrate and thus become a component of food using an extrapolation model, based on the principle of diffusion and confirmed by actual migration data even though the migration cannot be analytically detected.

2. GRAS substances

Congress established an exception to the Food Additives Amendment for GRAS substances principally to exclude from the rigors of premarket review ingredients that have a long history of use in foods, without evident harmful effect, such as apples, salt, and sugar. The Act, however, provides no formal mechanism for determining GRAS status. It does however create two basic categories of GRAS substances: those currently recognized as safe based on their common use in food prior to 1958 and those recognized as safe by experts on the basis of tests conducted before or since 1958.

The FDA has always acknowledged that a food manufacturer may initially determine for itself whether an ingredient is GRAS, although it runs the risk that the FDA will disagree and initiate regulatory action. The regulations amplifying this section of the statute require quantity and quality of scientific procedures and evidence to attain GRAS status or are required to attain approved food additive status.

Because GRAS ingredients do not fall within the statutory definition of food additives, they are not subject to the Delaney Clause. In practice, however, the Delaney principle prevents the introduction or continued use of a GRAS ingredient found to cause cancer when ingested by laboratory animals because such a finding will almost
certainly destroy any basis for general Expert recognition of an ingredient's safety and thereby render it a food additive. FDA approval is then required, and this would be precluded by the Delaney Clause. This is essentially what occurred to cyclamates in 1970.

Soon after the passage of the Food Additives Amendment, the FDA issued, and from time to time amended, a non-exclusive list of ingredients that the Agency was prepared to acknowledge as GRAS, and thus eligible for use without affirmative FDA approval. Because the Act makes no provision for the transition between GRAS status and approval as a food additive, the FDA has issued a regulation,\textsuperscript{21} establishing procedures for issuance of interim food additive regulations. An interim food additive regulation may be issued for an ingredient whose safety is brought into question but whose continued use, pending the conduct of the studies necessary to resolve the safety issues, poses no significant risk to human health.

The FDA also has established a program for reviewing the safety of GRAS ingredients and for "affirming" the GRAS status of individual substances.\textsuperscript{22}

3. Prior sanctioned ingredients

The Food Additives Amendment also contains a grandfather clause for ingredients that the FDA or U. S. Department of Agriculture (USDA) had affirmatively approved prior to the effective date of the Amendment.\textsuperscript{23} Although the FDA lacked formal authority to license food ingredients at that time, it responded to requests for opinions about the safety of individual ingredients. In addition, the USDA had issued regulations describing permitted uses of many ingredients in meat and poultry products, and in some instances the FDA had also formally acknowledged its sanctioning of certain substances for food use.

A prior sanctioned ingredient is permanently grandfathered, because it can never fall within the statutory definition of a food additive, at least for the purposes for which it was previously sanctioned, and therefore never becomes formally subject to the Delaney Clause. This means that a carcinogenic ingredient for which a prior sanction exists is not automatically forbidden to be used in food.

This does not mean that the FDA cannot prevent the use of a prior sanctioned ingredient that new evidence demonstrates to be unsafe. However, the Agency must be prepared to prove, ordinarily

\textsuperscript{21} 21 CFR 180.1. 
\textsuperscript{22} 21 U. S. C. 321(s) (4). 
\textsuperscript{23} 21 U. S. C. 321(s) (4).
in court, that the presence of the ingredient renders food adulterated
within the meaning of Sec. 402(a)(1). Accordingly, a finding that a
prior sanctioned ingredient is a carcinogen might permit the FDA
to prevent that ingredient's use, but it would not mandate that action.84

4. Color additives

The statutory definition of color additives is broad, and the
regulatory requirements are essentially similar to those applicable
to food additives.85 The sponsor must demonstrate the color's safety,
and the Delaney Clause is applicable.86 But because the Color Addi-
tive Amendments of 1960 have no provision for "generally recognized
as safe" colors and do not exclude from the definition of color additive,
the Delaney Clause applies to all such coloring agents.

Congress did, as noted above, authorize the FDA to "provisional-
ly list" colors that were in use in 1960 and that were believed to be
safe in order to permit the performance of the kind of toxicological
testing required to support contemporary scientific judgments of safety.87

The provisional list thus represents a form of temporary grand-
father clause, designed to permit an orderly transition from essen-
tially unregulated use of colors to a scheme in which all color addi-
tives are licensed in the same fashion as food additives.

The statutory procedures for disapproving or withdrawing ap-
proval of a color additive parallel those applicable to food additives,
with two important distinctions. First, if the FDA, after publishing
a proposal and receiving comment, issues a final order terminating
approval of a color, the filing of objections accompanied by a re-
quest for a hearing automatically stays the Agency's order pending
the hearing.88 Next, Sec. 706 also provides for a statutory advisory
committee to review the evidence when the Agency proposes to with-
draw approval of a permanently listed color due to carcinogenicity.89
Provisionally listed colors, however, may be summarily delisted mere-
ly by notice.90

5. New animal drugs

The FDA's most sophisticated regulation of carcinogens occurs
in the area of new animal drugs intended for use in food producing

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FOOD DRUG COSMETIC LAW JOURNAL—FEBRUARY, 1978
animals. Drugs are used in these animals for treatment and prevention of disease and for growth promotion, and the premarket review process is two-tiered with the sponsor, of course, having the burden of proof. First, the FDA must determine whether the drug is safe and effective for use in the animals, analogous to the risk/benefit assessment used for new human drugs, which, prior to enactment of the Animal Drug Amendments of 1968, was the statutory provision under which this part of the data were reviewed. Then, the Agency reviews the safety data to assess the safety of the potential residues that may occur in food deprived from the treated animals using the food additive standard of safety, which was the governing statutory provision before 1968.\(^4\)

Although these drugs are subject to the Delaney Clause, carcinogenic new animal drugs may be used in food-producing animals with two caveats: (i) the drug will not adversely affect the animals, and (ii) no residue of the drug will be found by methods of analysis designated by the Agency in any edible portion of the animal or food derived from that animal.\(^1\)

As noted earlier, this language has practical limits, and it has caused the FDA numerous problems in evaluating the safety of new animal drugs.

However, in 1973, the FDA proposed to codify principles that had evolved from the Agency's grappling with the problem on a case-by-case basis. In the Federal Register of February 22, 1977, it promulgated an extensive procedure of assessing the designating assays, which is geared to a modified Mantel-Bryan statistical procedure for assessing the risk of any undetected residues.\(^4\)

For all potentially carcinogenic new animal drugs intended for use in food-producing animals, the FDA's regulation established a six-step review procedure:

1. A threshold assessment to determine whether the sponsored compound or its metabolites requires carcinogenesis testing using all available chemical, biochemical, toxicological data. 21 CFR 500.80.

2. A comprehensive metabolite study of the sponsored compound in the target animal. 21 CFR 500.84.

3. Chronic toxicity testing in animals to measure the compound's carcinogenic potential. 21 CFR 500.87.


AN OVERVIEW
4. Application of the basic Mantel-Bryan procedure, with modifications developed by the FDA, to the data collected from the chronic carcinogenicity tests, in order to predict the risk of cancer associated with low levels of exposure to a carcinogenic compound. 21 CFR 500.87(b)-(d).

5. Specific criteria and procedures for evaluating and approving assay methods to assure no carcinogenic residues will occur in food. 21 CFR 500.80—500.90; and

6. A procedure for calculating withdrawal periods using the assay 99% confidence bounds on studies measuring the depletion of residues in the target animal. 21 CFR 500.92.

The new animal drug approval process is a licensing procedure, and the FDA must provide the applicants with notice and the opportunity for a formal hearing on its new animal drug application or proposal to withdraw approval of its application.44 But they must demonstrate that material factual issues are in dispute before the FDA must grant a hearing.45

IV. HUMAN DRUGS

A. New Human Drugs

Basically, new human drugs, drugs that are not generally recognized as safe and effective by qualified experts,46 are regulated in the same manner as new animal drugs.47 They are subject to premarket approval; their sponsors have the burden of proving their safety, and the approvals grant private licenses. However, new human drugs are not subject to a Delaney Clause.48 They are regulated through a general safety clause which permits extensive risk/benefit balancing both by the Agency and the prescribing physician since only the physician's patient will be directly affected by the drug's use, unlike the use of animal drugs in food-producing animals where many uninformned and perhaps unconsenting, individuals may be exposed to the drug. Many life saving drugs also have a carcinogenic potential, such as some of the antineoplastic drugs. Therefore, the risk of cancer from short term use of a drug for a life threatening or other important therapeutic use may be outweighed by the benefits provided by that drug. In those situations, it would be safe for

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FOOD DRUG COSMETIC LAW JOURNAL—FEBRUARY, 1978
use. As you can see, the normal rationales for regulating carcinogens are inappropriate in these cases.

The FDA also recently has taken a giant step in this area by mandating, through informal rulemaking, additional label warnings on the use of estrogens for general use.\textsuperscript{49} It requires new warnings to physicians, and, more importantly, the FDA now requires drug manufacturers to provide the physician and pharmacist with labeling for the patients so that each patient can be and is fully apprised of the risk of such therapy.\textsuperscript{50}

\textbf{B. Old Drugs or OTC Drugs}

For drugs that may be generally recognized as safe and effective, or drugs that are exempted by statute from the new drug application requirements, about which evidence of carcinogenicity becomes available, the FDA normally uses its general rulemaking authority to regulate.

First the Agency proposes to declare the article a new drug, setting forth the evidence upon which it has reached that decision in the notice. After evaluating comments, it then promulgates a final order declaring the article a new drug requiring approved new drug applications to market. The FDA proposes this action because the drug lacks sufficient benefit, and, it requests manufacturers of new drug products containing the ingredients to be reformulated. Therefore, barring some new evidence of extraordinary benefit from the drug's use, the Agency essentially bans it.\textsuperscript{51}

\section*{V. COSMETICS}

\textbf{A. General Ingredients}

The FDA has bare bones authority to regulate carcinogens in cosmetics, that is, articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or part for cleansing, beautifying, promoting attractiveness or altering appearance, and articles intended for use as components of cosmetics.\textsuperscript{52} The FDA has no premarket review authority, although it has such authority over color additives that are components of cosmetics. Therefore, while a Delaney Clause applies to color additives, neither Delaney nor a general premarket testing safety clause is available to regulate carcinogenic components of cosmetics.\textsuperscript{53} The FDA is limited to statutory language and authority about adulteration that is identical to that applicable to added food substances.
Section 601. A cosmetic is deemed to be adulterated—(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to use under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual...

The FDA has construed this section quite broadly since it is the only authority the Agency has to protect the public. Using that in conjunction with its broad rulemaking authority, the Agency has banned from use in cosmetics ingredients that have been found to be carcinogenic by ingestion tests on rodents. Therefore, it has concluded such tests demonstrate an unreasonable risk of harm at least for cosmetics that may be ingested and for cosmetics that are used topically, where there is evidence of absorption.

B. Coal Tar Derivative Ingredients

The adulteration section for cosmetics also contains language that has been judicially construed to restrict severely the FDA's authority to regulate coal-tar hair dyes. Congress added a proviso that the section shall not apply to coal-tar hair dyes whose labeling bears a statutorily prescribed label warning that the product may cause skin irritation and bears adequate directions for preliminary testing for this potential problem.

The FDA attempted to limit the exemption from adulteration to only those conditions that the statutorily prescribed warning specifically addresses. Unfortunately, the United States Court of Appeals for the Second Circuit concluded that coal-tar hair dyes labeled with the patch test warning are not adulterated no matter what their potential for harm since the FDA's position sought an enlargement of the statutory authority despite an apparently inadvertent congressional omission. The FDA can, however, require additional label warning statements for cosmetics containing these ingredients through its general rulemaking authority to prescribe informative labeling.

VI. CONCLUSION

The FDA's authority to regulate carcinogens in foods, drugs, and cosmetics is diverse. For noncoal tar dye cosmetics, at least its adequacy is uncertain, and its scope is untested by litigation. Clearly,

432

FOOD DRUG COSMETIC LAW JOURNAL—FEBRUARY, 1978
the Delaney Clause is no panacea, although it represents a logical approach to a complex scientific issue because so many unknowns exist about cancer. The FDA has begun to use other procedures to deal with carcinogens, such as broader disclosure and statistical analyses of risks, but these approaches also pose problems. Can the public really understand the risk associated with the use, for example, of saccharin? Or is the Agency accurately assessing the risk associated with that use? There are no easy answers but full disclosure is the first step in conjunction with more extensive use of risk analysis. For the latter, I favor more regulations prescribing risk analysis, particularly in the areas of indirect food additives and cosmetic components.

[The End]
REGULATORY COUNCIL

Statement on Regulation of Chemical Carcinogens: Policy and Request for Public Comments

AGENCY Regulatory Council.

ACTION Notice of Policy and Request for Public Comments

SUMMARY This policy is being published in the Federal Register to inform the public of the practices and principles the participating Federal regulatory agencies will follow in initiating regulatory actions relating to chemical carcinogens.

The Regulatory Council would welcome any comments from the public, particularly any additional information pertinent to these policies which may have been considered in the preparation of the statement.

Because much of the scientific basis for the policies on identifying chemical carcinogens and assessing human risk relies on the analyses and discussion in the document "Scientific Bases for Identification of Potential Carcinogens and Estimation of Risk," published at 42 FR 30503, July 8, 1977 (Annex B to this document), we request potential commenters to read that document carefully before commenting on the scientific issues addressed in the Regulatory Council's statement. We would further suggest that any comments on the substance of Annex B be addressed to that document which is currently undergoing public review and comment as well. The comment period on that document is being extended to October 11 by separate notice to allow additional comments to be received.

DATES: We would appreciate receiving comments by November 15, 1979, to ensure speedy consideration of additional public views.


Copies of this document including the background summary statement are available from:


Signed In Washington, D.C. this 6th day of October 1979.

Peter R. Hall
Director


Statement on Regulation of Chemical Carcinogens

Introduction

Assessing the Risk of Cancer to Humans. Setting Priorities for Regulating Carcinogens

Consulting Regulatory Action. Federal Agencies Having Primary Roles in the Regulation of Chemical Carcinogens. Annex B

Scientific Bases for Identification of Potential Carcinogens and Estimation of Risk. Annex C

Statement on Regulation of Chemical Carcinogens

Carcinogen. Annex D

PUBLIC COMMENT

IIIRULATORY COUNCIL

Recognizing the importance of determining whether a substance is a carcinogen, the agency has
asked key scientists and other staff from its own laboratories, the National Cancer
Institute, and the National Institute of Environmental Health Sciences to
prepare a document setting forth the scientific bases for making regulatory
decisions on carcinogens. This group prepared a document entitled "Scientific
Bases for Identification of Potential Carcinogens and Estimation of Risk" (as
Annex A) which represents the basis of the participating activities on the
scientific principles applicable to identifying and evaluating substances
that may present a risk of cancer in humans.

The Regulatory Council's assignment was to consider the scientific issues
addressed in the IRG document along with the many other aspects of the
government's efforts to regulate carcinogenic and to prepare a
regulatory paper which reflected their actions to promote more effectively the public health
without imposing unnecessary burdens on the economy, and to eliminate potential uncertainties and
inconsistencies in the government's regulatory program.

In carrying out this assignment the Council focused on not only the
IRG document, but many other reports and activities relating to the
prevention of cancer. These included reports by the
President's Office of Science and
Technology Policy and the In Ergency
Young Substances Strategy Committee,
the analyses and comments relating to
the progress of the National Cancer
Administrations cancer policies, and the activities of the National
Toxicology Program, the National
Institute of Health, and the National
Cancer Advisory Board.

Although the content of this statement benefited from all of the
above efforts, it is based more substantively upon the document prepared by the
IRG. That document, attached as
Annex A should be referred to for
additional information. The IRG
document has a longer scientific presentation
review and is currently receiving public
comment any changes made in it as a
result of the review and comment
process will be incorporated into this
report.

There are many important aspects of
the government's efforts to reduce the
terrible and the problem of cancer in
our society. These range from basic
research on the biology and the causes of
cancer, through efforts to improve the
diagnosis and treatment of the disease.

Regulatory agencies will base their
determinations of whether a substance is
likely or not to cause cancer on
rigorous evaluation of all relevant,
available scientific evidence.

Epidemiological studies of natural
and animal tests provide the best evidence of
carcinogenicity, but other types of
information still be important.

Although they cannot be adequately
summarized in a few sentences it is very important for an understanding of several basic concepts
involved in these evaluations.

Epidemiological Studies. Properly
designed and conducted epidemiological
studies showing a significant statistical
relationship between human exposure to
a substance and an increased occurrence of cancer in the exposed
population are considered to provide
good evidence that the substance is
carcinogenic.

In the past many people argued that
such studies should be conducted
precise to understanding any
significant regulatory action. There are,
however, limitations on the usefulness of epidemiology. Everyone is exposed to
many chemicals for years. And cancer may not occur until 30 years or
more after exposure to a carcinogen.
Thus, there may be a substantial delays,
allowing many additional people to be
exposed before any epidemiological
evidence can be obtained. Even then, it
may be very difficult to associate the
occurrence of cancer with exposure to
specific chemicals even when they were
previously demonstrated to cause cancer.

Epidemiological studies often cannot
detect large increases which could
involve thousands of people in the
occurrence of cancer resulting from
exposure to substances. For these
reasons:

- The failure of an epidemiological
study to detect an association between
the occurrence of cancer and particular
substances is not by itself evidence that
these substances are not carcinogenic.

- Because it is unacceptable to allow
exposure to potential carcinogens to
continue until human cancer actually
occurs, regulatory agencies should not
wait for epidemiological evidence before
taking action to reduce human exposure
to substances considered to be
carcinogenic.

Testing in Animals. Formally
designed and conducted tests of laboratory
animals provide good evidence of a
substance's potential human
carcinogenicity. From a biological
perspective the development of cancer is
similar in humans and animals, even
dough different specific carcinogenic
agents of a species may demonstrate
different sensitivities to specific
A substance that causes cancer in animals, when tested under appropriate conditions, will be considered a potential human carcinogen.

- Animal tests provide valid information even though the dose administered to the animals may be higher than doses likely to be experienced in humans. Animals are given relatively high doses because increasing the sensitivity of the test by maximizing the likelihood that a cancer-causing substance will actually produce cancer, and in comparison for the relatively small number of animals typically used in the tests. Although the likelihood of detecting a carcinogenic effect and the time between exposure to the carcinogen and the occurrence of cancer may be related to the dose level tested, the intrinsic ability of a substance to induce cancer is independent of dosage. A carcinogen can be tested at a low dose administered in high doses, but it will not directly cause cancer at any dose level. In fact, the majority of chemicals tested in humans or even at high doses, has not been found to be carcinogenic.

- Evaluation of the results of animal testing is simplified when the animals are tested in groups, and when the same routes by which people are or will be exposed, but the carcinogenicity of a substance is assessed in animal tests where exposure is by different routes. For instance, if a substance causes cancer when tested by ingestion, there is good reason to expect it to be able to cause cancer when inhaled.

- In evaluating results of animal tests, the occurrence of benign tumors in the treated animals is an indication that the substance being tested may produce malignant tumors as well. Benign tumors are a precursor stage of malignant tumors. Furthermore, virtually all existing carcinogenic substances that have produced benign tumors have also produced malignant tumors.

- If a substance has been shown to be carcinogenic under the conditions of a single properly designed and conducted test, it should be considered as posing a risk to humans. Although the agencies should attempt to obtain additional data, they should not take the risk involved in waiting the two to four years required to complete an additional animal bioassay before taking regulatory action.

- Evidence that a substance is a carcinogen is strengthened if test results involving carcinogenicity under two or more test conditions (e.g., at two or more dose levels, in both sexes, or in two or more animal strains of species). Similarly, evidence that a substance is not a carcinogen is strengthened if there is a lack of carcinogenic response in two or more properly designed and conducted tests. In tests where there are conflicting results from more than one properly designed and conducted test, results falling to demonstrate a carcinogenic response do not detract from the validity of testing. Similarly, testing such as tests of different strains of animals were used, and they do not invariably detect from such results if the same species used. Even known carcinogens would be expected to show no response in some tests, particularly, for instance, when relatively few animals are involved, dose levels are low, or an insensitive animal strain is used.

Other Types of Evidence. In recent years there has been encouraging progress in developing certain short-term screening tests (involving animals, mammalian cells, or microorganisms) and in using chemical structure to predict carcinogenic potential. Such approaches may provide a substantially faster and less expensive way of obtaining evidence on a substance's potential carcinogenicity. Such evidence, although currently only considered suggestive, can properly be used for the following purposes:

- To help identify chemicals that should be more thoroughly tested.
- To help in planning priorities for regulatory actions.
- To help in evaluating the results of long-term testing in animals.
- To support regulatory actions dealing with groups of substances having similar chemical or biological properties.

Testing Policy: Because long-term testing in animals is an important step in evaluating the cancer-causing potential of chemicals, and because such testing is time-consuming and expensive and requires specialized expertise and specialized facilities, it is essential that it be performed as efficiently as possible. The current government policy on this testing is that:

- The primary responsibility for much of this testing, as specified in several federal laws, lies with the firms involved in manufacturing chemical substances. Agencies having the authority to do so should ensure that any required testing is carried out properly and as economically as possible.
- The federal regulatory agencies, when they identify a chemical for testing and the testing procedure has the approval of the industry, and ensure industry compliance with the procedures, may require that the testing requirements be conformed to the federal law. Agencies responsible for laws relating to cancer research and treatment, in support of the development and validation of new testing procedures and to perform testing (as well as epidemiological studies) in certain circumstances, for instance, where it is not possible to rely on industry to do so or where an agency is not authorized to impose such requirements on industry.

Although a substance may sometimes lead to its testing more than once to detect its potential carcinogenicity under differing conditions, regulatory agencies will avoid, whenever possible, imposing duplicative or conflicting testing requirements. The NIOSH agencies are already preparing testing guidelines to accomplish this goal.

Assessing the risk of cancer in humans

After it has been determined that a chemical substance is likely to be carcinogenic, the next step is regulatory decision-making to assess the risk that people face of developing cancer from their exposure to the substance. Guidance of the NIOSH agencies on risk assessment contains two basic components. The first is an analysis of the evidence of the carcinogenic potential of the substance, and the second is an analysis of the human exposure to the substance in order to assess the health risk it may pose.

The analysis of the carcinogenicity describes the preceding section of this statement, involves a determination of whether a substance is likely to cause cancer in humans, accomplished by a characterization of the nature and quality of the evidence supporting this determination. It is also an analysis of the relationship between the observed carcinogenic effects and the dose levels used in animal tests or the expected levels of exposure to humans in epidemiological studies. The analysis of human exposure involves at least an estimate of the size of the exposed population, and may also include such factors as exposure sources, routes, and conditions, the duration, frequency, and intensity of exposure, and the relevant characteristics (e.g., age, sex, health) of the exposed population. The agencies will use these measurements when...
...and Eotln,otion of RInkel.

Scientific studies have revealed that certain substances can provide benefits, but their impact on health is uncertain, as highlighted in the Eotln,otion of RInkel. When they are used properly, they can reduce the risk of certain diseases, but overuse can lead to negative outcomes.

A regulatory system is designed to assess the risk of substances and establish standards to protect public health. Regulatory agencies have the authority to prioritize risks and set priorities based on scientific evidence.

In general, regulatory agencies will not regulate a substance unless there is strong evidence of harm. However, in some cases, the risk of a substance may be so low that it is not practical to regulate, even if it is known to be harmful. This is known as the "safety in numbers" principle, where the cumulative effect of low-risk substances can be more significant than the risk posed by a single high-risk substance.

The regulatory agencies consider the risk of a substance in the context of other substances and their potential impact. When prioritizing risks, they take into account the severity of the potential health effects, the likelihood of exposure, and the existing regulatory frameworks.

In summary, the regulatory system aims to balance the need for risk reduction and the potential for harm. While it is not a perfect system, it provides a framework for making informed decisions about the regulation of substances that affect public health.
Confiders associated economic and environmental costs and benefits can be considerable. When making regulatory decisions, agencies must consider the feasibility of achieving regulatory goals and the economic and social costs of any approach. The economic and social costs of reducing environmental releases of hazardous substances pose a challenge to regulatory agencies. When making regulatory decisions, they must consider the feasibility of achieving regulatory goals and the economic and social costs of any approach.

Technical and Economic Feasibility. Various federal laws require that regulatory decisions be based solely or primarily on the feasibility of achieving regulatory goals and the economic and social costs of any approach. The economic and social costs of reducing environmental releases of hazardous substances are determined by the feasibility of achieving regulatory goals and the economic and social costs of any approach.

Comparing Costs and Benefits. Various federal laws require that regulatory decisions be based solely or primarily on the feasibility of achieving regulatory goals and the economic and social costs of any approach. The economic and social costs of reducing environmental releases of hazardous substances are determined by the feasibility of achieving regulatory goals and the economic and social costs of any approach.

In some instances, Congress has enacted a section of the Federal Insecticide, Fungicide, and Rodenticide Act that requires the Environmental Protection Agency to develop uniform safety standards for consumer products. The Consumer Product Safety Commission is to protect the public against unreasonable risks to health and safety in the use of consumer products. The Consumer Product Safety Commission is to protect the public against unreasonable risks to health and safety in the use of consumer products. The Consumer Product Safety Commission is to protect the public against unreasonable risks to health and safety in the use of consumer products.
regulations, and to promote research and investigation into the causes and prevention of product-related deaths, diseases, and injuries.

The Commissioner assesses the health risks associated with the use of those chemicals in consumer products, and where necessary, recommends restriction or prohibitions, or both, to prevent or reduce risks. The act also authorizes the Secretary of Health and Human Services, by rule, to set performance standards for packaging and labeling of products to ensure their safety and effectiveness.

The purpose of the Food and Drug Administration (FDA) is to protect the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, vaccines, biological products, medical devices, and food. FDA also regulates the use of food additives, including artificial colors and flavors, and the labeling and promotion of foods. The agency also conducts research on the potential health effects of emerging technologies, such as nanotechnology and biotechnology.

The Food and Drug Administration (FDA) is responsible for ensuring the safety and effectiveness of all products regulated by the agency, including pharmaceuticals, medical devices, and food. FDA also regulates the labeling and promotion of products to ensure that they are truthful and not misleading. The agency also conducts research on the potential health effects of emerging technologies, such as nanotechnology and biotechnology.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is the primary federal statute that regulates the use of pesticides in the United States. FIFRA is designed to protect human and environmental health and safety by regulating the use of pesticides and other toxic substances to control pests. The act also establishes a regulatory framework for the development and registration of new pesticides, and requires the testing of pesticides to ensure their safety and effectiveness.

The Hazardous Materials Transportation Act (HMTA) is a federal statute that regulates the transportation of hazardous materials in commerce. The act establishes a regulatory framework for the transportation of hazardous materials by rail,公路, and water, and requires the testing and labeling of hazardous materials to ensure their safe transport.
provide information on the impact of environmental factors on human health in order to aid those agencies charged with devising and instituting controls on therapeutic measures.

The product of this coordinated research effort is the Interagency Regulatory Liaison Group (IRLG), established in 1977 by four agencies (the Consumer Product Safety Commission, the National Institute of Occupational Safety and Health, the Food and Drug Administration, and the Consumer Product Safety Commission). The purpose of the IRLG is to coordinate the activities of the regulatory agencies and to assist them in implementing their regulatory programs in a consistent and cost-effective manner. The IRLG is comprised of representatives from the federal government, state and local governments, and nongovernmental organizations.

The IRLG meets periodically to discuss issues related to the regulation of carcinogens and to develop strategies for coordinating the work of the various agencies involved in this area. The IRLG's work is guided by the National Cancer Institute, which provides technical advice and support to the group.

An example of legislative coordination mechanisms would include provisions in several of the health and safety statutes which require the implementing agency to consider the views of research done by other agencies and the appropriate laws and regulations in making recommendations to other agencies. For example, the National Institute of Environmental Health Sciences (NIEHS) has established the Interagency Carcinogen Evaluation Committee (I-CEC), which includes representatives from the National Cancer Institute, the Environmental Protection Agency, the National Institute of Occupational Safety and Health, and the National Institute of Allergy and Infectious Diseases. The I-CEC is responsible for evaluating the carcinogenic potential of chemicals and for making recommendations to the agencies that regulate them.

Another example of legislative coordination is the Interagency Carcinogen Evaluation Committee (CEC), established by the Environmental Protection Agency to assess the carcinogenic potential of chemicals and to make recommendations to the agencies that regulate them. The CEC includes representatives from the National Cancer Institute, the National Institute of Environmental Health Sciences, the National Institute of Occupational Safety and Health, and the National Institute of Allergy and Infectious Diseases.

The IRLG has also established several subcommittees to analyze and report on particular issues of interest to the board. The subcommittees are comprised of representatives from the various regulatory agencies and are charged with providing technical expertise and advice to the IRLG.

The IRLG has also developed a framework for coordinating the work of the various agencies involved in the regulation of carcinogens. This framework includes the establishment of work groups to address specific issues and the development of a work plan to guide the activities of the group. The work plan is updated regularly to reflect the changing priorities of the agencies and the needs of the public.

The IRLG has also established a series of working groups to deal with specific issues related to the regulation of carcinogens. These working groups include representatives from the various regulatory agencies and are charged with developing recommendations and strategies for addressing specific issues. The working groups meet periodically to discuss issues related to the regulation of carcinogens and to develop strategies for coordinating the work of the various agencies involved in this area.

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...supporting its research programs to gain a better understanding of the mechanisms by which they affect humans. The larger programs are supported by the National Cancer Institute, the National Institute of Environmental Health Science, the National Institute of Occupational Safety and Health, the Environmental Protection Agency, the Food and Drug Administration, the Department of Energy, the Department of Defense, the Department of Commerce, and the Department of Agriculture.

According to one tabulation, these agencies have a total of approximately $600 million dollars in FY 1977 in research related to toxics activities, a large proportion of which was focused on the problem of cancer and carcinogenesis. These research programs tend to develop in a largely uncoordinated fashion, but during the past year there have been several major efforts to gain a better understanding and improve the coordination of many agencies research programs. These include the various national research planning work groups. These groups focused many of its activities on the environmental health sciences, and the National Cancer Institute. This program was given authority to plan and coordinate with the research effort for the national institutes—NCI, NIEHS, and NIOSH. and analyzed information in terms of the toxicological sciences and carcinogenic substances. This program was given authority to plan and coordinate with the research policy and information in terms of the toxicological sciences and carcinogenic substances. This program was given authority to plan and coordinate with the research done under different auspices and to coordinate the exchange of information and the sharing of resources among agencies in the department. Although established within HEW, it includes liaison members from the Department of Commerce, the Department of Education, and the Department of Energy.

One of the tasks of this effort is primarily concerned with the programs and activities of the National Cancer Institute. However, each accomplishes some significant coordination among other agencies. The membership includes representatives from Federal agencies having significant interest in toxicology, and thus gene research. A similar effort was initiated by the Institute of Environmental Health Sciences and the National Institute of Occupational Safety and Health. The coordinating committee includes representatives from other agencies, and these include the Environmental Protection Agency, the Food and Drug Administration, the Department of Energy, the Department of Defense, the Department of Commerce, and the Department of Agriculture.

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Some consistency in priority setting was accomplished through various advisory committees of which NCI's Carcinogenesis and Environmental Carcinogenesis were perhaps the most important. Although NCI and other testing agencies did attempt to respond to regulatory needs when they were expressed, the regulatory agencies often did not have strong input to these committees.

The creation of the National Toxicology Program has established a more vigorous forum for coordinating testing priorities. This program is developing a uniform set of testing priorities which reflects the needs of both the regulatory agencies and the research institutions. The regulatory agencies, represented on the program's Executive Committee, will also have a stronger role in selecting the specific substances tested for all of the IRLG testing programs covered by the NTP.

Another major program established to coordinate testing is the Intergency Task Force, Substances Testing Commission. The committee was established by section 4 of the Toxic Substances Control Act of 1976 and includes members from eight agencies involved in regulating toxic substances. Its role is to ensure current knowledge of the potential acute effects of different substances, and recommend to EPA which of these substances should receive the highest priority for testing. EPA, in turn, will advise these recommendations to regulatory agencies which will establish guidelines for testing to be conducted by industry under the Act.

The National Toxicology Program and the Intergency Task Force Substances Testing Commission substantially improve the amount of coordination occurring between the testing programs. The National Toxicology Program will serve to coordinate testing priorities among the research agencies and the regulatory agencies, and the testing committee will serve to coordinate priorities between the government and private sector. Coordination between these entities will enable the better alignment of the senior agencies represented on both.

Evaluation

Evaluation of the interagency testing program is an ongoing and changing aspect of the program. Because the number of different experimental methods tends to be underestimated, it is necessary to evaluate these methods and often results in discovery of more efficient and accurate procedures. However, for the purpose of making regulatory decisions, the agencies must have confidence in the quality of testing, and in the consistency of results.

Efforts to promote such quality and consistency can take several forms. The first stage is usually the development of standard analytical methods for use within an agency. Some of these will be adopted by other agencies as well. For example, the National Center for Health Research has manuals containing recommended testing methods for determining carcinogenicity. The National Academy of Sciences has prepared similar manuals. The IRLG has also prepared manuals for testing substances that pose a risk of cancer to humans. The document describes the format for making a qualitative evaluation of whether a particular substance presents a carcinogenic hazard, and how the results of epidemiological studies and animal bioassays, along with other types of information, are to be used in making that evaluation. The document is currently receiving public and scientific review and comment.

Another effort in the government has been the publication of the IRLG Risk Assessment Working Group report titled "Scientific Base for the Identification of Potential Carcinogens and the Estimation of Risks." This document represents the judgment of the agency scientists on the scientific concept and methods used to identify and evaluate substances that pose a risk of cancer to humans. The document describes the format for making a qualitative evaluation of whether a particular substance presents a carcinogenic hazard, and how the results of epidemiological studies and animal bioassays, along with other types of information, are to be used in making that evaluation. The document is currently receiving public and scientific review and comment.

Several other efforts in the government have also addressed this area. The National Cancer Advisory Board's Committee on Environmental Carcinogenesis is preparing a document which is similar to the one prepared by the IRLG. The Office of Science and Technology Policy in the Executive Office of the President has also prepared a similar effort in the area of science and technology policy, and the National Cancer Advisory Board has recommended that the scientific community receive public and scientific review and comment.

Assessing Human Risk

Most of the government's attention on issues relating to the assessment of human risk has been focused on the scientific concept and methods used to identify and evaluate substances that pose a risk of cancer to humans. The document describes the format for making a qualitative evaluation of whether a particular substance presents a carcinogenic hazard, and how the results of epidemiological studies and animal bioassays, along with other types of information, are to be used in making that evaluation. The document is currently receiving public and scientific review and comment.

Identifying Carcinogens

With the proliferation of different testing and regulatory programs, there is some concern that different agencies may make inconsistent assessments of the potential carcinogenicity of a particular substance. This concern has been expressed in a recent report by the Institute of Medicine entitled "Scientific Base for the Identification of Potential Carcinogens and the Estimation of Risks." The document describes the format for making a qualitative evaluation of whether a particular substance poses a carcinogenic hazard, and how the results of epidemiological studies and animal bioassays, along with other types of information, are to be used in making that evaluation. The document is currently receiving public and scientific review and comment.
Decision Analyses

The major conclusion on decision analyses has resulted from Executive Order 12044 issued by President Carter and The National Environmental Policy Act. The National Environmental Policy Act requires each agency to analyze the environmental implications of those actions which may have a significant impact upon the human environment. The Council on Environmental Quality implements these provisions and has issued regulations governing the preparation and processing of environmental impact statements. However, there are some variations among agencies regarding how and when they undertake environmental impact assessments related to regulatory activities.

Executive Order 12044 applies to all agencies which potentially have a major economic impact issue by agencies within the Executive Branch. It requires agencies proposing these regulatory process to undertake regulatory analyses which are published for review and comment. The Council on Wage and Price Stability and the Office of Management and Budget have prepared guidelines regarding the content of these analyses and the way in which they should be done.

Selected regulatory analyses are also reviewed by the Regulatory Analysis Review Group (RARG). This group is chaired by the Chairman of the Council of Economic Advisers and is made up of representatives from the Office of Management and Budget and the principal Executive Branch economic and regulatory agencies. RARG reviews the reports to examine the consistency of the impact assessments within and between agencies. The implementation of Executive Order 12044 has resulted in substantial consistency with respect to the issues of what economic analyses will be conducted and what they should contain.

The IRLG (Interagency Regulatory Liaison Group) is also concerned with what analyses are done and how they are coordinated among the IRLG agencies. The IG also has a group of Senior Economic Analysts to coordinate the economic analyses carried out by the agencies.

Regulatory Policies

Until recently, efforts to coordinate agency actions in regulating carcinogens have been focused on the carcinogenicity of substances. The testing and assessment of substances is the primary concern. As the number of known carcinogenic substances increases, the role of the agencies becomes more complex.

The agencies have established a special subgroup composed of key officials from the relevant agencies. These subgroups have the responsibility for coordinating the activities of the various agencies, ensuring that they are consistent with one another and informing the public about the scientific and policy judgments that the agencies make in their interpretations.

Regulatory Authorities

The IRLG's regulatory activities involve coordination among agencies. Each agency has established a Regulatory Development Subgroup, which is responsible for coordinating regulatory actions in their respective areas. The subgroups coordinate the development of regulations that are likely to be affected by the actions of other agencies. The subgroups are composed of key officials from the relevant agencies and meet regularly to coordinate their regulatory activities.

The Regulatory Council's regulatory calendar should also serve as an important coordinating mechanism. The calendar identifies the significant events that are likely to influence regulatory activities. The regulatory authorities under which each agency operates are currently considering regulating upon the economic environment. The implementation of Executive Order 12044 requires agencies to coordinate their regulatory actions with the regulatory authorities under which they operate. The IRLG agencies are attempting to coordinate their regulatory activities through the Regulatory Development Work Group. The work group has identified the hazardous substances which two or more of the IRLG agencies are currently considering regulating. For each of these substances, the work group has established a special subgroup composed of key officials from the relevant agencies. These subgroups have the responsibility for coordinating the activities of the various agencies, ensuring that they are consistent with one another and informing the public about the scientific and policy judgments that the agencies make in their interpretations.

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identify potential conflicts, inconsistencies, or instances of overlap. The potential for coordination and the benefits that can result if the agencies do work closely together are clearly demonstrated in the regulation of chlorofluorocarbons. Chlorofluorocarbons were at one time used extensively as propellants in aerosol sprays, among other uses. They were found, however, to be causing a potentially serious depletion of ozone in the atmosphere.

Various scientific studies demonstrated that such depletion could have very serious long-range impacts on health and the environment. These agencies, EPA, CFC, and FDA, had partial jurisdiction. When it became evident that there was a potentially serious problem, these agencies got together to consider possible regulatory responses. As a result, they developed a joint regulatory approach that embodied an agreement on the actions that each of these agencies should take and the timing of these actions. This arrangement was agreed to by the EPA and CFC and was implemented by the IRLG agencies as a joint effort. The coordination carried out by the interagency committee was closely coordinated with those being addressed by the CEQ Environmental Data and Monitoring Group and the IRLG Environmental Quality to review environmental data and monitoring. Finally, the CEQ Interagency Task Force on Environmental Data and Monitoring was established by section 4(f) of the Toxic Substances Control Act. Its purpose is to facilitate: the exchange of information on toxic substances among agencies. Although the focus is on information exchange, the CEQ must also consider who should collect the information and how they should collect it. The issues being addressed by the CEQ interagency committee are closely coordinated with those being addressed by the IRLG Information Exchange Working Group, which serves a similar role among the IRLG agencies. However, neither of these efforts has yet led to an intensive effort to improve the coordination of ambient monitoring activities by the different agencies. The coordination carried out by the CEQ also involves the Office of Management and Budget, which is responsible for providing support to government programs through the sharing of information and resources. The coordination between the CEQ and the IRLG is important in responding to emergency episodes such as spills or releases, as well as in coordinating the release of toxic chemicals. The IRLG Environmental Quality Committee established an interagency committee to address this problem. It has concentrated on improving the information capacity of the state and local...
levels, better organizing EPA's response system, and achieving better coordination between EPA, the Department of Transportation, and the private sector. In addition, the IRLG agencies have developed, at both regional and headquarters levels, emergency notification schemes and emergency response plans to deal with such episodes. These are currently being integrated with the national response system established by the Clean Water Act involving the Council on Environmental Quality, the Department of Transportation, and EPA to respond to oil and hazardous substances spills.

Conclusion

This appendix describes some of the ongoing coordination efforts which are most relevant to the regulation of carcinogens. Additional efforts are also occurring in areas less directly related. Further information about the activities of the major coordinating efforts can be obtained by contacting the following:

Interagency Regulatory Liaison Group (IRLG)

The Environmental Protection Agency (EPA), 1200 Independence Avenue, S.W., Washington, D.C. 20460

National Cancer Advisory Board

National Toxicology Program

National Cancer Institute

The following table lists some of the ongoing coordination efforts which are most relevant to the regulation of carcinogens.

Table 1: Interagency Coordination Efforts

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<th>Effort</th>
<th>Office of Management and Budget</th>
<th>National Toxicology Program (NTP)</th>
<th>National Cancer Advisory Board (NCAB)</th>
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Test Priorities:

- NTP
- Interagency Toxic Substances Testing Committee
- NCAB
- Environmental Protection Agency (EPA)
- Office of Management and Budget
- National Toxicology Program (NTP)
- National Cancer Advisory Board (NCAB)
- National Cancer Institute (NCI)
- Interagency Regulatory Liaison Group (IRLG)

Regulatory Priorities:

- NTP
- Interagency Toxic Substances Testing Committee
- NCAB
- Environmental Protection Agency (EPA)
- Office of Management and Budget
- National Toxicology Program (NTP)
- National Cancer Advisory Board (NCAB)
- National Cancer Institute (NCI)
- Interagency Regulatory Liaison Group (IRLG)
November 15, 1979

Toward a Sound National Cancer Policy

AIHC Comments on the Statement of the Regulatory Council Entitled

"Regulation of Chemical Carcinogens"

The purpose of this memorandum is to provide suggestions of the American Industrial Health Council (AIHC) for the improvement of the statement of the Regulatory Council entitled "Regulation of Chemical Carcinogens" released September 28, 1979 (44 Fed. Reg. 60038). We do not believe that line by line comment on the statement would be helpful. Our purpose is to identify those areas where we believe the Council's statement could be materially strengthened so that the statement embodies the latest scientific expression of the state-of-the-art in risk identification and estimation. In the letter which this memorandum accompanies, AIHC has made recommendations for the next steps to be taken to develop a sound national cancer policy. These recommendations will also be discussed briefly in this memorandum.

AIHC was formed to coordinate the scientific and administrative resources of its 120 member companies and 60 participating associations to address the problem of regulation of substances which present a chronic health hazard.

A prime objective is to mobilize the scientific talent, industrial experience and administrative expertise of its members to assist government agencies in the development of sound carcinogen control. A list of AIHC members is attached.

I. Scientific Risk Assessment Should be Improved and its Use Extended

Within the specific focus of regulation of particular substances addressed in the Regulatory Council statement, there is an urgent need to develop policies which will provide a basis to evaluate for regulatory consideration the rapidly increasing number of substances for which some evidence of possible carcinogenicity will be developed from the greatly expanded government and private research programs and the expanding array of testing methodologies.

Mr. Cootie's public statement in connection with the release of the Regulatory Council's statement tended to obscure rather than address the problem. To substantiate the assertion that "everything does not cause cancer", he stated that only 500 out of 7,000 chemicals tested have been shown to cause cancer. However, as he noted, the quality of the studies on 7,000 substances varied widely. He referred also to a 1969 study done by Litton for NCI on 120 pesticides where 11 were found carcinogenic, but the protocols followed would probably not be used today.

The fact that nearly one half of the substances tested in the NCI bioassay program provided some evidence of
Carcinogenicity in animal tests is probably a more accurate forecast of the outcome of the enormously increased public and private testing programs. The need for good scientific tools to discriminate and evaluate different risks is important in fields other than industrial chemicals. This conclusion is confirmed by the recent statement of the Food and Drug Administration that "many, perhaps most, foods in a supermarket" may contain "an inherent carcinogenic ingredient or a carcinogenic contaminant (in contrast to a deliberately added carcinogenic substance) . . . ." (44 Fed. Reg. 59513, October 16, 1979).

The important point is that improved procedures are necessary to evaluate carcinogenic risk and to regulate those substances that are carcinogenic according to the risk they present.

In these circumstances it is vitally urgent that the government develop the tools to assess the risk presented by this vast myriad of substances which will be implicated by some evidence. Substances vary greatly in carcinogenic potency. The Interagency Regulatory Liaison Group Report (IRLG) stated that the range in variation in potency is more than a million-fold. (44 Fed. Reg. 39875). The range of hazard from these substances will be much greater because of differences in exposure levels.

It is indispensable that the government develop the means to select which substances in this large and growing group should have regulatory attention. Scientific identification and quantitative estimation of the risk are essential.
to enable sound decisions to be made. The IRLG Report is a welcome beginning in the development of objective scientific risk assessment. AIHC has commented on the IRLG Report in detail. A summary of the AIHC comments is attached to this memo. The full text of the AIHC comments is being submitted to the Regulatory Council.

The endorsement of the IRLG Report by the Regulatory Council is welcome, but we are disappointed in three respects.

1. The summary/primer style description of the "evidence" of carcinogenicity results is a distortion of complex, qualified scientific principles.

2. The Regulatory Council does not encourage full use of risk estimation.

3. The Council's statement repeats points from the IRLG Report which public input will indicate should be corrected, modified or qualified.

The statement which appears to be a key to the Regulatory Council's policy that "the intrinsic ability of a substance to induce cancer is independent of dosage" (44 Fed. Reg. 60040) is a misleading overstatement. Where the mechanism by which a substance acts is epigenetic (e.g., tissue damage) a threshold is likely. (See AIHC comments on the IRLG Report at III-12 and III-13.) Moreover this statement overlooks the significant role of hormones and micronutrients.
such as Vitamin A, cobalt, chromium, nickel, selenium, etc., which are essential to life but may cause cancer at high doses.

The statement points out that evidence that a substance is carcinogenic is strengthened by test results indicating carcinogenicity under two or more test conditions. This might be correct if the statement referred, as it does in the next sentence, to "two or more properly designed and conducted tests." (44 Fed. Reg. 60040). It is clear, however, that the author of the statement intended no such meaning because the parenthetical clause, "two or more tests or test conditions" is defined to mean "at two or more dosage levels, in both sexes, or in two or more animal strains or species." To suggest that one study with two doses is the equivalent of two tests or that one study with both sexes is the equivalent of two studies goes beyond any assertions in the IRLG Report or elsewhere.

Another example where the Regulatory Council's summary overstates the value of evidence of carcinogenicity is with reference to short term tests. (44 Fed. Reg. 60040). None of these tests has been validated so that different laboratories following the same protocol consistently get the same result. To suggest that results of such tests, without specifying a properly validated battery or the design and conduct of the tests, can be used to support "regulatory actions dealing with groups of substances having similar chemical or biological properties" elevates improperly the test results which the statement acknowledges are only "suggestive." Combining
the short term tests with another criterion, similarity in structure, which also is at best only suggestive, to support regulatory action goes beyond any proposal by the IRLG or any agency except the proposed CPSC policy (43 Fed. Reg. 25658) which has been withdrawn. (44 Fed. Reg. 23821). The limitations of short term test data is discussed in greater detail in the AINC comments on the IRLG Report at II-10 to II-16.

(2) The statement fails to provide leadership for the improvement and wider regulatory use of quantitative risk assessment. The "minimum" risk assessment called for by the statement consists merely of qualitative identification of potential carcinogenicity of a substance and a determination that people are likely to be exposed. Other significant factors necessary to properly quantify human exposure "may also" be included in the risk assessment but unfortunately are not required elements of the Regulatory Council's recommendations.

Such an inadequate non-quantitative risk assessment provides no guidance whatsoever to the nature of the risk, provides no basis for assessing alternatives and will not enable the agency or the public to determine whether the health benefits from the regulation bear a reasonable or, indeed, any relationship to the cost.

The Regulatory Council should underline the importance of a full quantitative risk assessment to sound regulation.

(3) The Council includes a number of statements from the IRLG Report which AINC believes public comment will show should be corrected, qualified or modified. This includes
statements which fail to give appropriate weight and encouragement to the collection of human data; overemphasize the significance of tests at maximum tolerated dose and positive animal test results; fail to emphasize the importance of comparative metabolism; give undue weight to benign tumors and fail to give due weight to differences in route of exposure; fail to urge selection of all methodologies and models on the basis of scientific validity rather than conservatism; and others.

Three major statements on cancer have been published by the government in quick succession without evaluation of public input: The IRLG Report; the draft Report of the Toxic Substances Strategy Committees (TSSC); and the Regulatory Council statement. The comment period was extended for the IRLG Report which forms the basis of much that is contained in the TSSC draft report and the Regulatory Council statement. Public comments have not been evaluated. While the Regulatory Council promised to include modifications of the IRLG Report in its statement, it is very unfortunate that a government document as important as the Regulatory Council statement should be issued before public comments were evaluated.

AIHC's comments on these and other points are summarized in the attachment to this memo and are developed in detail in the AIHC comments on the IRLG Report.

II. The Scientific Basis for Risk Estimation Should be Strengthened

Much of the statement by the Regulatory Council either characterizes or refers to the scientific input to
the regulatory process. We find it unusual, therefore, that the Regulatory Council gave no guidance to the agencies to assure that regulation is based on the best available science.

Four principles should be enunciated by the Regulatory Council to provide direction to the agencies in making scientific risk estimations which are an essential part of a regulatory analysis.

First, the scientific functions of qualitative risk identification and quantitative risk estimation, which the President's Office of Science and Technology Policy (OSTP) called "Stage I" in the regulatory process, should be separated from the regulatory function which OSTP calls "Stage II", where societal values (risks, benefits, costs, safety factors etc.) can be expressly considered by the regulator in deciding what action to take for risk avoidance;

Second, the scientific risk assessment should have the objective of presenting to the regulator (and to the public) the most objective unbiased assessment based on scientific evaluation of all the facts. To accomplish that objective, the scientific analysis must not be constrained or biased in some undisclosed way by "conservative" assumptions or models. Individual scientists may be conser-
tative or liberal but science must be objective.

Third, the agencies should reward good science by recognizing the significance of new data and new methodologies. The agencies should be open-minded to new data, particularly as it relates to the validity of the extrapolation of animal data to man.

Fourth, the Regulatory Council should ensure that the agencies establish consistent minimum standards of quality for acceptable data - scientific peer review, etc.

The Council should make the upgrading of the science upon which the regulatory agencies must rely an essential objective of its policy statement. AIHC gave this objective prime priority by its recommendation that an independent science panel of the highest qualifications be created to make the scientific risk evaluation; this would ensure the best objective science as a basis for regulatory decisions. The Council should also take leadership in encouraging the improvement in scientific risk estimation by the regulatory agencies.

III. The Regulatory Council Should Provide Guidance to Assure that Regulatory Objectives are Achieved in a Cost Effective Manner

The cost of regulation has become a matter of urgent national concern. A recent study prepared for the Joint Economic
Committee of the Congress estimated regulatory costs for 1979 to be over $100 billion. The $97.9 billion cost of compliance component in that total is, the study states, "substantially underestimated."

These cost considerations highlight the Council's objective to help ensure that regulations are achieved in a cost effective manner. The Council's statement should be amended to provide guidance to the agencies in the following important respects.

First, as we have pointed out earlier, supra p.6, the approval by the Council of a "minimum" risk estimation consisting only of qualitative identification of a carcinogen and an observation that people are likely to be exposed provides no guidance to the regulator whether the benefits of the proposed regulation bear a reasonable relation to the cost. For a regulation to be cost effective requires consideration of alternatives. A minimum risk estimation provides no basis for assessing alternatives.

Second, a report by the IRLG demonstrates that, with respect to twenty or more substances, two or more of the regulatory agencies are considering or preparing regulatory action. In some cases more than ten different statutes are involved. Encouragement to the agencies to coordinate their efforts is a good beginning, but provides no guidance on national priorities. Resources are limited and, absent some consideration of national priorities, coordination becomes a matter of exchange.
of information and timing. The Council should recommend that an effort be made to determine whether the benefits from the combined efforts of the agencies bear any reasonable relationship to the costs.

The Regulatory Council focuses mainly on health benefits from regulation. It is important to remember in making regulatory decisions that there are other benefits — social and economic benefits derived from the substance and, in appropriate cases, preserving the individual choices and preferences of the consumer.

Third, while one of the recommended Regulatory principles envisions coordinated development of multiple agency regulations controlling a specific substance or problem, the particular criteria espoused by the Regulatory Council on substitutes may be inconsistent with that principle. Unless a coordination mechanism is provided, the net effect of multiple agency reviews of substitutes within separate statutory authorizations could be a de facto ban of all functionally equivalent substances in a given industrial/consumer area.

The Regulatory Council has recognized a division of each agency's interest derived from its statutory mission. Thus, a substance regulated for its risk to consumers — on the basis of an available substitute — may present little risk to workers, while the substitute itself may present a serious risk to workers. Two agencies, operating within their statutory scope and guided by the "substitution" test, may
each take separate and inconsistent regulatory actions on
the alternate substances without regard to a balancing of
the relative consumer/worker risks or the quantification of
such risks in the context of societal need for at least one
of the substances.

Among the specific charges which the President
gave the Regulatory Council was to improve regulatory management
and make new rules more cost effective. It was also charged
with analyzing the cumulative regulatory impact on economic
sectors facing multiple regulatory action. The Council has
not addressed in its statement what actions or procedures it
plans to institute to ensure that the agencies will follow the
principles and precepts the Council has endorsed. In reissuing
its statement this matter should be specifically addressed.
The Council should also explain how it will assess cumulative
impact upon economic sectors facing multiple regulatory
actions and how it will assure that those multiple regulations
are cost effective and that the benefits will bear a reasonable
relation to the cost.

IV. A Sound National Cancer Policy Should
Address the Whole Problem Not Just a Segment

In the letter which this memorandum accompanies,
AIHC has urged the Council to take two important actions in
the progress to a sound national cancer policy.
1. The Council should reissue, for public comment, the statement on Regulation of Chemical Carcinogens after reissuance of the IRLG Report following evaluation of public comment. It is unfortunate that the Toxic Substance Strategy Committee draft Report and the Council's statement, which are interrelated and dependent on the IRLG Report in a significant way, were all issued prior to evaluation of public input on the underlying IRLG Report. We are confident these comments will not only lead to improvements in the various documents, but will also provide significant illumination of factors to be considered in a national cancer policy.

2. AIHC recommends that the Federal government provide a forum for launching of dialogue intended to provide a better and more sophisticated understanding of the relative contributors to cancer as a requisite to actions which government, industry, or individuals might take to reduce the incidence of cancer. The first essential step in the development of a sound national cancer policy is a dispassionate, objective and complete statement by the government of the scope of the national problem and the predominant causes of cancer. The national policy should be designed to address the whole problem, not just a small segment. (Eminent independent scientists in government, research and universities have identified lifestyle - smoking, diet and alcohol - as the predominant cause of cancer.)

The Regulatory Council statement focuses on regulation.
of manufactured chemicals. This narrow focus and the failure to address lifestyle as the predominant cause of cancer results in a distorted perspective. Recitation of the national figures as to the medical costs of caring for cancer victims and the losses of earnings of those who died of cancer give the misleading perspective that the Regulatory Council is addressing the whole problem in its statement when in fact only a small segment is addressed. A policy based on that distorted perspective will achieve little reduction in the incidence of cancer and provides no basis for assessing the priorities for research and other policy objectives to achieve that reduction.

The narrow perspective of the Regulatory Council statement also leaves the erroneous impression that the predominant cause of cancer is industrial pollution from chemicals added to food, water and air or in the workplace. The table on the following page demonstrates that there is no correlation between the growth in production of industrial chemicals and mortality from cancer. The mortality rate has remained essentially flat when measured as the age adjusted number of deaths per 100,000 while industrial chemical production has increased by many orders of magnitude. Use of incidence figures leads to the same conclusion. The American Cancer Society reports that "[t]he overall incidence of cancer has decreased slightly in the past 25 years." Dr. Phillip Handler, President of the National Academy of Sciences, referred also to the fact that the incidence of cancer has remained "approximately constant for a half century."

PRODUCTION OF CHEMICALS AND ALLIED PRODUCTS: F.B.I. INDEXES (1947 = 100) (—-—)
The cancer burden is world-wide, impacting both industrial and non-industrial nations. There is no discernible trend linking national cancer burdens to industrialization. The World Health Statistics Annual (1972-1973) identified Scotland as the country with the highest rate for males (on the basis of age-adjusted cancer deaths per 100,000). The Netherlands had the highest rate for females. The United States is ranked 22nd for men and 21st for women behind non-industrial nations such as Switzerland, Northern Ireland and New Zealand.

Dr. Phillip Handler, President of the National Academy of Sciences, stated recently that:

"The possible effects of all known man-made chemicals, when totalled, would contribute only a miniscule fraction of all carcinogens in our population."

Dr. John Higginson, Director of the International Agency for Research on Cancer said recently that those who seek to place the "blame" on industrial pollution are "confounded" by the fact that the cancer rate in Geneva, Switzerland, which has no industry, is higher than the rate in Birmingham, in the center of England's great concentration of industry. Similarly, in the United States the Third National Cancer Survey (1969-71) found higher rates of cancer in "clean" cities - Minneapolis, Atlanta, San Francisco, and Dallas - than in "dirty" cities - Detroit, Pittsburgh and Birmingham.

The state-of-the-art of scientific risk identification and estimation is developing with almost explosive speed. The
national cancer policy, therefore, should have built into it the flexibility to take account of new developments. The Regulatory Council appears to encourage generic regulations. If that is the intended meaning of the Council's statement, it should be re-evaluated. A generic policy can substitute administrative determinations for scientific evaluation. The inflexibility of generic administrative determinations can stand as a bar to new developments. The convenience and speed which are said to be the benefits of generic regulations are not a reasonable trade-off for administrative determinations which freeze science. The Regulatory Council should discourage any such generic regulations.

The speed with which new developments occur means also that any policy put forward today should be reconsidered periodically. Otherwise, programs which have lost their purpose will be continued and new programs which are needed will not come into existence. AIHC stands ready to assist the Regulatory Council in the important task of developing a sound national cancer policy.

V. Conclusion

We hope that no statement in this memorandum will be construed as in any way downgrading or minimizing the importance of controlling exposure to manufactured chemicals which may cause cancer. Cancer and its causes are a matter of great concern regardless of its source. AIHC and responsible leaders of industry are committed to its control. Our purpose is to urge perspective on the federal regulatory activities which the Council addressed in its statement "Regulation of Chemical
Carcinogens" and to suggest the next steps to move from the narrow focus of the Council's statement to a national cancer policy.

AMC strongly recommends that the Regulatory Council:

1. Strengthen its generally laudable overall objectives, but clarify that the scope of the statement, relating principally to manufactured chemicals, addresses only a relatively small portion of the total cause and potential control of cancer.

2. Strengthen its guidance in matters of science by encouraging greater development and use of scientific risk assessment, emerging scientific data, and balancing of benefits or proposed regulations against costs of compliance.

3. Exert leadership and support or sponsorship for the IRLG to comprehensively review public comments on its "Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks" (44 Fed. Reg. 39858), and encourage issuance of an updated document by IRLG. Subsequently, the Regulatory Council should reissue its "Regulation of Chemical Carcinogens" statement to reflect the revised IRLG document.

4. Support and encourage a federal program that will provide a proper categorization and setting of priorities with reference to causes of cancer, inform the public objectively as to the predominant cause of cancer and initiate changes in policies to develop a national policy directed toward the total cancer burden.
References


11. 1979 Cancer Facts & Figures, American Cancer Society
AMERICAN INDUSTRIAL HEALTH COUNCIL

MEMBER COMPANIES

Abbott Laboratories
Air Products & Chemicals, Inc.
Aluminum Company of America
Allied Chemical Corp.
American Bakersies
American Cyanamid Co.
American Hoechst Corp.
AMOCO Chemical Corp.
Apollo Colors, Inc.
ARCO Chemical Co.
Aearco, Inc.
Ashland Chemical Co., Div. of Ashland Oil, Inc.
Bausch & Lomb Corp.
BASF Wyandotte Corp.
Borden, Inc.
Borg-Warner Chemicals, Div. of Borg-Warner Corp.
Bristol-Myers
Buffalo Color Corp.
Burlington Industries, Inc.
Carus Corp.
Celanese Corp.
Certainteed Corp.
Chemplex Co.
Chesebrough-Ponds, Inc.
Chevron Chemical Co.
Church & Dwight Co.
Clina-Grey Corp.
Cities Service Co.
Clorex Company, The
Columbia Nitrogen Corp.
Cosden Oil & Chemical Co.
Dart Industries Inc.
Diamond Shamrock Corp.
Dow Chemical, U.S.A.
Dow Corning Corp.
Eastman Kodak Co.
Eaton Corp.
E. I. du Pont de Nemours & Co.
Eli Lilly and Co.
Essex Chemical Corp.
Ethyl Corp.
Evans Chemetics, Inc.
Exxon Chemical Co., U.S.A.
Fairmont Chemical Co., Inc.
Ferro Corp.
Firestone Tire & Rubber Co.
First Chemical Corp.
FMC Corp.
GAF Corp.
General Electric Co.
General Mills, Inc.
General Mills Chemicals, Inc.
Georgia Pacific Corp.
Goodrich Chemical Co., B.F.
Goodyear Tire & Rubber Co.
H. R. Grace & Co.
Great American Chemical Corp.
Guardian Chemical Corp.
Gulf Oil Chemicals Co., Div. of
Gulf Oil Corp.
Halcon Research & Development Corp.
Hercules, Inc.
Hoffmann-La Roche, Inc.
Hooker Chemicals & Plastics Corp.
Hughson Chemicals, Lord Corp.
ICI Americas, Inc.
International Minerals & Chemical Corp.
Kay-Fries Chemicals, Inc.
Koppers Company, Inc.
Linden Chlorine Products, Inc.
Loctite Corp.
Mallinckrodt, Inc.
Merrill & Co., Inc.
Merck & Co., Inc.
Milliken Chemicals, Div. of Milliken & Co.
Mobil Chemical Corp.
Mobil Chemical Co.
Monsanto Co.
Mooney Chemicals, Inc.
NALCO Chemical Co.
National Distillers & Chemical Corp.
National Steel Corp.
Neville Chemical Co.
NL Industries, Inc.
Northern Petrochemical Co.
Oil In Corp.
Owens-Corning Fiberglass Corp.
Owens-Illinois, Inc.
Oxirane International
Pennwalt Corp.
Pfister Chemical Corp.
Pfizer, Inc., Chemicals Div.
Phillips Chemical Co., Div. of
Phillips Petroleum Co.
Pope Chemical Corp.
PPG Industries, Inc.
Procter & Gamble Co.
Quaker Oats Co.
Reilly Tar & Chemical Corp.
Republic Steel Corp.
Revlon Foundation
Reynolds Metal Co.
Rhodia Inc.
Shell Chemical Co., Div. of Shell Oil Co.
Stauffer Chemical Company
Sun Chemical Corp.
Synalloy Corp.
Tenneco Chemicals, Inc.
3M Co., Commercial Chemicals Div.
Union Carbide Corp.
Unifroyal Chemical, Div. of Uniroyal, Inc.
United States Steel Corp.
UOP, Inc.
Upjohn Co., The
Velsicol Chemical Corp.
Virginia Chemicals, Inc.
Vulcan Materials Co., Chemicals Div.
Witco Chemical Corp.
APPENDIX B

AIHC Comments on the IRLG Report

SUMMARY

I. The IRLG Report Should Affirmatively Encourage Good Science by Clearly Distinguishing Between the Scientific and Regulatory Functions

1. The scientific function and regulatory function should be clearly distinguished. The scientific function of risk identification and risk estimation should not be mixed with the regulatory function of deciding what reasonable steps are required for risk avoidance. The objective of the scientific risk estimate should be to identify the most probable human risk based on evaluation of all the data, with an indication of the precision of the estimate. The function of the regulator is to assess benefits, safety factors, costs, and other factors relevant to the societal/regulatory decision. Interjection of "conservative" models or assumptions in the scientific evaluation mixes the scientific function and the regulatory function. AIHC agrees with the Office of Science and Technology Policy that safety factors or conservatism should be addressed explicitly by the regulator and not concealed in some undisclosed way by adoption of conservative factors or models as part of the scientific evaluation.

2. The Report should encourage good science. Extrapolation models should be selected on the basis of scientific validity. The Report should reject "conservative" assumptions such as a direction to use the most sensitive model for extrapolation. The Report recognizes inter-species differences and the objective should be to find the animal model which is the best surrogate for man. If the Report makes clear that the most valid scientific extrapolation models should be used, we agree that this is consistent with the regulatory function.
tion models will be used and comparative metabolism will be used to select the most valid animal model, it will encourage the development of the data and encourage good science.

3. The IRLG should examine the Food and Drug risk analysis of aflatoxin in peanut products. FDA used human epidemiology to select the best animal model and attempted to make the most probable risk estimation without conservative assumptions. The regulatory options were realistically analyzed based on the scientific risk estimation.

4. To assure the highest quality and impartiality of the scientific risk estimations AIHC has proposed the creation of a science panel selected from nominees named by the national scientific academies and associations. The Office of Science and Technology Policy has also proposed a science panel as part of the National Toxicology Program under a committee from the regulatory agencies. AIHC believes that there is greater assurance of separation of the scientific and regulatory functions and of impartiality if a panel independent of the regulatory agencies is created as proposed by AIHC.

II. There Should Be Significant Modifications in How the IRLG Would Qualitatively Identify Carcinogenic Hazard

1. The Report biases the qualitative identification of carcinogenic risks by conservative assumptions. The result is a drive toward zero. All test results should be evaluated for quality and relevance. There should not be a bias in favor of positive results. All should be evaluated to determine whether they are valid evidence of carcinogenicity.
2. The Report recognizes inter-species metabolic differences, but in its bias in favor of positive results, fails to give appropriate scientific weight to the metabolic differences between man and the test animal. We urge the IRLG to encourage development of comparative metabolic data by assuring that the data when available will be used to improve the validity of extrapolation from animal data to man.

3. The Report places undue weight on short-term tests. Until the tests have been validated, they should, as the Office of Science and Technology Policy and the International Agency for Research on Cancer propose, be used only as screening devices for further testing.

4. The IRLG has adopted the hypothesis that all exposures to carcinogens are additive. Although there is evidence of additive or synergistic effects from exposures to some carcinogens, the Report itself recognizes that many substances act as inhibitors. The Report should identify the assertion of additivity of exposure as a hypothesis to be examined in each case. Where the data support a conclusion of additive, multiplicative or inhibitive effect, these data should be used in the risk estimation.

5. The IRLG fails to give due weight to negative human epidemiological studies. We urge the IRLG to adopt the more balanced view of the National Academy of Sciences and the EPA. Negative epidemiology can serve to mark the upper limit on human risk and to assess the extrapolation of animal data to man.

6. The IRLG report, by a determination that induction of benign tumors is the equivalent of induction of malignant tumors.
disregards the scientific reasons for making distinctions. AIHC agrees with the International Agency for Research on Cancer (IARC) that, if a substance is shown to induce only benign tumors, further investigation is required. AIHC also urges the IRLG to consider, as proposed by the IARC, the limited weight to be given to certain mouse neoplasms in evaluation of carcinogenicity.

IRLG recognizes that potency of carcinogens varies by several orders of magnitude. A substance which induces only benign tumors is of a completely different order of activity than one that produces highly malignant tumors.

To lump all substances that may be carcinogenic is scientifically unsound and confounds the IRLG's own comments on potency.

7. Historic experience in strains of test animals to assess test results must be used with caution. The incidence of spontaneous tumors may change in a colony over a period of time.

III. The IRLG Report Should Support Scientific Risk Estimation Methodology Selected on the Basis of Scientific Validity

1. Risk quantification methodology including selection of mathematical models should be made on the basis of scientific validity, not conservatism.

2. It may be reasonable to use a single mathematical model to make preliminary risk evaluations in setting priorities. Risk estimation, however, should not be made using conservative models or assumptions which improperly inject societal/regulatory values into the scientific process. The objective of the scientific function is to estimate the most probable human risk. Use of
conservative" models presents a worst-case estimate biased in some undisclosed way. The FDA risk analysis of aflatoxin used human data to select the test species most like man and to evaluate extrapolation models. We urge IRLG to use a similar approach.

1. Mathematical models should be selected for scientific merit. IRLG was correct in not selecting any model as a generically valid model. AIHC urges the IRLG to express an open-mindedness in selection of a model or models on the basis of statistical evaluation of goodness-of-fit. We also urge the IRLG to encourage and support the improvement of models. The model selected should also reflect the biological data. The linear-through-zero and one-hit models which the Report emphasizes are inappropriate in those cases where the mechanism is epigenetic.

AIHC urges the IRLG to establish guidelines for evaluation and selection of models:

1. Because no model can at present be selected generically on the basis of scientific merit, several models should be evaluated in each case and those with the highest relative validity used to generate a bracket of human risk.

2. By evaluation of all data and exercise of scientific judgment the most probable risk can be estimated.

4. IRLG recognizes the importance of pharmacokinetic data in qualitative risk identification but does not underline the
importance of using these data in assessing the appropriateness of a model.

5. Risk estimation procedures should use human epidemiological data. The IRLG should recognize the use of negative human data in indicating the upper bound of human risk.

IV. Procedural Safeguards to Assure Due Process in the Identification, Estimation and Evaluation of Human Risk

Preliminary risk assessments made for purposes of priority setting should not be used to "blacklist" a substance. The commercial consequences of such a "blacklisting" cannot be erased by a final risk estimation; hence serious due process issues could arise. Moreover, the IRLG should focus on the method for suitable public input in the process of scientific evaluation.
FOOD SAFETY POLICY

In dealing with food safety policy, there are three major ideas which may help lead to clear thinking. First, food safety policy is not the same as food safety science. Second, the ability of food safety science to resolve food safety policy problems is severely limited. Third, the food safety problems faced by this society are an integral part of the web of environmental health difficulties that this Nation is just beginning to grapple with. This set of realities makes the food safety debate one of the most searing and potentially most significant current debates about the kind of future that this society will have.

Taking the points in inverse order:

Food safety problems are an important part of the environmental health situation. Currently, most cancers are of unknown origin, virtually all mental retardations and other birth defects are of unknown origin, and a relatively high incidence of spontaneous abortions and genetic damage to newborns in the society are of unknown origin. In the face of these facts, national researchers estimate that in excess of 60 percent of the cancer in this country has its origin at least in part in environmental causes. Similar conclusions about birth defects and genetic damage have been reached by researchers in their respective fields.

At the same time chemicals added to and occurring naturally in food have induced cancer, birth defects, and genetic damage in animals and/or bacteria and cells mediation systems.

It is no longer possible for any knowledgeable person to argue that the American food supply is without potential hazard. Since it has not been able to eliminate serious potential health hazards from the food supply this society now faces the problem of how to manage the food supply to minimize the health damage to which it contributes.

In this situation simple sounding ideas have appeal for policymakers. Currently, idea systems based on the assumption that we have sound complete scientific knowledge, supported by scientific demonstrable facts about the nature and extent of risks in the food supply are competing for the attention of decision and policymakers. One set of ideas argues that it is possible to rank various risks by kind or degree of risk and regulate more rigorously one set of risks—the big ones—other sets of risks—the lesser ones.

Another set of ideas suggests that we can measure the risks currently accepted by the society (cigarette smoking and skin diving are two kinds of examples often cited) and allow the risks in the food supply to exist to a degree comparable to these already accepted risks. A third set of risk-based ideas asserts that specific food safety issues
should be measured by a risk benefit measure and those substances or policies which pose less risk than they supply benefits should be allowed or adopted.

Each of these proposals has its own set of limiting weaknesses. However, they all share the major disability that they do not address the problem of how to keep the food supply safe enough to eat. Specifically, each of them deals only with known risks which have been measured. Any risk-based food safety system ranking risks, comparing risks, or weighing risks against benefits excludes from policy consideration and management that overwhelmingly large set of safety problems that result from what is currently unknown, currently unmeasurable, or currently undetected. It does not focus on improving the health of or insuring safety for individual people.

Focusing on known and measurable risks to the exclusion of possible, potential, or even imaginable—but as yet undetected risks—is the most serious policy error currently clouding the food safety debate. A sounder policy approach would be to accept the fact that the food supply contains risks of all magnitude and all states of detectability from obvious to not even imagined. Then the policy should focus on those aspects of the food component problem which are manageable no matter the degree of risk. In this situation materials added to food, additives, pesticides, animal drugs, etcetera, become more appropriate for control by exclusion than naturally occurring toxicants. On the other hand, methods to diminish the amount present of naturally occurring toxicants became an appropriate focus for policy activity.

Already many food companies have begun policies of review on food safety matters beginning with the question "What can we remove from our food—in the way of chemicals, additives, residues, etcetera—because they are not necessary regardless of the kind or degree or absence of risk presented." Such a policy shifts the focus from controlling known and measurable risks to elimination of as many potential sources of risk as can be eliminated whether the potential risk is actually discovered and/or measured or not.

Step 1 of a sound policy is to remove all sources of potential risk that can be removed. Unless a strong case can be made for the use of an additive, the need for a pesticide residue, or the need for an animal drug, they should not be used. For those which have a strong need, then risk information must be vigorously ferreted out and organized. But organization should follow, not precede, a determination of the need for any non-naturally occurring addition to the food supply.

Only when it is recognized that the potential lack of safety in materials added to the food supply is the starting point of a food safety policy can inroads be made into the actual damage being done by aspects of the food supply. Cancer, birth defects, and genetic damage are long-term problems of great seriousness with profound implications for the well-being of the future of this society. It is increasingly clear that some unknown portion of these problems are related to the consumption of food. Food safety policy must begin with this recognition.

Identify those added substances which cannot be dispensed with. Develop methods for the elimination of those naturally occurring
substances which must be dispensed with. Then figure out which risks cannot be taken no matter how important the added or naturally occurring substances. This is the beginning of a policy approach to food safety.

The next step could be to expend meaningful resources on the continuous scientific monitoring of substances which find their way into the food supply under this kind of a policy. Sophisticated epidemiological techniques should be used to monitor, on a long-term basis, any substance so important it must be added to the food supply and not so unsafe it must be excluded, or any naturally occurring substance which cannot be eliminated and which is safe enough to live with. Such an epidemiological program could provide a growing data base on food safety matters related to substances thought to be safe enough to allow in the food supply. The four step policy suggested here is:

1. Identify essential additive materials;
2. Identify naturally occurring potential dangers which cannot yet be eliminated;
3. Exclude, limit, or otherwise control materials that pose some risk but not so much that they should be excluded;
4. Systematically monitor those substances allowed to be added to food and those naturally occurring which potentially pose a hazard.

This four step policy is a rough outline of a policy that begins from a point of view that does not initially assume that all existing risks are known, measurable and detectable. Any program that assumes the ability to identify, quantify, and evaluate risks present in food will lead to serious damage to individual members of the population.

Resting food safety policy on the assumption that all existing risks are known, measurable and easy to evaluate is the primary mistake made by many individuals who propose food safety policies. The hazards of concern in the food safety debate are too integrally related to the general environmental hazard problems of the society for it to be assumed that we have found the risks and they are ours to be eradicated. The biggest food safety problem is that most of what is harmful, more likely than not, is still unknown. This is the only sound starting point for a food safety policy. Misunderstanding the nature of the risk is the first mistake that policymakers must guard against.

The second mistake that policymakers must avoid is the assumption that food safety science can solve food safety problems. Policymakers must learn that science is limited in its ability to determine food safety policy. In addition to the fact that the suggested potential problems of safety contained in the food supply are unknown, it is also a fact that the ability of science to be conclusive even in areas where it is highly developed is severely limited.

When a scientist argues that saccharin should be phased out of the food supply because it is a cancer-causing substance he is not giving a science answer. Only the part of his recommendation concerning the cancer-causing nature of the chemical is scientific. Whether the substance should be immediately banned, phased out, or allowed in the food supply is a policy recommendation on which a scientific researcher is not particularly qualified to comment. Discussions of the Delaney anticancer clause are included (attachment A), in an effort
to present the policy arguments about how to respond to limited scientific material.

The serious limitations of science as a substitute for sound food safety policy are set out in attachments B and C. The fact that the food safety issue is a policy and not a science issue is nicely set out in attachment D by a food company executive who has thought extensively about these problems. In addition to recognizing the fact that ordering or measuring risks cannot be the starting point of an effective food safety problem, policymakers must also recognize that science, even where it is measuring and evaluating risks, is a severely limited tool.

Ordering and/or weighing food safety risk is not a sound way to begin a food safety problem because the biggest risks are the unknown risks which by their very nature cannot be ordered, measured, or weighed. Even where risks are known or at least highly probable science is severely limited in describing, measuring, or otherwise characterizing them. This leaves policymakers with relatively small help from science and a not very clear idea of what task they are undertaking.

In this situation it is tempting for policymakers, whether regulatory or legislative, to direct "prestigious" academic bodies to mull the questions over more in order to buy political time rather than to produce a policy answer. The problem with this maneuver is that time always runs out and the policy issues are not being addressed because the policymakers have ducked the issue. What is important to recognize, however, is the fact that policymakers have a distinct skill which has as much expertise to its use as the skills of the academic/scientific world.

Serious attention must be paid by the policymakers to their own unique expertise in policy developments. Policymakers have a legitimate role to play in shaping and resolving national health and safety issues such as the safety of the food supply. Continued deferring of hard food safety questions to scientific bodies will lead eventually to Congress having delegated away its health and safety authority. The attached paper "How Safe Is Safe" (attachment B): attempts to set out the distinction between science and policy in a way useful to the consumers' point of view to the food safety debate.

Managing known, measurable, or suspected risks, as difficult as that task is, makes up only the smallest part of the food safety policy problem. Dealing with unknown, unmeasured, or unsuspected risks is where the heart of the policy problem lies. Because dealing with known measurable or suspected risks seems more immediate and easier to manage, it continuously becomes the focus of the food safety debate. In fact, it is possible if not probable that the unknown, unmeasurable, or unsuspected risks pose the greater threats to the future well-being of this society. To the extent that this is true, certain policy approaches make more sense than others.

To the extent that managing unknown, unmeasured, or unsuspected risk is the focus of food safety problems, the following policy approaches make sense. These are examples; others need to be developed.

1. Control what can be controlled. To the extent that natural dangers exist, substances which might increase these natural dangers should be curtained.
2. To the extent that possible dangers are allowed or discovered in the food supply, continuous epidemiological monitoring of these possible dangers should be undertaken.

3. Scientific examination of food safety problems should be organized to increase and upgrade the available scientific data. A proposed testing system to achieve this goal is attached.

Proposed testing system

Currently a substance designed for use in food is tested at the proponent's expense and the results are given to the FDA for evaluation. It could be possible for the FDA to certify a set of laboratories for testing; receive a proposal for testing of a substance from a proponent and then refer the substance for testing on a randomized basis to a certified laboratory. The testing would be paid for by the proponent as is now the case, but the results would be relied on for prima facie disposition of the risk question.

Such a system has already been introduced in legislation in the U.S. Senate.

[ATTACHMENT A]

THE DELANEY ANTICANCER CLAUSE: A MODEL ENVIRONMENTAL PROTECTION LAW

(By James E. Turner*)

I. INTRODUCTION

In October 1969, the artificial sweetener cyclamate was banned from sale in the United States by Secretary of Health, Education, and Welfare Robert Finch. To justify his action legally Finch chose to rely on the so-called Delaney anticancer clause of the Food, Drug, and Cosmetic Act of 1938. Consequently, the Delaney clause, with its requirement that any substance producing cancer in animals be removed from the American food supply, became an immediate center of controversy. The Secretary himself criticized the clause as an undue restriction on administrative decisionmaking and as an unscientific limitation on scientific discretion. When asked if the Delaney clause should be modified, Food and Drug Administration Commissioner Charles C. Edwards reflected Secretary Finch's view in replying:

*I think the scientific community is rather well split on this issue. There are those who feel that it is just what it ought to be right now. My personal view and

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1 "I have acted under the provisions of * * * the so-called Delaney amendment, enacted eleven years ago, which states that any food additive must be removed from the market if it has been shown to cause cancer when fed to humans or animals * * * because I am required to do so." Announcement of cyclamate ban, press release of Secretary Finch, Oct. 19, 1969, at 3.

2 "(N)ot additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal; or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal. * * * Food Additives Amendment of 1958, sec. 409(c) (3) (A), 21 U.S.C. sec. 348(c) (3) (A) (1964).

* "But who is to say that using Fresca or some other diet drink * * * isn't better for you than the problems of overweight or diabetes." Finch Takes Position Against Delaney Clause, Food Chemical News, Nov. 10, 1969, at 3.
that of the FDA is that we have to have more flexibility in interpretation or we are put into a position we were with cyclamates— all or nothing.

The contrary point of view was reported to the Surgeon General in 1970 by an eight-member committee of scientists with a staff of six senior scientists from the National Cancer Institute. After reviewing the state of cancer research and its relation to the Delaney clause, the committee stated:

It is essential to recognize that no level of exposure to a carcinogenic substance, however low it might be, can be established to be a "safe level" for man. The current legislation in the field of food additives, with its "anti-cancer clause," is based on this principle.

Although the Delaney clause has faced criticism from some quarters, careful analysis of the clause reveals that it seems to serve well as a vehicle for the proper balancing of administrative discretion and scientific independence on one hand with public protection on the other; because of the analogous policy conflicts that arise in many areas of consumer concern, the clause represents a valuable model for all environmental protection legislation.

II. THE STRUCTURE OF PROTECTION UNDER THE FOOD, DRUG, AND COSMETIC ACT OF 1938

Prior to the enactment of the Food, Drug, and Cosmetic Act of 1938, a food was considered adulterated, and therefore excluded from interstate commerce, if it contained any added poisonous or deleterious ingredient that might render it injurious to health. This state of the law proved to be unacceptable because, before a food could be barred from the national market, the Government had the obligation of showing affirmatively that it contained an added poisonous or deleterious substance which might be harmful under normal conditions of use.

In passing the 1938 act to alleviate this problem of proof, Congress altered food protection law in two ways changing both essential definitions and basic operating procedures. First, section 402(a) redefined adulteration:

A food shall be deemed to be adulterated if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406. An unsafe substance was defined in section 406(a):

Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402(a).

Second, procedures were prescribed that for the first time allowed poisonous or deleterious substances to be added to the food supply if the amount was within tolerances promulgated as safe by the Secre-

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*Food and Drug Act of 1906, ch. 3915, secs. 2, 7. 84 Stat. 768.
*1933 FDA Annual Report 14.
*Id. 8406(a).
The new definition of adulteration, however, did not resolve the chronic burden-of-proof problem. Under the 1938 act the evidentiary issue was simply moved back one step, and the Food and Drug Administration (FDA) found itself compelled to show affirmatively in the first instance that a particular chemical was poisonous or deleterious. The difficulty in the application of section 406's test to various chemical substances arose because the drafters of the section attempted to define an acceptable level of human risk by utilizing the constructs "safe" and "unsafe." From the legislative history of the act it clearly is demonstrable that by using the words "poisonous" and "deleterious" Congress sought to designate all unsafe substances. Understood in this way, sections 402 and 406 form a legal non sequitur.

The circular nature of the food protection device becomes evident when the word "unsafe" is substituted for the terms "poisonous" or "deleterious" as they occur in the act. Section 402(a)(2) would read: "A food shall be deemed to be adulterated if it bears or contains any added unsafe substance which is unsafe within the meaning of section 406." Section 406 would read: "Any unsafe substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for the purposes of the application of clause (2) of section 402(a)." Manifestly, Congress attempted to devise a formula for establishing tolerances for poisonous—unsafe—ingredients in food. Just as clearly, however, by defining circularly the term "unsafe," Congress forced the FDA to prove in each instance the poisonous or deleterious nature of the chemicals. Often this placed the FDA in the position of attempting to answer legally, scientific questions unanswerable in the laboratory. The Food Safety Panel of the 1969 White House Conference on Food, Nutrition, and Health underscored the problem, stating: "It is not possible to determine with absolute certainty the safety of the ever-increasing number of chemicals added to or present in our foods." Because of its definitional difficulties, the
1938 act, like its predecessor, proved to be ineffective and food protection problems increased.14 Faced with the nearly impossible task of establishing safety for every controversial chemical, the FDA once again sought changes in the law. Between 1950 and 1953 New York Congressman James J. Delaney conducted a series of hearings into the nature and use of chemicals added to the food supply.15 From these hearings three major pieces of legislation resulted: the Pesticide Amendments of 1954,16 the Food Additives Amendment of 1958,17 of which the Delaney clause is a part; and the Color Additive Amendments of 1960.18 The originally straightforward prohibition of unnecessary or avoidable poisonous or deleterious substances from food became the complicated prohibition of:

(A) * * * any added poisonous or added deleterious substance (other than one which is (1) a pesticide chemical in or on a raw agriculture commodity; (2) a food additive; or (3) a color additive) which is unsafe within the meaning of section 346 * * * * or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of 346(a) * * * * or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 348 * * * *.

Each piece of inserted language, covering pesticides, food additives, and color additives, represents an involved regulatory system spelled out in detail within the act. The administrative discretion granted by this machinery requires the FDA to weigh the value of each proposed chemical use on a scale that balances the rights of the chemical producer against those of the general public; however, proof of safety remains the objective of each part of the act.

The pesticide, food additive, and color laws all contain essentially the same regulatory structure, consisting of a chemical-by-chemical analysis by "the Secretary." This authority has been delegated to the Commissioner of Food and Drugs for food and color additives and to the Administrator of the Environmental Protection Agency for pesticide chemicals. In each case the process begins by the filing of a petition seeking a ruling by the Secretary that either allows the chemical to be used, or bars its use, in the ways sought by the petitioner. The decision of the Secretary comes in the form of an order that specifies the ways in which the chemical may be properly used. Detailed procedural rules govern the process that the Secretary and all interested parties must follow from the time the petition is filed until the time of a final order and dictate the way in which the appeals from the final order are to be brought to the attention of the courts.20 It should

The definitional problems could have been obviated if the section had been drafted without reference to the notion of safety. For example, it could have read "no chemical substance shall be added to any food except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice." The tolerance-setting procedure under this language would be used to determine whether a chemical was avoidable or was required in food production. This was apparently the very concept that Congress intended to introduce into the section. At this stage the FDA could defer to scientific judgments of safety when they existed.

See Hearings on H.R. 74 Before the House Select Committee To Investigate the Use of Chemicals in Food Products, 86th Congress 2d Session (1951).


21 C.F.R sec. 120 (1977) (pesticides); 21 C.F.R sec. 121 (1971) (food additives); 21 C.F.R sec. 8 (1971) (color additives).
be noted that the complex statutory apparatus leaves unresolved the definitional problems inherent in the use of the word “unsafe,” the same problem that caused the 1906 and 1938 food protection laws to founder.  

III. THE PROOF-OF-SAFETY PROBLEM—UNSUCCESSFUL ATTEMPTS TO SOLVE IT.

The Food Additives Amendment of 1958 contains three distinct attempts to alleviate the FDA’s burden-of-proof problem: (1) the generally recognized as safe (GRAS) approach that resulted in the GRAS list of chemicals approved by the FDA for addition to foods; (2) the Delaney anticaner clause that bans from food any substance which causes cancer when fed to animals; and (3) the administrative structure that emanated from FDA regulations designed to evaluate item by item any chemicals which do not fall into either category one or two. Each of these three legal stratagems endeavored to circumvent the problem of scientific uncertainty, but only the Delaney clause succeeded. Before detailing the accomplishments of the Delaney clause, the reasons for the failure of the two mechanisms should be outlined for comparative purposes. In particular, that effectively controls chemical contamination of the environment must seek to block the use of substances that present undue risk without putting unreasonable restraints on chemicals that provide important benefits to the public.

To initiate the GRAS procedure, the Food and Drug Administration asked 300 scientists to comment on the safety of the first substances...
proposed for the GRAS list. Rather than achieving the scientific consensus assumed possible by the GRAS theory, the FDA harvested a scattering of opinions. Of the 900 scientists questioned, 350 replied with only 194 or 21 percent of the total group ratifying the entire list. The performance of the FDA in accurately predicting the safety of specific chemicals, even after some doubt had been raised, was similarly imperfect. The FDA, for example, dismissed the complaints of a number of scientists against safrole, vitamin D, and most notably cyclamate, only to find it necessary to act against the challenged chemicals in subsequent years. Thus the GRAS list mode of procedure proved to be ineffective in discriminating between safe and unsafe substances because the system presented the same problem of scientific choice that the earlier acts had been unable to deal with. Where the agency earlier had tried to choose which chemicals and which foods were safe, it now foundered trying to choose which scientists were the best judges of safety. An FDA memorandum spelled out the guiding principle of this choice.

In our final evaluation of the safety of a substance we have taken cognizance of the fact that all opinions are not of equal value and thus have weighed most heavily the opinions of scientifically recognized and often world-renowned experts.

Under this pick and choose procedure the basic GRAS list grew to approximately 700 items with various loopholes and exceptions allowing as many as another 1,000 items to be treated as on the GRAS list by the FDA. Food manufacturers, faced with a minimum of an estimated 2 years of study before gaining permission to market a new additive, sought to achieve recognition of their chemicals through the loopholes in the GRAS list procedure. By the end of 1970 the situation had become so unwieldy that the agency moved to revise the entire GRAS procedure by attempting to reintroduce suspect chemicals currently on the GRAS list into the chemical-by-chemical investigation.

As previously noted, the chemical-by-chemical procedure relies on the ability of scientists to distinguish safe from unsafe substances. That portion of the act authorizing this approach states: "No regulation shall be issued if its fair evaluation of the data before the Secretary—that is, a fair evaluation of the data before the Secretary—fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe." All parties to the discussion of the 1958 Food Additives Amendment accepted the assumption that safety or the lack of it could be established in each case, and accordingly, the FDA issued a regulatory definition of safety that said, "Safe means that there is convincing evidence which establishes with reasonable certainty that..."
no harm will result from the intended use of the food additive." 11 Faced with reviewing the GRAS list that contained many items for which scant, controversial, or no evidence existed, the FDA, interestingly enough, moved to redefine "safe." "Safe" must be understood to connote that the Food and Drug Administration, after reviewing *all available evidence*, can conclude there is no significant risk of harm from using the substance as intended. 12 This second definition allows untested or only partially tested chemicals to be added to the food supply, while the former definition required the initial presentation of some convincing evidence of safety. The change in definition represents a significant erosion of the safety concept, one of the unfortunate side effects that results when a regulatory agency expected to enforce policy is required to resolve scientific conflicts. The Surgeon General's committee on low-level carcinogens demonstrated the folly of the FDA's new safety definition. It reported that bioassays are incapable of detecting carcinogenic effects below the 10-percent level, and therefore so-called negative data are grossly inadequate to give assurances of safety for man. 33 More importantly, leading scientists 44 are increasingly making the same argument about the chemicals related to genetic problems, birth defects, and mental retardation. The current FDA attempt to revise the GRAS list and its redefinition of safety concede the difficulty of giving empirical meaning to the term "unsafe" while the whole area is the subject of scientific controversy. This difficulty is further demonstrated by the FDA's new interim regulation policy.

If after a responsible and substantial question of safety has been raised regarding a substance previously listed as GRAS the main weight of the scientific evidence still indicates safety (at least within certain limits), an interim food additive regulation will be proposed. This will permit further scientific investigations to define the conditions of safe use for a food additive regulation of indefinite duration.° This statement seems to be at variance with the provision of the act that requires that "no such regulation shall issue if a fair evaluation of the data before the Secretary—(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe * * *" 35 The FDA, however, argues that an interim time period serves merely as one more condition of use under the law, and this interpretation has been upheld in Federal district courts. The practice of issuing interim regulations further erodes the assumption that the food supply contains only safe chemicals.

1. 21 C.F.R. sec. 121.1(1) (1971) (emphasis added). Commenting on the safety provision, Charles Wesley Dunn, the general counsel for the Grocery Manufacturers of America stated: "Such a requirement is basically a pretesting requirement for new food additives. * * * Whereas the FDC Act now prohibits a food that is unsafe, this prohibition normally applies after the food is sold and consumed, and its enforcement may be long delayed for various reasons. * * * Moreover, in such an enforcement proceeding the Government has the burden of proving that the food is unsafe, whereas this requirement would instead compel the manufacturer of a food to prove in advance that it is safe." Hearings on H.R. 8112 supra note 28.
3. National Institutes of Health and National Cancer Institute, supra note 1.
4. Examples of scientists who are concerned with chemicals causing birth defects and genetic damage include Dr. Samuel Epstein of Case Western Reserve University, Dr. James Crow of the University of Wisconsin, Dr. John W. Olney of Washington University, and Dr. Marvin Legator of the FDA.
6. The oral opinion of Judge Gerhard Gesell was reported in Food Chemical News, July 12, 1971, at 17.
The FDA, after 65 years of failure, still struggles to solve scientific controversies about safety with legal tools. One apparently overlooked fact underlies this struggle. When scientists agree that a chemical is either safe or unsafe, no controversy about its use erupts. Only when a scientist challenges the label of "safe" attached to a chemical or class of chemicals by other scientists does the FDA engage its balancing mechanism. Otherwise, chemicals enter the food supply virtually unnoticed. As a result, whenever it enters a controversy the FDA overrules one set of scientifically supported arguments with a legal or regulatory judgment.

The twisting and turning of the food and drug laws since 1906 resulted from using the word "safety" to denote two distinct concepts. First, it includes the scientific observation that a chemical additive or food does not cause damage to humans. Second, it includes the policy judgment that even though a chemical might cause injury to a human, the damage it causes is outweighed by the benefits it imparts. Only the Delaney clause of the Food and Drug Act escapes this pitfall by avoiding any reference to either concept of safety. Instead, it allows scientists to ascertain the degree of risk presented by the use of a particular chemical and assigns policymakers the task of judging whether the scientifically defined risk is acceptable to society. For this reason it serves as a model for all other environmental protection legislation. Despite the simple logic underlying the clause, and despite its ready applicability to other regulatory fields, this clause has often been misunderstood by regulators and the public alike.

IV. THE DELANEY CLAUSE: A MODEL FOR ENVIRONMENTAL PROTECTION LEGISLATION

A. Misunderstanding the Delaney clause

Food and Drug Commissioner Charles C. Edwards restated accurately the misunderstanding of the Delaney clause when he said of it:

"...my personal view and that of the FDA is that we have to have more flexibility...or we are put into the position that we were with cyclamates—all or nothing. And it becomes a highly emotional issue at that point, allowing no discretion on our part or anyone else's..."

This statement implies that but for the Delaney clause the FDA would have allowed cyclamates to remain in the food supply in some amount even though this chemical causes cancer in rats. The Commissioner's characterization of the Delaney amendment as a usurpation of administrative discretion is incongruous because other parts of this food protection law, although operating more slowly than the anticancer clause, also would have required cyclamates to be completely banned from the food supply. At the onset of the cyclamate controversy, the chemical was generally recognized as safe by the FDA. After a substantial safety question was raised, the Secretary officially removed cyclamates from the GRAS list. At this point the law, absent the Delaney clause, requires that the chemical be shown to be safe before a petition can be granted allowing its addition to food. In view of...
the state of scientific knowledge about cancer-causing substances, it is unlikely that cyclamate could have met this burden of proof; therefore, cyclamate could have been removed from the food supply without reference to the Delaney clause. In fact, some of the most vigorous proponents of the Delaney clause call it an unnecessary duplication of existing authority.

When the Commissioner asks for "discretion" to decide when a chemical that causes cancer in animals can still be used in food for human consumption, he is asking for the discretion to decide an issue that thousands of cancer researchers have been unable to resolve. The dangers of this position were put forth accurately by former Secretary of Health, Education, and Welfare, Arthur S. Flemming:

The rallying point against the anticancer provision is the catch phrase that it takes away the scientist's right to exercise judgment. The issue raised is a false one, because the clause allows the exercise of all the judgment that can safely be exercised on the basis of our present knowledge. The clause is grounded on the scientific fact of life that no one, at this time, can tell us how to establish for man a safe tolerance for a cancer-producing agent.

As I pointed out in my original testimony, the opposition to inclusion of an anticancer clause arises largely out of a misunderstanding of how the provision works. It allows the Department and its scientific people full discretion and judgment in deciding whether a substance has been shown to produce cancer when added to the diet of test animals. But once this decision is made, the limits of judgment have been reached and there is no reliable basis on which discretion could be exercised in determining a safe threshold dose for the established carcinogen.

The fact that the country's highest food and drug officials still believe that this kind of discretion should be granted demonstrates the need for more effective policy setting by Congress.

B. Expanding the Delaney Clause to Other Areas of Environmental Protection Legislation

From the FDA's experience in attempting to differentiate between safe and unsafe substances, it seems apparent that in order to shield the environment from further chemical contamination, the policy issues and the scientific issues, although interrelated, must be approached separately. The report to the Surgeon General on environmental carcinogens clearly defined the problem and divided the scientific and policy responsibility. "While science can provide quantitative information regarding maximum risk levels, the task of ultimately selecting socially acceptable levels of human risk rests with society and its political leaders." The role of the scientist is to describe physical phenomena—this chemical caused lesions in mouse brains under these conditions; that chemical caused cancer when fed to mice in certain quantities; those chemicals caused birth deformities when injected into chickens in designated amounts at certain ages. Scientists can offer less...
definite—but still important scientific opinions on the degree to which damage to man can be predicted from damage to animals. Without knowing the levels of risk that society will tolerate, however, scientists cannot effectively differentiate between “safe” and “unsafe” substances.

Congress, on the other hand, taking into consideration the certainty or relevancy of the scientific findings, must set broad policy guidelines. Several issues suggest themselves as important for the consideration of the Nation’s policymakers. Which purposes served by chemicals are worth the apparently increasing risk of their use in foods? Resolving this issue involves a reassessment of the “required for” or “unavoidable in” food production concept of section 406. If additional uses of chemicals are found necessary to improve the food supply, these concepts could be expanded. In addition, Congress must determine which extrapolations from animals can be made to man. In the cancer area it is policy that if a chemical affects animals it will not be given to humans. This practice was adopted because under the present state of scientific knowledge a safe tolerance for man of a substance that produces cancer in animals cannot be established.

What chemicals should be added to the “zero tolerance” list now containing only carcinogens? Already chemicals causing birth defects and genetic damage in animals have been suggested for addition to the list. Congress must collect and review the evidence that other irreversible biological damage can be caused by chemicals and set a “zero tolerance” policy for these areas where necessary.

The Delaney clause can serve as a model for environmental protection legislation because it delegates to scientists the responsibility for making scientific judgments and to Congress the task of making policy decisions. The scientist, after an analysis of all technical data, specifies the degree of risk that would result if any amount of known carcinogens were allowed in the Nation’s food supply; Congress, after considering all other relevant information, determines that the risk is unacceptable. The FDA is then charged with the responsibility of removing carcinogenic chemicals from the food supply. The procedure outlined for developing a new food protection or any other environmental protection law should not include any effort to define “safety.” Instead, criteria should describe a degree of risk as accurately as possible. Congress then should decide whether that risk is worthwhile. In the development of a more effective food protection law, reference to the Surgeon General enunciated one additional fundamental point: “Chemicals should be subjected to scientific scrutiny rather than given individual ‘rights’; they must be considered potentially guilty unless and until proven innocent.”

The authors of that report directed their comment at carcinogens, but the same observations may now be made for chemicals relating to genetic damage or birth defects.

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a The Food Safety Panel of the White House Conference suggested some additional criteria that Congress might consider: “(That) no additional chemicals should be permitted to or on foods unless: They have been shown with reasonable certainty to be safe on the basis of the best scientific procedures available for the evaluation of safety and meet one or more of the following criteria: 1. They have been shown by appropriate test to be significantly less toxic than food additives currently employed for the same purpose; 2. They significantly improve the quality or acceptability of the food; 3. their use results in a significant increase in the food supply; 4. they improve the nutritive value of the food; and 5. their use results in a decrease in the cost of food to the consumer.” White House Conference on Food, Nutrition, and Health, supra note 13.


c National Institutes of Health and National Cancer Institute, supra note 5, at 19.

d Id. at 15.
V. CONCLUSION

The nearly uninhibited addition of chemicals to the environment for the last several decades lies at the heart of the so-called environmental crisis. To control this use of chemicals requires a new combination of scientific expertise and legal policy. The drafters of the Delaney clause of the current food protection law were successful in writing into the legislation a proper balancing of the policy function and the scientific function. Congress heard scientists describe the level of known and unknown risk associated with cancer-causing chemicals. It set the policy that no chemical known to cause cancer in animals would be allowed in the food supply. The regulatory agency was assigned the scientific task of distinguishing those chemicals that cause cancer in animals from those that do not. The Delaney clause sets clear public policy and allows complete scientific freedom.

Congress, by setting the public policy concerning cancer-causing chemicals itself and by assigning the scientific implementation of that policy to the agency that regulates food, established a procedure for effectively weighing environmental dangers and acting to prevent them. All chemicals—whether they be pesticides in or on foods, industrial chemicals that contaminate the water or air, hazardous substances that are used in the home, or any one of hundreds of other environmental pollutants used in this society—must be subjected to a rationalized policy. Congress, guided by the state of scientific knowledge, must place limits on the risks to be assumed by society; the appropriate regulatory agency, again guided by scientific research, must not allow that established risk to be exceeded. This is the principle of the Delaney clause and for this reason the Delaney clause serves as a model for other environmental legislation.

ATTACHMENT B

HOW SAFE IS SAFE?—THE DESIGN OF POLICY ON DRUGS AND FOOD ADDITIVES

A CONSUMER'S VIEWPOINT

(By James S. Turner)

"How safe is safe?" is a misleading question for a conference on the design of policy on drugs and food additives. It implies the quest for an objective, scientific, if you will, standard of safety acceptable to all interested in the issue being considered. Unfortunately, in the real world today's acceptable standard of safety may be more or less acceptable than yesterday's or tomorrow's.

In addressing the problem of nuclear reactor safety, Dr. Alvin Weinberg, director of the Oak Ridge National Laboratory, put the matter more precisely when he asks, "How safe is safe enough?" That is the question underlying the design of policy on drugs and food additives. It is not primarily a question for scientists; it is a policy question.

Dr. Weinberg spelled out the distinction effectively when he spoke at the dedication of the Paul B. Johnson Science Tower at the University of Southern Mississippi in January 1972:

Many of the issues that arise in the course of the interaction between science or technology and society—e.g., the deleterious side effects of technology, or the
attempts to deal with social problems through the procedures of science—hang on the answers to questions which can be asked of science and yet which cannot be answered by science. I propose the term trans-scientific for these questions since, though they are, epistemologically speaking, questions of fact and can be stated in the language of science they are unanswerable by science; they transcend science. Insofar as public policy depends on trans-scientific rather than scientific issues, the role of the scientist in contributing to the promulgation of such policy must be different than in his role when the issues can be unambiguously answered by science.

In conclusion Dr. Weinberg states:

When what we do transcends science and when it impinges on the public, we have no choice but to welcome the public—even encourage the public—to participate in the debate. Scientists have no monopoly on wisdom where this kind of trans-science is involved; they shall have to accommodate the will of the public and its representatives.

Safety as it has come to be used within the context of the food and drug laws and the complex of regulations supporting them is a trans-scientific problem. Under current laws a substance can be found safe only if it has passed through three phases of consideration. The nature of the safety problem may be better understood if it is examined within this context.

First is the objective, scientific determination of the discernible effects involved in the chemical’s use. This determination is the responsibility of scientists.

Second is the judgment about which of these effects is a risk and which is a benefit. This judgment is ultimately made by the public, acting through its representatives and spokesmen or as individuals, but acting with a high degree of guidance from scientists, physicians, or other trained professionals.

Third is the decision that the agreed upon benefits of a given chemical exceed its agreed upon risks. This is a public, not a scientific, decision, made in public forums in which scientists act as equal, though in some cases better informed, participants with other segments of the public.

A safe chemical is one that has passed through all three phases satisfactorily. Its effects are known and agreed upon with some certainty by qualified scientists. The benefits and risks of the chemical have been sorted out accurately to the general satisfaction of the society. The society then has decided that the benefits of the use of the chemical in the way permitted outweigh its risks.

Unfortunately, this is not the way the determinations of chemical safety always work. Certain dramatic regulatory decisions during the past 20 years illustrate why the public increasingly doubts industrial, regulatory, and scientific assertions that the food and drug supplies are safe enough. The approval and then the subsequent banning of cyclamate, including the unnecessary references to the Delaney anticancer clause, illustrate the problems that occur when scientists cannot agree on the potential effects of a given chemical, but regulators act as if they do. The premature approval of the Salk polio vaccine and the subsequent 280 cases of vaccine-associated polio, 10 of which resulted in death, delineate the tragedy that can result when risks and benefits are improperly identified or weighed. The negligent release of certain lots of Sabin Type III oral polio vaccine and subsequent findings against the Government for that action suggest that the public is going to hold
science and scientists to an increasing degree of responsibility for their decisions. Each of these events has a lesson which can be helpful in determining how safe is safe enough.

In 1963, the Division of Biologic Standards (DBS) of the National Institutes of Health, then the Nation’s vaccine regulators, approved certain lots of Sabin Type III polio vaccine for use in a Philadelphia mass-immunization campaign. A Philadelphia housewife, who was 11 years old at the time, took a dose of one of the lots and contracted polio from the vaccine. She became a permanent quadriplegic.

After reviewing the case during 7 years of legal proceedings, the Federal district court in Philadelphia ruled that the vaccine lots had been released negligently by the DBS. It awarded damages of over $1 million to the injured party. Evidence showed that Government scientists responsible for protecting the public had kept shoddy, incomplete, or misleading records about vaccine safety. It showed that the statistical methods used to evaluate test findings were poorly constructed—so much so, in fact, that the presiding judge pointed to them as “...a perfect example of the old "garbage in, garbage out."”

Evidence introduced into the record suggested that when the mass-inoculation campaign was in the planning stages the Public Health Service’s ad hoc polio advisory committee voted 6 to 4 to include a warning against the use of the Sabin Type III oral vaccine by adults. Subsequently the committee was informed by the manufacturer that “...the company must give serious consideration to the possibility that the type III vaccine will have to be withdrawn from commercial sale...if labeling precautions cannot be written with adequate safeguards that will not deter its sale.” Following this statement by the company the committee reversed itself, removing the warning about adults.

A careful examination of the regulatory records on Sabin polio vaccine revealed a nightmare of improper, mistaken, or negligent action—including a total lack of familiarity with the laws and regulations governing vaccine control on the part of the responsible officials—all taken in the name of and on behalf of science. The surprising reaction of officials faced with the responsibility for the $1 million judgment was to suggest that the regulations be changed so that their actions would become legal.

When the safety problem is viewed in this context the issues related to benefit and risk become less esoteric, abstract, and philosophical. The problem becomes a practical one. Mechanisms must be designed to ensure that the individuals charged with applying the available scientific knowledge to regulatory decisions have a proper sense of responsibility and a clear knowledge that they will be held accountable for their mistakes, as well as rewarded for their contributions. Until these mechanisms are developed, the public sense that the chemical environment is not safe enough will continue to grow. Unless the world of scientific decisionmaking on behalf of the public is opened to public scrutiny and evaluation, more and more policy restraints will be placed on the granting of responsibility to scientists. Alvin Weinberg puts the situation bluntly: “The republic of science can be destroyed more surely by withdrawal of public support for science than by intrusion of the public into its workings.”
The Government's problem with certain lots of Sabin vaccine suggests how skeptical the public, through its trans-scientific institutions, is becoming of so-called scientific discretion. However, the Salk vaccine incident introduces another dimension. It suggests that the real safety problem involves not only a better weighing of benefits and risks, but the development of a better identification of benefits and risks.

The 260 victims of polio contracted from the Salk vaccine have often been the centerpiece in a number of theoretical discussions about risk-benefit. The trade-off is always between the number injured by the vaccine versus the number who would have been injured if the vaccine had not been used. H. V. Wyatt, in his article appearing in the January 26, 1973, issue of Nature, "Is Polio a Model for Consumer Research?" sums it up: "The situation, although regrettable, was certainly less severe than it might have been if the vaccine had not been used."

This is a comforting thought. But it lets science and the regulatory officials responsible for applying it off the hook too easily. If they had done their job properly the full benefit of the vaccine could have been had without the 260 casualties. This certainly would have been better than what occurred.

Dr. James Shannon said, in a 1986 address to the Oklahoma Frontiers of Science Foundation, that the Salk vaccine represented a scientific error. "...the decision of the Foundation—National Foundation for Infantile Paralysis—to throw its resources behind the development of an inactivated vaccine markedly increased the difficulties and greatly protracted the time required to develop the generally adopted polio vaccine we have today." The New York Times article reporting that speech states that "Dr. Shannon felt the "error" of the National Foundation derived in part from the secrecy of its operations, which limited the input of external ideas."

Dr. Shannon's view is a retrospective one. It can be considered in future situations, but reasonable men could have disagreed about the choices when they were made in 1955. It is more difficult to accept the fact that in 1955 the bench scientists at the Division of Biologic Standards responsible for evaluating the safety of Salk vaccine refused free doses for their children. They did so because more than 6 months before the beginning of the Salk's mass-immunization program three monkeys came down with what appeared to be a paralysis caused by the vaccine. This warning did not cause those responsible for the program to search out a potential problem, 6 months later, when the first five vaccine-related cases of polio were detected, a massive crisis program was undertaken to find and correct the problem. Within 30 days the reason for live polio contamination of the vaccine had been discovered, corrected, and the vaccine was back on the market.

In a program as important, sensitive, and dramatic as the Salk mass-immunization campaign, three sick monkeys should have been an effective early warning of the problems to come. That they were not suggests important weaknesses in the system for identifying risks and benefits which must be corrected before the weighing of benefits and risks can be seriously undertaken.

The manipulation of science to make risks appear more acceptable, illustrated by the Philadelphia Sabin case, and the failure of science to
detect warnings, as in the Salk case, feed public skepticism about claims that all is well with food and drugs. This skepticism, shared by a good number of scientists, underlies the strong support for the Delaney anticancer clause of the food and drug law, which prohibits the use in human foods of any chemical which has caused cancer when ingested by man or animal.

In October 1969, the Secretary of Health, Education, and Welfare removed cyclamate from the list of food chemicals generally recognized as safe, better known as the GRAS list. He removed the chemical not because scientists agreed that it was unsafe, but because it could no longer be said that scientists agreed that it was safe. A number of observations contributed to this doubt concerning cyclamate. It produced a human metabolite which caused genetic damage in rats. It and the metabolite caused teratogenic damage in rabbits. It bound itself to plasma, thus inhibiting drug delivery to the body. It inhibited the effect of vitamin C. It had caused some unreported cancerous tumors in 1950 FDA tests. When combined with saccharin, it had caused cancer in rats.

For apparently political reasons the Secretary made unnecessary references to the Delaney anticancer clause to justify removal of the chemical from the GRAS list. The clause reads as follows: "Provided, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal..."

It was unnecessary even to refer to the clause in banning cyclamate because once safety became a question, the chemical could not be used unless it had been tested and shown to be safe. This meant that its effects had to be demonstrated, that its benefits and risks had to be sorted out and then weighed. If qualified scientists had found during this period that the chemical did cause cancer when ingested by man or animal, then the Delaney clause could have been invoked. The previously made public determination that the potential risk of including a cancer-causing chemical in the food supply outweighs any benefits that the chemical might have would then have controlled the situation. If this procedure, as outlined in the law, had been followed, the importance of the Delaney clause could have been more accurately assessed and appreciated. Instead, the premature reference to the clause led to a widespread misunderstanding of the purpose and principle underlying it.

The principle of the Delaney clause is that weighing of benefits and risks is not a purely scientific question; it is a policy question that requires an informed public decision. The principle of the Delaney clause is that the weighing of benefits and risks is not the sole province of a regulatory agency or its scientific advisers. The Delaney clause applies this principle to those chemicals which cause cancer when ingested by man or animal. It does this on the advice of a large segment of the scientific community which argues that the effects of even traces of a cancer causing substance cannot be predicted. Relying on this advice the public had adopted the policy that no benefit is worth the possible hazard of adding a cancer-causing chemical to the food sup-
ply. The clause rests on scientific discretion. Scientists—and scientists alone—make the determination that an ingested chemical has caused cancer. The clause rests on the accepted operating principle that there is some relationship between the effects of the chemical on animals and its effects on man. This is the principle that allows drugs and food additives to be shown safe and to be marketed. The clause avoids the demand of absolute safety. Instead it says that in relation to the cancer risk the food supply will be safe enough only if no additional cancer-causing chemicals are added to it.

The Delaney clause can certainly be improved, but the central principle on which it rests must be kept intact. Safety is a policy question which demands the weighing of properly identified risks and benefits by the public. It is not an objective, scientific determination. The weighing mechanism can be improved, but improvement will not be accomplished by giving regulatory authorities more bureaucratic discretion. The Delaney clause, unlike any other section of the Food, Drug, and Cosmetic Act, recognizes and is premised upon the limitations of science.

The Food Safety Panel of the 1969 White House Conference on Food, Nutrition, and Health stated the limitation on proving food chemical safety. The panel said, "It is not possible to determine with absolute certainty the safety of the ever-increasing number of chemicals added to or present in our foods." As a member of the panel I concurred with that statement. It appeared to me to be a warning. Since science could never be sure of a chemical's safety, it seemed obvious that as a matter of policy we should be cautious in allowing the use of chemicals in food. Unfortunately, many individuals both inside and outside of science took this statement to mean the opposite. Since safety cannot ever be proven conclusively, they argued, we ought to be cautious in restricting the use of chemicals. It is this attitude against which public sentiment is reacting.

Increasingly scientific evidence relates various chemicals to serious problems of human health. Responsible scientists have suggested that some chemicals may contribute to the development of certain kinds of mental retardation, 95 percent of which is of unknown origin. A large portion of the cancer research community spends its time evaluating the capability of various chemicals to cause cancer, although the cause is yet to be found. Some geneticists suggest that chemicals used in foods and drugs might play an important role in causing much of the society's genetic and mutagenic damage. For example, 20 to 30 percent of American pregnancies end in spontaneous abortion, stillbirth, or deformity.

Scientific research has identified a number of serious health problems for which the causes are at best elusive. It has also generated enough evidence to suggest a possible relationship between these disease conditions and the growing use of a number of chemicals in the drug and food supply. Diseases of unknown origin and chemicals with suspicious side effects combine to raise questions of drug and food additive safety and policy to a high level of public concern.

Increasingly pointed public questions are being raised about assumptions underlying chemical regulation. Dr. Jacqueline Verrett and Jean Carper, both of whom played an important role in the
What industry tomes around the term benefit-risk, what do they mean? Do they mean consumer health benefits weighed against consumer health risks? Or consumer economic benefit against consumer health risk? Or some kind of consumer social benefit, such as time saving, against consumer health risk? Or, on the other hand, do they mean industry economic benefit against consumer health risk?

My experience is that industry means all of these. This fact, too, raises the level of public concern about drug and food additive safety and policy.

The point of all this is that the safety of drugs and food additives as a function of the weighing of benefits and risks is not what the public concern is all about. The real problem is twofold. The effects of chemicals in food and drugs have not yet been determined satisfactorily. No generally accepted definition of benefits and risks has been agreed upon. It is on these two problems that from the consumer's point of view the attention of science should be focused.

ATTACHMENT C

CONSUMER VIEWS OF THE DELANEY AMENDMENT
(By James S. Turner)

OBJECTIVE

This paper describes the authors views and interpretations of the contemporary consumer movement with regard to the Delaney anticancer clauses of the Federal Food, Drug, and Cosmetic Act, its rationale; possible alternatives; and consumer interpretation of and reaction to recent public critiques of the clause.


1. 409(c)(3)(A) provided that no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, except that this provision shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subjected (f) and (g) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal;

2. 706(b)(5)(B) A color additive (i) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary...
to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive if after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal:

Provided, That clause (i) or this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal.

3. 512(d) (1) (H) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that—

such drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, induces cancer in man or animal, except that the foregoing provisions of this subparagraph shall not apply with respect to such drug if the Secretary finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice (I) such drug will not adversely affect the animals for which it is intended, and (II) no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (c), (d), and (h), in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals; he shall issue an order refusing to approve the application.

SUMMARY

Consumption is the sole end and purpose of all production; and the interest of the producer ought to be attended to only so far as it advances that of the consumer.

But in the mercantile system, the interest of the consumer is almost constantly sacrificed to that of the producer; and it seems to consider production, and not consumption, as the ultimate end and object of all industry and commerce.


Organized consumer groups, consumer advocates, and consumer spokesmen place the health and welfare of the individual consumer at the center of the controversy about whether cancer-causing chemicals should be allowed in the food supply. They believe that opponents of the Delaney anticancer clauses—which prohibit from the food supply chemicals which cause cancer when fed to animals or men—are primarily concerned with the well-being of food and chemical producers and only secondarily concerned with the health and well-being of individual consumers.

Specifically, growing indications of potential hazards to the individual consumer which might be related to environmental chemicals, has led to consumer support for the Delaney clauses type of restrictions
on chemicals in foods which have not been shown to be safe. For example, cancer is a major cause of human death for which no generalized cause has been identified but which some experimentation and some experience relates to the ingestion of chemicals. Birth defects occurring at an alarming rate (1 in every 14 births involves a defect according to the March of Dimes), are largely of unknown origin, and have been related to environmental chemicals by both research and experience. Genetic damage which can be inherited from one generation to the next, also has been related to environmental chemicals.

The President's Science Advisory Committee Panel on Chemicals and Health stated the situation succinctly in its 1974 report:

The absence of these former sources (common infectious diseases and nutritional diseases) has left the field clear for the chronic degenerative diseases, some of which are likely to have external chemical causes. We need now to develop ways to deal with these slower acting and less direct causes of death and chronic sickness.

The loose collection of organizations and individuals generally called the "consumer movement" in the United States tend to believe that the principle of social policy embodied in the Delaney clause is the best way to deal with these slower acting and less direct causes of death and chronic sickness. In general, they are also highly skeptical that any better principle for dealing with the chemical threat to man can be found. Since the time between coming in contact with a dangerous environmental chemical and recognizing the injury, its causes may be 20 or more years, consumer defenders of the Delaney clause principles argue that waiting until human injury is obvious will unnecessarily condemn millions of individuals to death or disability.

The argument on behalf of the Delaney clauses rests on making a distinction between its public aspects and its scientific aspects. When this distinction is made, the controversy over the Delany clauses forms into two related but distinct issues. One, should chemicals known to cause cancer be allowed in human food? Two, how do we determine which chemicals cause cancer?

There is really little debate about issue No. 1. Everyone seems to agree that cancer-causing chemicals should be kept out of food. Dr. Phillip Handler, president of the National Academy of Sciences, hosted a May 15, 1973, Academy Forum on the "Design of Policy on Drugs and Food Additives." In his concluding summary after a day-long discussion which often touched on the Delaney clauses, Dr. Handler said:

"Certainly, on its face, all other things being equal, it (the Delaney clause) is a perfectly rational guide to desirable social behavior. No one in his right mind wants to put carcinogens into anything intended for human consumption."

In spite of its apparent reasonableness and rationality, the Delaney clauses continue to be the recipient of vigorous attack. Bernard L. Oser, Ph. D., who has been responsible for testing many food additive as a private contractor to industry and Government, wrote in the August 13, 1973, issue of Chemical Engineering News:

"In these days of increasing need to expand and preserve food supplies, to develop new sources of nutrients and to improve acceptability, pragmatic considerations justify the removal of unnecessarily restrictive regulations founded on hypothetical hazards implicit in the present interpretation of the Delaney Clause."
Consumer defenders of the Delaney clauses view such attacks as arguments made on behalf of food and food chemical producers, and to the detriment of consumer safety and health. The charge that the clause is unscientific is defended against by pointing to the large number of scientists, including researchers at the National Cancer Institute, who support it. The belief that only scientists should determine the benefit/risk for chemicals used in food is countered by the argument of pro-Delaney advocates that determining how much risk the public should bear is a public policy issue not primarily a scientific issue.

At the heart of the Delaney controversy is how public policy should be set when the experts are at odds over the meaning of the scientific facts which underly the policy. Consumer defenders of the Delaney clauses argue that since they know so little about the nature of cancer and are at constant odds about the meaning of their research on cancer, the caution built into the Delaney clauses principle is the best policy.

INTRODUCTION

"How safe is safe enough?" is the question central to regulation of food additives in the American food supply in general and evaluation of the Delaney anticancer clauses in particular. This question is not primarily a question for scientists; it is a policy question to be answered by society through its chosen representatives.

Dr. Alvin Weinberg, formerly Director of the Oak Ridge National Laboratory, spelled out the distinction between the question of science and the question of public policy in his address at the dedication of the Paul B. Johnson Science Tower at the University of Southern Mississippi in January, 1972:

Many of the issues that arise in the course of the interaction between science or technology and society—e.g., the deleterious side effects of technology, or the attempts to deal with social problems through the procedures of science—hang on the answers to questions which can be asked of science and yet which cannot be answered by science. I propose the term trans-scientific for these questions, since, though they are epistemologically speaking, questions of fact and can be stated in the language of science, they are unanswerable by science; they transcend science. Insofar as public policy depends on trans-scientific rather than scientific issues, the role of the scientist in contributing to the formulation of such policy must be different than is his role when the issues can be unambiguously answered by science.

In conclusion Dr. Weinberg states:

When what we [scientists] do transcends science and when it impinges on the public, we have no choice but to welcome the public—even encourage the public—to participate in the debate. Scientists have no monopoly on wisdom where this kind of trans-science is involved; they shall have to accommodate to the will of the public and its representatives.

The principle of the Delaney clauses is that weighing of benefits and risks is not a purely scientific question; it is a policy question that requires an informed public decision. The principle of the Delaney clauses is that the weighing of benefits and risks is not the sole province of a regulatory agency or its scientific advisors.
The Delaney clauses apply this principle to those chemicals which cause cancer when ingested by man or animals. On the advice of a large segment of the scientific community, they exclude such chemicals from the food supply because the effects of even traces of a cancer-causing substance cannot be predicted. Relying on scientific advice the public, acting through Congress, has adopted the policy that no benefit currently known to man is worth the possible hazard of adding a cancer-causing substance to food.

Scientists—and scientists alone—make the determination that an ingested chemical has caused cancer. The Delaney clause rests on the accepted operating principle that there is some relationship between the effects of a cancer-causing chemical on animals and its effects on man. This is the principle that allows drugs and food additives to be marketed to men after tests show them to be safe for animals. The clause does not demand absolute safety. Rather, it demands that no additional cancer-causing chemicals be added to the food supply.

Consumer defenders of the Delaney clauses argue that their central principle must be kept intact. Safety is a policy question which demands the weighing of properly identified risks and benefits by the public. Safety is not the result of solely an objective, scientific determination. It also involves a matter of opinion. The mechanism for sorting and weighing opinion and fact can be improved but not by giving regulatory authorities more bureaucratic discretion.

Pure scientific knowledge, alone and unaided by commonsense and doubting public questions, is a weak reed on which to rest the entire future and well-being of the American public. The imperfect science of a regulatory agency is even less suited to be the repository of unrestricted confidence that the well-being of individual consumers will be its sole objective. The Delaney clauses recognize the imperfections and limitations inherent in science and in regulatory agencies.

Safety, as it has come to be used within the context of the food and drug laws and the complex of regulations supporting them, is a trans-scientific (in Weinberger's words) problem. A "safe" chemical is one that has passed through three phases of consideration satisfactorily and is approved for use. Its effects are known and agreed upon with some certainty by qualified scientists. The benefits and risks of the chemical have been sorted out accurately to the general satisfaction of the society. The society has decided that the benefits of the use of the chemical in the way permitted, outweigh the risks. The Delaney clauses are society's determination that cancer-causing chemicals pose such a potential risk that they should not be added to food whatever their alleged benefit.

In the Delaney clauses, the American society has recognized both the limitations of science and public role in defining acceptable risks. The Food Safety Panel of the 1969 White House Conference on Food, Nutrition, and Health stated the limitation on proving food chemical safety. The Panel said, "It is not possible to determine with absolute certainty the safety of the ever-increasing number of chemicals added to or present in our foods."

This observation can be taken two ways. It can be a warning. Since science could never be sure of a chemical's safety, it seems obvious that as a matter of policy we should be cautious in allowing the use of
chemicals in foods. Unfortunately many individuals, both scientists and nonscientists, take this statement to be the opposite of a warning. Since safety cannot ever be proven conclusively, they argue, we ought to be cautious in restricting the use of chemicals. It is against this argument that the Delaney clause has been constructed and against which consumer defenders of the Delaney clause are reacting.

The following sections of this paper attempt to explore three aspects of consumer attitudes of the Delaney clauses. First, the scientific opinion, which consumer defenders of the Delaney clauses believe provide a sound basis for support of the clause, is presented. Second, some consumer attitudes on the policy aspects of the clauses are outlined. Third, some suggestions, proposals, and expectations concerning supplements, explanations, and applications of the Delaney clauses are outlined.

I. THE SCIENTIFIC BASIS OF THE DELANEY CLAUSES

The most recent scientific consideration of the Delaney clauses appear in Chemicals and Health the September 1973 report of the Panel on Chemicals and Health of the President’s Science Advisory Committee. It focuses on and describes the major dispute with the Delaney clauses expressed by its critics—its zero tolerance of cancer-causing chemicals:

"A 'no-detectable amount' clause," the Panel states, "is a refuge in the face of ignorance. Was mature scientific knowledge presently available regarding dose response relationships and extrapolation to man, the problem of carcinogenicity could be dealt with (in) a scientifically rational manner." The clauses are currently necessary, the report suggests, because of lack of detailed knowledge telling how little of a carcinogen will be harmful when ingested.

On two additional occasions in the report the Panel talks of the lack of scientific information surrounding carcinogens, the lack of discretion allowed to the administrators of the food and drug law by the clause and makes the allegation that the clause limits scientific direction.

When considering a decision and faced with incomplete and insufficient information, the administrative and legislative processes tend strongly to the side of a conservative prudence in the name of health. There are several notable examples which Congress has replaced with scientific discretion by statutory mandates to "protect" human health inflexibility. The Delaney clause to the Food, Drug and Cosmetic Act is probably the best known.

In some cases, the Congress has clearly assumed the role of judge of social issues concerning how safe is safe enough. The amendment to the Food, Drug and Cosmetic Act which determines the destiny of food additives found to be carcinogenic in animals or man (Delaney amendment) is perhaps the best known example. It is interesting to note that it seems to be the very lack of sufficient information plus an implied threat in each case which has led Congress to take social judgment making into their own hands.

It is interesting to note that though the language is colored in a way to suggest dissatisfaction with the Delaney clauses, the President’s Panel comes out on the side of retaining the Delaney clause as they are because of the continuing lack of the information needed to do anything else. The Panel report supports the consumer advocates of the Delaney clauses using the very same arguments which brought the
clauses into being originally and which has sustained for retaining the clauses. Arthur Flemming, then Secretary of Health, Education, and Welfare, testified twice for the clause in 1960 when it was extended to cover color additives. His comments are somewhat long but they spell out in detail what has become, over the last decade and one-half, the position of the Delaney clauses proponents.

The Department's position is that the proposed color additive legislation should include an anticancer clause that makes illegal the use of any color that will induce cancer when tested by appropriate methods. We believe this position to be the only sound public policy in view of the fact that our experts tell us present scientific techniques do not permit them to state unequivocally how much or how little of a substance that induces cancer when administered to animals will induce cancer when administered to man.

The rallying point against the anticancer provision is the catch phrase that-it takes away the scientist's right to exercise judgment. The issue thus made is a false one, because the clause allows the exercise of all the judgment that can safely be exercised on the basis of our present knowledge. The clause is grounded on the scientific fact of life that no one, at this time, can tell us how to establish for a man a safe tolerance for a cancer-producing agent. Until cancer research makes a breakthrough at this point, there simply is no scientific basis on which judgment or discretion could be exercised in tolerating a small amount of a known carcinogenic color or food additive.

So long as the outstanding experts in the National Cancer Institute and the Food and Drug Administration tell us that they do not know how to establish with any assurance at all a safe dose in man's food of a cancer-producing substance, the principle in the anticancer clause is sound. (Statement by Hon. Arthur S. Flemming, Secretary of Health, Education and Welfare before the House Committee on Interstate and Foreign Commerce, May 9, 1960.)

Secretary Flemming left the door open for the future in his testimony before the House Committee:

Whenever a sound scientific basis is developed for the establishment of tolerances for carcinogens, we will request the Congress to give us that authority...

The only point that seems to offer the possibility of controversy is the anticancer clause. Secretary Flemming has made a very strong case for it in his testimony before the House Committee. This is grounded on the scientific fact of life that no one, at this time, can tell us how to establish a safe tolerance for a cancer-producing agent. No one knows how much or how little of a substance which produces cancer in test animals is needed to cause cancer in man, or when the cancer may develop. Until cancer research makes a breakthrough at this point, there is no scientific basis on which discretion could be exercised in tolerating a small amount of a known carcinogen, either in food, drugs, or in cosmetics. When and if science can assure us that a safe tolerance can be established, the Department will ask the Congress to modify the anticancer clause.

In discussing the practical operation of the anticancer clause, Secretary Flemming said:

Some of the opposition to inclusion of an anticancer provision...afflict out of a misunderstanding of how this provision works. It has been suggested that once a chemical is shown to induce a tumor in a single rat, this forecloses further research and forever forbids the use of the chemical in food. This is not true. The conclusion that an additive is found to induce cancer when ingested by man or animals is a scientific one. The conclusion is reached by competent scientists using widely accepted scientific testing methods and critical judgment. An isolated and inexplicable tumor would not be a basis for concluding that the test substance produces cancer.
It has also been suggested that when a compound shown to produce cancer in test animals has been modified in chemical structure so that it no longer produces cancer, it continues to be incriminated by its past history. This, too, is erroneous. The Food and Drug Administration would—and should—take a close look at the modified compound to be certain that it did not have the same cancer potential as its parent. But once convinced that the cancer potential had been eliminated, the precaution clause would not preclude use of the substance.

Finally, doubt has been expressed about the authority of the Department to reverse a decision in this area. This, of course, is unfounded doubt. When new evidence is presented the Department must only the right, but the obligation to evaluate this evidence and determine whether a previous decision should be reversed.

This, I believe, is as far as our discretion should go in the light of present scientific knowledge. We have no basis for asking Congress to give us discretion to establish a safe tolerance for a substance which definitely has been shown to produce cancer when added to the diet of test animals. We simply have no basis on which such discretion could be exercised because no one can tell us with any assurance at all how to establish a safe dose of any cancer-producing substance.”


While this diversion into the original testimony of Secretary Fleming is long it is valuable because it forms the basis of current consumer support for the existing Delaney clause. In addition, it demonstrates that the problems discussed by the 1973 Presidential Panel on Chemicals and Health are not new and suggest why that Panel ended up supporting the Delaney clause even though it probably would rather not have.

In 1974 the Surgeon General of the United States, faced with a continuing resistance with the Delaney clauses on the part of food chemical manufacturers and parts of the scientific community, gathered a special ad hoc committee of cancer experts to help him address the problem. After reviewing the Delaney clauses and the threat of environmental carcinogens, the ad hoc committee quoted extensively from the 1960 testimony of Secretary Fleming. The committee then said, "the scientific basis on which the Government's position was established in 1960 remains valid. The progress of knowledge in carcinogenesis in the last decade has only strengthened the points made in Secretary Fleming's testimony."

There has been a tendency to go back and forth about the Delaney clauses for its entire existence. Specifically, from its inception, an argument has raged about whether the Food and Drug Commissioner should have the authority to set tolerances for cancer-causing substances. The scientific arguments of Secretary Fleming in 1960 reiterated a decade later by the ad hoc committee of the Surgeon General were directed at the belief expressed by some individuals that such authority should be granted to the Commissioner.

*The full report of the ASK Committee is entitled "Evaluations of Environmental Carcinogens". It is called the "Report of the Surgeon General, USPHS Apr. 22, 1970. Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens." National Cancer Institute, Bethesda, Md. 20014. Requests for reprints of the report should be sent to Dr. John A. Cooper, Building 37-3307 National Cancer Institute. The report has also been reprinted at pp. 150 to 198 of the Senate hearing "Chemicals and the Future of Man" before the Subcommittee on Executive Reorganization and Government Research, Apr. 6-7, 1971.
Secretary Flemming relied on an earlier report from the National Institutes of Health which concluded "that there is at present no way to determine how much or how little of a carcinogen is necessary to produce cancer in a human being, how long it would take for a cancer to develop or how to control levels of ingestion or exposure where more than one source of exposure is likely." The quotation is from Toulan, "Treatise on Food and Drug Law" and reports the conclusions of the report on "The Role of Certain Chemical and Physical Agents in the Causation of Cancers."

In 1970, the Surgeon General's ad hoc committee felt it necessary to once again knock down assertions that seemed to imply that safe levels of a carcinogen could be established. "It is essential to recognize," the committee reported, "that no level of exposure to a carcinogenic substance, however low it might be, can be established to be a 'safe level' for man... The current legislation in the field of food additives, with its anticancer clause, is based on this principle."

The attack on the requirements of zero-tolerance for cancer-causing substances in food has been the central thrust of anti-Delaney clauses spokesmen. However, repeated the scientists most directly concerned with cancer research have affirmed that they are unable to say at what level a cancer-causing substance becomes safe and therefore have supported the Delaney clauses. This support from the scientific community has been the major scientific argument used by consumer advocates of the Delaney clauses.

A second but less persistent argument, which has been turned to more frequently as the zero-tolerance argument has met persistent scientific opposition, is the one-most-irrelevant-test argument. This argument appears to be based on both the theory and effect of the Delaney clauses. The more unsophisticated presentation of the argument is that if one mouse is given massive doses of a chemical and the mouse contracts cancer, then the chemical is forever banned from food use thereby depriving the food industry and the public of a potentially useful chemical and discouraging research into the chemical. It was this argument that Secretary Flemming attempted to defeat when he pointed out that "the opposition to inclusion of an anticancer clause arises largely out of a misunderstanding of how this provision works. It allows the Department and the scientific people, full discretion and judgment in deciding whether a substance has been shown to produce cancer when added to the diet of test animals. But once this decision is made, the limits of judgment have been reached and there is no reliable basis on which discretion could be exercised in determining the safe threshold dose for the established carcinogens."

Thus, only if tests involved, of however many mice at whatever levels, show that the chemical is a cancer-causing chemical is the act engaged. Thus, if a test is considered to be irrelevant by the scientific community or it showed that if an intervening event, not the chemical, caused cancer, then the Delaney clause would not be engaged.

Unfortunately, the misunderstanding about the way in which the Delaney clauses work have persisted, in spite of repeated arguments...
and legal action making explicit what Secretary Flemming testified to. (Incidentally, his testimony, as the major part of the legislative history of the clauses forms the most significant guide to what Congress meant when it adopted the clauses and thus has important legal force of its own.) Even the prestigious Presidential Panel on Chemicals in Health repeated a very sophisticated form of the argument.

On page 121 of its report, the Panel said, "It can be argued that as additional understanding accumulates as to biological mechanisms underlying neoplastic disease, and as one obtains more detailed information on how chemicals interact with biological issues; the Delaney clause may well be modified." On page 11, the panel says "once he (the Commissioner applying the Delaney clauses) acts, almost all motivation to study either benefits or risks further is gone, thus keeping us from ever learning more about what should have been done." Together, these two arguments represent a statement of the misunderstanding about the Delaney clauses which Secretary Flemming addressed in 1960.

On January 15, 1973, the New York Academy of Sciences held a symposium on the Delaney clauses. The transcript of the meeting is still in the process of being edited for publication. However, the consensus of scientists present was clear and reported by the press. In the January 22, 1973, edition of Food Chemical News they reported that "The overriding consensus was that change should not be made in the Delaney clauses because there is yet no scientific basis for setting a tolerance for carcinogens in the food supply . . . the formal presentations included several views of the cancer mechanism, ranging from the single molecule theory of cancer causation to interference with the complicated enzyme system of humans and animals."

It was suggested during the meeting that it was demonstrated by accepted scientific procedures, that if during an animal feeding, testing for cancer, if it appeared in a significant amount in the animals but that a separate cause for the cancer distinct from the chemical was the reason for the cancer, the Delaney clause would not apply. Thus if the peculiar enzymatic action of the test in animals caused the cancer or if a dose related toxic precondition such as cirrhosis of the liver had to be present for the cancer to occur and the chemical was shown not to be the cause of the cancer, then the Delaney clauses would not apply. This would result from the fact that scientists agreed that the chemicals were not the cancer-causing agent.

On April 27, 1973, the FDA proposed a food additive regulation (in the Federal Register of that date), with regard to selenium, a nutrient for addition to animal feed which explained and endorsed the theory of the clauses outlined during the January 15 meeting of scientists. It would seem reasonable that if the cancer-causing effect of a metabolic situation rests on the need for the existence of a toxic effect which is agreed upon by scientists to be dose-related, that chemical is not a carcinogen and that therefore the Delaney clauses do not apply. Whether it should apply or not is a separate question. This explanation of the interpretation of the Delaney clauses in this situation is long but, nonetheless, is of enough importance to be included in its entirety:

5. The applicability of the anticancer clause (sec. 400(c) (3) (A)) of the act to the addition of selenium to animal feed has been thoroughly considered because of the questions that have been raised concerning the possible carcinogenic...
genic activity of selenium. Available data have been evaluated by the Food and Drug Administration and the National Cancer Institute. Based on these evaluations, it has been concluded that the judicious administration of selenium derivatives to domestic animals would not constitute a carcinogenic risk. In three of the six studies available on the subject, test animals were found to have developed neoplastic lesions. These lesions were concluded to be a consequence of the liver cirrhosis produced by frank selenium toxicity. Further evaluation of the results of these three studies was complicated by the unusually high levels of selenium that had been administered—usually experimental design, and/or infectious conditions present in the animal colonies used. Results of the remaining three studies, all of which were well controlled investigations, were negative for carcinogenic activity.

Selenium at high dietary levels (above 2 ppm for experimental animals) in a proven hepatotoxic agent. Early studies at dietary levels of 5, 7, and 10 ppm showed liver damage and regeneration in rats and an increased incidence of hepatoma in treated animals as compared with controls. Hepatoma did not occur in the absence of severe hepatotoxic phenomena. In more recent studies, hepatotoxicity was observed in rats fed selenium at 2 ppm. At 16 ppm severe liver damage was observed but was not associated with hepatoma. No hepatotoxic effects were noted at 0.5 ppm or below.

In this respect, selenium is no different from a number of foods and drugs available in the marketplace today. Beverage alcohol, for example, is associated with a higher incidence of liver cirrhosis. Which, in turn, is associated with a higher incidence of liver cancer. Other common agents, at high levels, may produce the same result.

The Commissioner is of the opinion that these foods and drugs are not, by reason of their capacity to induce liver damage when allowed to be consumed at high levels, properly classified as carcinogenic because of their potential association with a higher rate of liver cancer. The various antitumor clauses contained in the act (secs. 409(c) (3) (A), 512(d) (1) (II), 766(b) (5) (B), 72 Stat. 1296, 82 Stat. 345, 74 Stat. 400; 21 U.S.C. 348(c) (3) (A), 360(b) (1) (II), 378(b) (5) (B)) were predicated on the theory that, since we do not know the mechanisms of carcinogenesis, even one molecule of a carcinogen should not be allowed into the food supply. The antitumor clauses do not apply in the case of an agent that (1) occurs naturally in practically all foods, (2) is used in a manner such that the natural level in food is not increased, (3) has a definite hepatotoxic effect/no-effect level, and (4) has a possible carcinogenic effect which is associated only with the hepatotoxic effect.

Accordingly, the Commissioner has concluded that: (1) The available information does not support classification of selenium or its compounds as having carcinogenic activity. (2) The use of selenium as set forth below constitutes no carcinogenic risk, and (3) the limitations set forth below, while satisfying the animals' dietary need for selenium, will assure safety to animals treated with selenium selenide or sodium selenite and to consumers of edible products of such treated animals. 38 FR 10450–10456 (Apr. 27, 1973).

Thus, it can be seen that the belief of the President's Panel that as "additional understanding accumulates as to biological mechanism underlying neoplastic disease..." the Delaney clauses may well be modified" is not necessary to joining the reasoned progress of science with the legal restraint of the Delaney clauses. Indeed, the Delaney clauses, under close scrutiny, turn out to a singularly well-constructed piece of social legislation.

Properly understood, the Delaney clauses not only do not inhibit scientific research, as the Panel suggested, but they actually encourage it. Under the Delaney clauses, animal tests which ended with significant amounts of cancer in their test groups would have two possible interpretations. One, that the chemical caused the cancer. The other, that some other intervening dose-related toxic event caused the cancer. It would seem that with this possibility, existent researchers would jump at the chance to discover which group their chemical fell into.
Incidentally, one of the strongest defenders of the Delaney clauses, and an outspoken scientific critic of the FDA, for its inadequate regulation of nitrates in food, Dr. William Lajinsky believed that: "The present use of selenium compounds in animal feeds should not pose a legal dilemma." "The object," he says, "is to raise the nutritional status of these animals on selenium deficient diets to that of animals on diets with normal selenium content." Analysis of the meat of such animals would show no abnormal residue of selenium.4 Dr. Lajinsky does not believe that selenium is a carcinogen because of conflicting, incomplete, and inadequate test results.

The Presidential Panel evidenced another misunderstanding about the working of the Delaney clauses when it commented on the removal of cyclamate from the marketplace. The Panel said on page 166 of its report:

On October 12, 1969, a leading producer provided evidence to the FDA that cyclamate had caused cancer in animals. It seems highly likely that even if no Delaney provision in the law existed and no FDA action had been issued, that any responsible producer of ethical pharmaceuticals would have taken action to limit the use of cyclamates or perhaps even to withdraw them.

This observation implies that the Delaney clauses were relied upon by HEW to remove cyclamates from the marketplace. This was not the case. It also implies that the Delaney clauses, the FDA would have no authority to remove cyclamates from the marketplace. This also is erroneous. Actually, the FDA removed cyclamates from its list of food chemicals, generally recognized as safe under the authority of the 1958 Food Additive Amendments of which the Delaney clauses is only one small section.6

Under the food additive amendments, only those chemicals which are either generally recognized as safe or proven safe and granted food additive status can be added to food. Given the current lack of scientific knowledge about the likelihood of harm from low levels of cancer-causing chemicals, no chemical which causes cancer in animals can be added to food irrespective of whether the Delaney clauses are a part of the act or not. In a very broad sense, the Delaney clauses are a legal redundancy. It is not an administrative redundancy, however, since often actions are taken for reasons which lie outside the workings of the Delaney clauses but are explained to the public as if they were mandated by the Delaney clauses.7

On May 15, 1973, the National Academy of Sciences held an Academy Forum on food additive and drug regulation. During that symposium, Peter Hutt, the Assistant General Counsel of HEW for the Food and Drug Administration, explained the workings of the Delaney clauses. He pointed out that on only two occasions, both involving obscure packaging ingredients, had the Delaney clauses been invoked as a legal justification for agency action.

Commenting on the Delaney clauses in his closing summary of the May 15, 1973, National Academy of Sciences Forum, Academy presi-

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4 Senate Select Committee on Nutrition and Human Needs, hearing on food additives, Sept. 21, 1972, pt. 4, p. 1649.
6 See the "Chemical Feast" by James S. Turner, ch. 1, and p. 250 footnote for a detailed account of the legal implications of the banning of cyclamates.
dent, Dr. Phillip Handler, himself a sometime critic of the clauses, made a number of important observations about the clauses:

Mr. Hutt told us that, point of fact, the Delaney clause has been invoked only two times. I share Mr. Hurd's surprise that it had not been invoked in the case of cyclamates. This may be taken as a demonstration of our communicative failure; evidently we need many other forums and places in which to talk and attempt to reduce our misunderstandings.

The Delaney clause was discussed in several ways. For my part, I began to view that clause as a red herring rather than as a problem in our society. Certainly, on its face, all other things being equal, it is a perfectly rational guide to desirable social behavior. No one in his right mind would want to put carcinogens into anything intended for human consumption. We should be perfectly willing to accept that guideline until the day when we find ourselves in the position of banning as a carcinogen some chemical entity which also offers great benefit. Until that time comes, we will not have to test the validity of the Delaney principle. When it does come, we will have no recourse but to test the validity of the principle in a real life situation.

Meanwhile, talking about a problem that is nonexistent in reality doesn't serve our purposes particularly well. It has been said that the great harm of the Delaney clause is its deterrence to those who might otherwise be exploring new and important food additives. No such real case in point is known to me. I agree that one must be troubled by a law that, in effect, seems to say: "Since compound X has been shown to be tumorigenic in high doses, go further; do not look at the lower end of the dose-response curve, regardless of benefit." Such a situation seems, to me, to be repugnant. The time to address it will be the day when a real test case is before us.

Thus Dr. Handler, viewed by consumer advocates supporting the Delaney clauses as an opponent because of previous attacks on the clauses, comes out at nearly the same point as Anita Johnson, staff attorney of the Ralph Nader supported health research group and one of the staunchest and most articulate of the consumer advocates of the Delaney clauses. In her publication, "Cancer Prevention and the Delaney Clause" she wrote:

If a carcinogenic food additive is thought to be so crucial to civilization that it is worth possibly great cancer risk, Congress can be approached for an exemption for that individual additive.

Dr. Handler and Anita Johnson both conclude that the Delaney clauses should remain intact until a difficult case presents itself and then the issue can be raised with Congress in the context of that case.

II. THE SOCIAL PUBLIC POLICY DIMENSIONS TO THE DELANEY CLAUSES

The scientific principle of the Delaney clauses is that since the effects of low doses of known cancer causing chemicals are unknown, none should be added to food. The public policy principle underlying the Delaney clauses is that Congress should grant administrative discretion to regulatory agencies only when enough clear, sound scientific, or technical data exists to make the proper exercises of the discretion likely.

The special ad hoc committee of the Surgeon General addressed the meaning of and distinction between these principles in its "Evaluation of Environmental Carcinogens:"

It is impossible to establish any absolutely safe level of exposure to a carcinogen for man. The concept of "toxicologically insignificant" levels (as advanced by the Food Protection Committee of the NAS/NRC in 1969) is of dubious merit in any life science, has absolutely no validity in the field of carcinogenesis. Society must be willing to accept some finite risk as the price of using any carcinogenic material in whatever quantity. The best that science can do is to estimate the upper probability limit of that risk. For this reason, the concept of
"safe level for man", as applied to carcinogenic agents, should be replaced by that of a "socially acceptable level of risk."

While science can provide quantitative information regarding maximum risk levels, the task of ultimately selecting socially acceptable levels of human risk rests with society and its political leaders. The evaluation of the balance of benefits and risks, required for such a decision by society, should not be the result of uninformed guesswork but should be reached on the basis of complete and pertinent data, social as well as scientific. It is necessary therefore, to define the extent of arbitrariness and uncertainty inherent in the processes of interpreting animal response data and subsequently extrapolating them to man. The principle of zero tolerance should be applied in all but the most extraordinary cases.

At the 140th meeting of the American Association for the Advancement of Science held in San Francisco in February 1974, Dr. Alexander M. Schmidt, Commissioner of the FDA echoed the sentiments of the ad hoc committee. He termed the Delaney clauses a "legitimate legislative expression of society's increasing concern with technologic advances in the food industry and its reluctance to accept less than absolute safety in the food supply." He went on to say:

(While detection methods increase in sensitivity, the ability of scientists to relate these findings to human health are not keeping pace. The more practical course is to try to find out if it makes any difference to human health that minute traces of various chemicals exist in human food—and if so, at what levels.

This track requires low-dose, long-term toxicological testing in animals, and better ways to extrapolate these findings to the human situation. And that's a job for science. Only after such a job is done can the legislators and the regulators make benefit risk judgments that will let us get on with the business of protecting the public safety and still meet the nutritional needs of an ever greater population.

Commissioner Schmidt also added that while carcinogens pose problems it is important to remember the "equally serious questions of mutagenesis and teratogenesis."

It seems apparent that in order to shield the environment from further chemical contamination, the policy issues and the scientific issues, although interrelated, must be approached separately. The role of the scientists is to describe physical phenomena—this chemical caused lesions in mouse brains under these conditions; that chemical caused cancer when fed to mice in certain quantities; those chemicals caused birth deformities when injected into chickens in designated amounts at certain ages; or to follow in detail the research track suggested by the Commissioner. Scientists can offer less definite, but still important scientific opinions on the degree to which damage to man can be predicted from damage to animals. Without knowing the levels of risk that society will tolerate, however, scientists cannot effectively differentiate between "safe" and "unsafe" substances.

Congress, on the other hand, taking into consideration the certainty or relevancy of the scientific findings, must set broad policy guidelines. Several issues suggest themselves as important for the consideration of the Nation's policymakers. Which purposes served by chemicals are worth the apparently increasing risk of their use in foods? Is it necessary to reassess—either to narrow or expand—the food and drug law prohibition on the use in food of any chemical not "required for" or...

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* Hearings before the Subcommittee on Executive Reorganization and Government Research of the Committee on Government Operations, U.S. Senate, 92d Congress, 1st session, Apr 6, 7, 1971 p 1-46

* This and the following three paragraphs are adapted from James S. Turner, "The Delaney Anticancer Clause: A Model Environmental Protection Law," Vanderbilt Law Review Oct 1971 p 8
"unavoidable in" food production? Which classes of chemicals should be added to the "zero tolerance" list now containing only carcinogens? Teratogens? Mutagens?

Determining the safety of a food chemical involves several steps. First, is the objective scientific determination of the discernible effects involved in the chemical's use. This determination is the responsibility of scientists.

Second, is the judgment about which of these effects is a risk and which is a benefit. This judgment is ultimately made by the public, acting through its representatives and spokesmen, or as individuals, but acting with a high degree of guidance from scientists, physicians, or other trained professionals.

Third, is the decision that the agreed-upon benefits of a given chemical exceed its agreed-upon risks. This is a public, not a scientific, decision, made in public forums in which scientists act as equals, though in some cases better informed, participants with other segments of society.

The Delaney clauses are a perfect model of this process at work. They delegate to scientists the responsibility for making scientific judgments and to Congress the task of making policy decisions. The scientists, after an analysis of all technical data, specify the degree of risk that would result if any amount of known carcinogens were allowed in the Nation's food supply. Congress, after considering all other relevant information, determines that the risk is unacceptable.

The FDA is then charged with the responsibility of removing carcinogenic chemicals from the food supply.

In this way Congress balanced the policy function and the scientific function. In adopting the clause the Congress accepted a principle spelled out by the Surgeon General's committee more than a decade later. "Chemicals sold are to be subject to scientific scrutiny not given individual 'rights': they must be considered potentially guilty unless and until proven innocent." This is the fundamental principle of the entire food/chemical regulatory structure of the food and drug law.

In relation to cancer-causing substances, Congress heard scientists describe the known and unknown risk associated with cancer-causing chemicals. It set the policy that no chemical known to cause cancer in animals would be allowed in the food supply. The regulatory agency was assigned the scientific task of distinguishing those chemicals that cause cancer in animals from those that do not. In this way Congress set a clear public policy of caution and allowed complete scientific freedom within the realm of available information.

Anita Johnson of the Ralph Nader-supported health research group has spelled out the public policy of a consumer advocate's view of implications of the Delaney clauses in her pamphlet "Cancer Prevention and the Delaney Clause."

THE DELANEY CLAUSE IN POLICY JUDGMENT

Congress determined that since cancer scientists cannot say at what level a carcinogen is "safe," the country should not suffer any risk of cancer from chemicals deliberately added to food. The judgment has so far not been extended to pesticides, carcinogens in the workplace or water supply, drugs or other consumer products, presumably because the benefit-risk balance is more complex.

FDA has special expertise in making scientific judgments but its personnel have no special qualifications to make social judgments on what amount of cancer risk certain food additives are worth. Under present law, FDA may determine
the side effects of a drug, such as dizziness, and then decide whether the benefits are greater than the risks. But wherever possible, FDA should be restricted to making scientific judgments, not social ones.

The recognition of Congress' role in setting social policy by adopting the Delaney clauses and restricting regulators to the making of technical or scientific judgments does not rest on the fact that the clauses deal with cancer-causing chemicals or set a zero tolerance. These are specific facts of a specific issue not central to the responsibility of Congress to set social policy.

The President's panel on chemical and health confuses the particular aspects of the Delaney clauses with the general requirement that Congress set social policy:

If one is content to separate the question of technical analysis from social judgment, then one is perhaps justified in inquiring as to which part of the government has the latter responsibility, the Executive branch or the Legislative. One school of thought has urged that the Executive branch be given only the responsibility of technical analysis leaving social judgments to the Congress. In fact, the pattern up to now has been a mixed one. In some cases, clearly the Congress has assumed the role of judge of social issues concerning how safe is safe enough.

The amendment to the Food, Drug and Cosmetic Act which determines the destiny of food additives found to be carcinogenic in animals or man (Delaney amendment) is perhaps the best known example. The Clean Air Act which determines the degree of reduction of automobile emissions is another. It is interesting to note that it seems to be the very lack of sufficient information plus an implied threat in each case which has led Congress to take social judgments in their own hands. In most regulatory activities dealing with chemical agents, the administrator of the law enjoys some discretion either as to time of regulation or as to degree of regulation. Thus, in most cases, both the Executive and Legislative branches have opportunities for offering surrogate judgments in the public's name.

The Panel implies that there is some alternative to addressing social and technical questions separately. In fact in passing laws, Congress is almost invariably making a social judgment. Conversely, regulatory agencies—hybrid quasi-legislative, quasi-judicial, quasi-executive institutions which should not be equated with the executive branch—draw their peculiar social and legal force from the presumption that they are the repository of specialized technical knowledge which peculiarly equips them to make technical analysis or scientific judgment.

Of course, there is no hard and fast line which can be universally agreed upon as the divider between the two parts of Government and the two types of decisions they arrive at. Congress uses technical expertise to make its social judgment. The technical analysis and scientific judgment of the regulatory agencies have social impact. But there is a difference in capability between the two institutions which makes it quite important to keep the differences in their roles clearly in mind.

What is a social judgment in an atmosphere of ignorance will become a scientific, technical judgment when enough information has been gathered. It was this point which the FDA Commissioner attempted when he suggested that new scientific information needed to be developed before the Delaney clauses could be safely and effectively changed.

The kind of confusion reflected in the President's Panel report can lead to the assigning of tasks to the wrong segment of Government by transferring responsibility where ignorance rather than enlightenment
exists. It is of course true that both the executive and the legislative, and the regulatory agency for that matter, offer surrogate judgments in the public's name. That is the purpose of all governments. The issues of concern is on what basis do they arrive at this judgment. Legislatures operate primarily on opinion and the resolution of differences by the voting of generally equal parties. Regulatory agencies are supposed to operate through the mastery of a particular set of objective facts of which they are the recognized master. Where those facts do not exist such agencies are not properly equipped to resolve matters of opinion. It is when they attempt to resolve such matters that they tend to cause damage.

Further, it is not necessarily true that except for dramatic interventions in the process like the Delaney clauses, the administrator of the law enjoys discretion about the time or degree of regulation. The food and drug law, for example, says that only safe food chemicals are allowed in the food supply. If a chemical in the food supply is discovered to be unsafe, say it causes brain damage when eaten by men, the administrator is bound by law to remove it from the food supply. Cyclamates, according to the FDA General Counsel, was removed from the market without reliance on the Delaney clauses.

In fact, Assistant Secretary of HEW, Elliot L. Richardson, indicated to Congress in 1958 that, while the Agency would not oppose inclusion of the Delaney clauses, they were redundant. Other provisions of the law, the Department argued, were as restrictive against cancer-causing substances as the Delaney clauses.

Since there is widely acknowledged scientific ignorance about the effects of low doses of cancer-causing chemicals on humans, whether tolerance for additions of such chemicals to food should be set has been and remains a social policy question. Social policy questions are the peculiar province of Congress. Congress has adopted a social policy which bans the addition of cancer-causing chemicals to food.

This is a sound and proper procedure irrespective of whether scientists embrace it or not. In this instance that segment of the scientific community most directly concerned with research on the control and prevention of cancer strongly supports Congress' social policy choice.

III. SUPPLEMENTS TO, EXPLANATIONS AND APPLICATION OF THE DELANEY CLAUSES

Senator Gaylord Nelson of Wisconsin, one of two Senators given a 100-percent proconsumer rating by the Consumer Federation of America in March of 1971, has introduced legislation which expands the Delaney clauses' principle into the area of chemicals which cause mutagenic and teratogenic damage. If adopted by Congress, a new social policy will once again be set. Congress will have made the finding that these particular health dangers are serious enough to require special congressional attention. However, the most important part of this extension of the Delaney principle is that it does not rely on an absolute zero tolerance. The new proposed expansion reads as follows:

Provided further. That no additive shall be deemed to be safe if it is found to have mutagenic or teratogenic effects when ingested by man or animal or if it is found, after test which are appropriate for the evaluation of the effects of food additives on man or animal, to have mutagenic or teratogenic effects on man or animal except that no additive shall be deemed unsafe under this provi-
sion if the Secretary (a) makes an affirmative finding, based on the recommendations of an advisory committee of experts (appointed by the Secretary) qualified by scientific training and experience to evaluate the mutagenic and teratogenic effects of food additives on man and animals, and includes such finding in his order issued under this subsection, that the hazard to the public health which might result by denying the use of such additive would exceed any hazard to the public health which might result by permitting the use of such additive as proposed by the petitioner, (b) gives public notice of his affirmative finding by publication in the Federal Register, and (c) within six months after the date on which such notice was so published, issues an order making his affirmative finding final.

This application of the Delaney principle suggests its flexibility. It involves a social policy judgment. Congress is asked to place certain restrictions on the use of a certain class of chemicals. But in this case, the Senator believes that scientific knowledge has developed to the point where a zero tolerance is inappropriate.

The situations presented by Senator Nelson proposing expansion of the Delaney principle suggest that debate about the Delaney clauses be drawn in several places. First, it can be drawn about the advisability of a zero tolerance for cancer-causing substances. Critics of the zero tolerance and only the zero tolerance would be happy if Congress allowed a tolerance.

Second, the issues can be drawn about the advisability of requiring food additives be proven safe before they are added to food. Those who believe such a policy is undesirable could only be satisfied by repeal of the entire food additives amendment.

Third, it should be argued that Congress is not competent to pass any legislation in fields which rest on scientific knowledge. If such a policy prevailed, the ability of Government to set and carry out policy would be crippled.

There are, of course, many gradations between each of these positions. Interestingly enough, as the debate about the Nelson bill begins to develop, those arguing against the anti-cancer clauses because they contain a zero tolerance will nearly all, if not all, be on the side of the opponents to the bill. When that occurs, consumers will be led to believe that certain opponents of the Delaney clauses really oppose all food legislation.

In fact, the Delaney clauses stand as a kind of litmus test of consumer commitment. Those who oppose the clauses are viewed by many consumer advocates, spokesmen, and groups as anticonsument. Thus, consumer groups tend to view with alarm any apparent attack on the clauses and to urge with vigor the support of the clauses. The Federation of Homemakers set the tone for many with a March 1973 resolution.

RESOLUTION OF THE FEDERATION OF HOMEMAKERS, INC., IN SUPPORT OF THE DELANEY AMENDMENT

1. FINDING OF FACT

The basic objective of the Federal Food, Drug, and Cosmetic Act is to protect the consuming public. As succinctly summarized by the Supreme Court of the United States:

"For purposes of this legislation those phases of the lives and health of people which, in the circumstances of modern industrialism are largely beyond self-protection. Regard for these purposes should infuse construction of the leg-
Dilation if it is to be treated as a working instrument of government, and not merely as a collection of English words." (United States v. Halter & Co.)

Recognizing the impossibility of establishing safe levels for carcinogens, the Congress of the United States in 1958 incorporated the Delaney amendment into the Federal Food, Drug, and Cosmetic Act, stating:

"No additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animals, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal . . ." (21 U.S.C. 348(c)(3)).

This amendment, which eliminated risk/benefit guidelines and prohibits the addition of any cancer-causing chemical or additive to our foods, has served as a valid safeguard against potentially carcinogenic foods being sold to unknowing consumers.

The importance of this legislation has been applauded by numerous consumer groups and supported by public governmental findings including the White House Conference on Nutrition, Food, and Health and the Minsk Commission on Pesticides and Their Relationship to Environmental Health.

Despite the recognized importance of the Delaney amendment, there is currently being observed several early signs of an intensified campaign on the part of food industry representatives, the Food and Drug Administration, and a small contingent of Congressmen to weaken or eliminate its provisions.

II. RESOLUTION

In consideration of the objective of the Federal Food, Drug, and Cosmetic Act to protect the consuming public, and in light of the noted danger of losing the strong protections afforded by the Delaney amendment, the Federation of Homemakers, Inc., by a quorum of its board of management, assembled in Arlington, Va., and voting this 10th day of March, 1973, declares its ardent support of the Delaney amendment in its present form and vigorously opposes any and all attempts to weaken or eliminate its basic protection. The uncompromising safeguard of the Delaney amendment is necessary to continue the effectiveness of the Federal Food, Drug, and Cosmetic Act as "a working instrument of government and not merely as a collection of English words."

Anita Johnson urged consumers to support the clauses which she argued was threatened by diverse industry and pseudoacademic groups. She wrote:

"Consumers should support the Delaney clause."

The Delaney Clause does not protect us from all exposure to carcinogens. Some natural foods, such as the tropical cycad nut, contain carcinogens. Contact with solar radiation and products of combustion, is unavoidable. Water and air, household products and drugs, carry carcinogenic pollutants. Several thousand new chemicals are invented every year. Hundreds enter commercial channels. Our environment is increasingly filled with synthetic chemicals, many not required by law to be tested for safety. Our bodies must fight a greater total carcinogenic burden. Compulsory testing of all environmental chemicals is needed, as is an application of the principles of the Delaney Clauses to other chemical exposures.

Food additives are chemicals of small benefit. Once added to food, additives are widely distributed, making their effects on long-range health impossible to trace, and of enormous potential danger. Exposure is easily preventable.

Prohibition of carcinogenic food additives is a sane, manageable approach to health preservation because it helps to prevent cancer. Defense of the Delaney clause from the pleas of private industry, is a top priority for all consumers.

Generally speaking, there is a growing recognition that other chemical hazards, most noticeable birth defects and genetic damage, are
in need of increased attention. To supporters of the Delaney anticancer clauses, this usually means expansion of the Delaney clauses into the other areas. Thus it would appear that the defenders of the Delaney clauses would become proponents of the Nelson bill applying the principles of the clause to mutagenic and teratogenic substances.

The approach to the Delaney clauses represented by the FDA selenium petition has met with a wide diversity of consumer reaction. One school of thought argues that selenium has not in fact caused cancer in animals or men and therefore is of no concern to the working of the Delaney clauses. Another school argues that selenium is not really an essential nutrient and so should not receive the special attention that FDA has given it.

Some suggestions have been made that certain mathematical models can be used to aid in handling the cancer-causing chemical problem. Generally speaking, consumer proponents of the Delaney clauses would support the use of mathematical models to the extent they would be useful in the identification of which chemicals cause concern. There is, however, great reluctance to rely on such models to establish any degree of human risk to the exposure of cancer-causing chemicals.

Dr. Marvin A. Schneiderman of the National Cancer Institute has suggested that serious thought be given to abandoning the strict risk benefit approach to safety balance and replace it with “mini-max solutions—solutions minimize the maximum possible losses.” Presumably this would mean that a chemical with a slim chance of causing a massive genetic disaster in three generations would be threatened as more dangerous than a chemical with a near perfect possibility of killing one person. This would be almost a reversal of the traditional way of looking at chemical hazards. However, the general thrust of this idea has been approved by the President’s Panel on Chemicals and Health. It said:

Improved safety is possible. But to make the greatest possible health advance we ought to react most to the gravest threats, as judged by their total consequences for all our people, particularly when these threats are either well-established, or both plausibly true and long-delayed in impact. We need also to react appropriately to less certain threats that can be avoided without appreciable disadvantages. Threats of lower priority should not be neglected but need not be reacted to as strongly.

CONCLUSION

The Delaney anticancer clauses have strong scientific arguments and important cancer scientists supporting it. It is the policy decision taken by Congress in the face of ignorance about the effects of low levels of cancer-causing chemicals in food. As such it has wide support among organized consumer groups, individual consumer advocates, and even among large segments of consuming public.

There is a growing pressure for expansion of the Delaney clauses principle into the area of chemically caused birth defects and genetic damage. Consumers who support the Delaney clauses tend to support the expanding of its principles into other areas. They also tend to view any opponents to the clauses or their expansion as primarily industry based with a financial interest in reducing the regulation of chemicals in food.

In general the arguments about the Delaney clauses have been the same since their inception in 1958. The scientific information on cancer
and its relation to chemicals has remained relatively undeveloped in that period. Therefore, every attempt to change the clauses in relation to food additives has been defended by the same arguments which get the measure enacted in the first place.

This flow of events has generally been regarded as a consumer victory.

THE FOOD SAFETY COUNCIL—AN INTRODUCTION

(By Dr. Richard L. Hall)

The Food Safety Council, now slightly over 2 years old, is a curious and unique organization. It responded to a need that is peculiarly characteristic of our time. And while it has antecedents, it has no precedents.

It is trite to say we live in an age of uncertainty. But while people yawn and accept the generality, they grow uncomfortable when uncertainty becomes specific—specifically when it concerns health, safety, and everyday necessities such as food.

The advance of science can narrow that uncertainty, often at great cost and effort, but it can rarely remove it. Indeed, biological science typically makes us more aware of uncertainty, or of new, different, more remote, but not necessarily, less alarming uncertainties.

We are a diverse population. We have many subtle, and a few not-so-subtle biological differences. We vary in our interests, wants, and fears. The inherent uncertainties of science and our diversities of nature provide much of the basis for our current concerns over food safety. But there is an even more important social basis.

Once our food was prepared at home from locally produced ingredients. We had the confidence that comes from familiarity and a sense of control. We had never heard of carcinogens or Clostridium botulinum, or PFB's. We had the confidence that comes from innocence. Today most of our food is grown thousands of miles away, processed by people we never see, through equipment most of us would not recognize. We have lost the confidence that came from familiarity and control. We read almost daily of some new risk, or old risk re-examined, but which we cannot personally evaluate. We have lost the confidence that came from innocence.

Our ancestors' abilities to know, control, and evaluate their food were very imperfect, as disease records and life expectancy tables bear witness. But even those imperfect assists are depleted. We have replaced them with an elaborate, confusing array of agencies, labeling, testing, and regulation, but this has not stilled the disquiet stemming from uncertainties of science, diversities of need, and loss of confidence. This is not just, or not even a scientific problem: it is a societal one. It was to meet this need the Food Safety Council was formed.

The Food Safety Council has two principal goals. The first is to devise a scientifically valid procedure for measuring the risk of consumption of any food additive, natural ingredient or contaminant which it may be desirable to evaluate. It must be based on sound science, up to date and updatable. It must employ that elusive principle of commensurate effort. It must allocate resources among problems in proportion with the potential for solutions to those problems
to promote the general health and welfare. It must interpret any unacceptable risks and it must do so with such economy of effort that it neither wastes scarce resources nor discourages useful products. That first scientific task, performed by the Scientific Committee of the Food Safety Council, is now at the state of publication for general discussion and peer review.

This leads to the second task, which relates to two key words I just used: They're "unacceptable risk," and "useful products." Animal tests and mathematical extrapolation and epidemiological studies can provide estimates of risk. They cannot judge the acceptability of that risk. Acceptance—or rejection—comes from individual or societal review of whatever advantages or benefits go with each risk and with a similar appraisal of the alternatives to that risk. It depends upon whether the risk is voluntary; that is, do we have some choice about accepting it, or is it imposed? It depends upon our own level of information or, lacking that, upon the level of our confidence in those making the choice for us. This raises the issues of consumer sovereignty expressed in choices in the marketplace and how those choices are to be made as informed as possible and as unrestricted as possible. It raises questions about those who are inherently unable to make informed choices and the extent to which provision for them must restrict everyone else. And, finally, it involves consideration of how the diversity of consumer needs can be expressed most effectively in such administrative and regulatory measures as are required.

This is an enormously complex subject in which the Social and Economic Committee of the Food Safety Council is truly breaking new ground. Their purpose is not to determine acceptable risk, but to outline the structures and procedures by which socially acceptable risk may be determined in each instance or class of instances. Their report is in preparation.

We are fortunate in having here today three members of the board of trustees. Each comes from a different and critical source of input into the council's activity. Each has contributed significantly to the progress already made. In their comments they will provide some insight into the goals of the council and how it appears those goals may be reached.
The Politics of Cancer
ELIZABETH WHELAN

It is the second leading cause of death in this country, claiming the lives of some 400,000 Americans a year: one every 90 seconds, 1,100 victims a day. One in four of us will develop it in our lifetime. An estimated 60 to 80 percent of it is caused by factors in our environment. The media inform us that our country has unusually high rates, with its incidence and mortality rates soaring, and imply that this trend results from advancing technology (industrialization) which leaves us victims of adulterated, overprocessed foods, dangerous drugs, polluted air and water, and hazardous workplaces. And now, through an elaborate network of regulations, restrictions and prohibitions, our government is supposedly going to protect us from it.

Cancer. Abnormal, undisciplined, seemingly unrestricted growth of body cells, with the resultant masses compressing, invading, and destroying contiguous tissues. Very often a painful, prolonged, undignified way to die, physically devastating for its victims, and frequently emotionally devastating for loved ones who must stand back and watch. It should be good news to learn that our government is taking action to spare us and our children from this fate. Of course, all this effort is very expensive for U.S. consumers. But, if removing cancer-causing agents from our food and drug supply, the workplace, the water we drink and the air we breathe will markedly reduce cancer's toll, the investment of time and energy and the accompanying return to a less technological society may be worth the costs.

On the other hand, if the underlying premises that have spurred this growth in government regulation of environmental chemicals are in conflict with the scientific facts, then our government's escalating war on cancer will be an effort in futility, one with far-reaching and, I believe, deleterious effects on our standard of living. In this regard, the cornerstones of the popular wisdom about cancer and the environment are worth reexamining.

Is there a cancer epidemic?
Apparently many people believe there is. One network television program on cancer opened with the statement: "The news tonight is that the United States is number one in cancer. The National Cancer Institute estimates that if you're living in America, your chance of getting cancer is higher than anywhere else in the world." And during the Carter-Ford Presidential debates in the fall of 1976, Mr. Carter made reference to the United States as "having the highest cancer death rate in the world."

Actually the United States ranks 21st in a list of 44 countries in cancer mortality, according to the international statistical comparisons of the World Health Organization. Scotland has the dubious honor of being "number one," followed closely by Czechoslovakia, Luxembourg, Uruguay, Austria, France, and the Netherlands. So what about this cancer "epidemic" we hear a great deal about?

Any discussion of cancer trends must distinguish between cancer incidence — the number of new cases of cancer diagnosed in a given time period for a specific population — and cancer mortality — the number of deaths from a form of malignancy in a given year for a specific population. It should come as no surprise that because of the growth of the U.S. population in the past few decades the gross number of cancer deaths has also increased. What is surprising is that despite the popular wisdom about our "epidemic," the number of new cases of cancer, taking into account all body sites for both sexes and adjustments for changes in the age distribution of the population, has decreased since the mid 1940s.

The incidence of certain types of cancer, specifically stomach cancers in men and women and cervical cancers, has decreased dramatically. The rates of certain other types of cancer, such as breast and intestinal cancers in white women, have stayed about the same. In men, there have been increases in the number of new cases of cancer of the prostate and the colon and increases in cancers of the esophagus and breast in nonwhite men and women. But the only body site of dramatic increase for all Americans in the past 25 years is the lung. Were it not for the sudden and continuing up-swing in lung cancer deaths starting in 1930, the overwhelming proportion of which are the result of

1. Dan Rather, "The American Way of Cancer," CBS.
The Politics of Cancer

Cigarette smoking, the age-adjusted American cancer death rate would be declining slightly.

Causes of Cancer

In the past five years frequent references have been made to the statement that “80 to 90 percent of all cancers are environmentally induced.” This figure was originally presented by the International Agency for Research in Cancer, a World Health Organization affiliate based in Lyon, France, and has, unfortunately, been subject to considerable misinterpretation. This estimate was derived by comparing the high and low cancer death rates in many countries around the world. The conclusion was that since human cancer rates differed so widely, some aspects of the environment were the bases of cancer causation. The scientists presenting the figure did not mean to suggest that we have the potential now to prevent 80 to 90 percent of human cancers, nor did they mean to suggest that environmental factors such as polluted air, water, food, and industrial chemicals played a major role. The cancer-causing factors they identified were primarily cultural in origin.

While epidemiologists differ somewhat in their estimates of the proportion of cancer deaths attributable to various causes, the majority of analyses of human disease patterns suggest that, except for superficial skin cancer, some 30 to 35 percent of cancer deaths are directly attributable to cigarette smoking (in addition to affecting the lung, tobacco exerts a carcinogenic effect on other sites, including the bladder and oral cavity); on a more speculative level another 30 to 35 percent of cancer deaths may be related to dietary habits. Perhaps, it has been suggested, diets high in calories and fat can increase one’s risk of certain forms of cancer. An additional 1 to 2 percent of total cancers may be linked to excessive alcohol consumption (generally in conjunction with tobacco use) and exposure to ionizing radiation and cancer-inducing viruses.

Contrary to what emerged from a mysterious, unpublished document from the National Cancer Institute, which was widely quoted by Secretary of Health, Education and Welfare, Joseph Califano, the International Agency for Research on Cancer estimates that occupational exposure to chemicals is the underlying cause of some 1 to 5 percent of the cancer deaths that occurred in 1978. (Mr. Califano attributes 20 to 40 percent
of cancers to this cause.) These deaths, however, are the result of exposure in the workplace 20 or more years ago when safety measures in chemical plants were not standard procedure as they are today, so that the 1 to 5 percent figure may overstate the problem existing today. Of all cancer risks that we as a society face at this time, the occupational risks may be no higher than 1 percent of the total and may possibly be closer to zero.

As far as we can ascertain from human epidemiological studies, food additives and pesticide residues are not responsible for any cases of cancer. Indeed, since the use of certain food additives has increased, the stomach cancer death rate has declined. While some carcinogens have been identified in the air and water of some U.S. communities, no studies have convincingly indicated either general water or air pollution as a cause of human cancer. Although there is no doubt that lung cancer death rates are higher in cities than they are in rural areas, the Royal College of Physicians concluded in 1970, after thoroughly examining the possible role of air pollution, "The study of time trends on death rate due to lung cancer in urban areas demonstrated the overwhelming effect of cigarette smoking on the distribution of disease." Other scientists, including two epidemiologists from the American Health Foundation agree: "On the basis of data accumulated in the U.S. we cannot conclude that the incidence of lung cancer is much affected by community air pollution in this country."

This should not excuse the indiscriminate or irresponsible pollution of our natural resources. There are many good and valid reasons, both health-related and aesthetic, for taking steps to keep our air and water as pure as possible. But the risk of cancer is not one of them.

The current federal preoccupation with chemicals and cancer involves many agencies. In addition to those agencies regulating materials such as cigarettes and alcohol, we are "protected" by the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA), the Consumer Product Safety Commission (CPSC), and the United States Department of Agriculture (USDA).

The Delaney Clause

The vanguard of legislation in the chemical-cancer arena is
The Politics of Cancer

the Delaney Clause, which now largely dictates the regulatory activities of the FDA with respect to food additives. The Clause, enacted in 1958 and authored by Representative James J. Delaney (D-NY), states: "No additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animals." In brief, the Delaney Clause requires the FDA to ban any food additive that is shown in any animal species, at any dose level, to cause an increased incidence of any type of tumor. Although many FDA representatives now claim that "It would have happened anyway," it is clear that the banning of cyclamates, Red Dye #2 and the recently proposed ban of saccharin are the results of the absolutism of the Delaney Clause.

The Clause has proved to be a regulator's dream. If Event A happens (cancer in an animal study) then Event B will occur (banning). This entails no weighing of cost and benefit, no scientific inquiries about what the animal study meant and how it should be interpreted — just regulatory action. Just such an inflexible and unscientific regulation led to the banning of a number of useful chemicals and most certainly has served as a disincentive for food technologists who might otherwise be seeking new types of food additives, including a variety of synthetic sweeteners. But for a while the concerned consumer, as well as those in American industry, could at least console himself that this simplistic approach was limited to the regulation of food additives.

In the last 15 years, however, a growing concern about many other chemicals and other possible environmental hazards has triggered a series of events which may ultimately lead to a Delaney-like regulatory approach to all the synthetic — and perhaps some natural — chemicals in our lives.

The National Cancer Institute, Environmental Protection Agency and Occupational Safety and Health Administration began, in the 1970s, to examine possible environmental threats and wrestled with alternatives for identifying and regulating carcinogens. Industry established the Chemical Industry Institute of Toxicology with the announced objective of creating the best toxicology testing operation in the world. During 1975 the NCI attempted to develop general criteria for
assessing whether specific environmental agents constituted a carcinogenic hazard in humans. But in issuing a report in June 1976, the NCI concluded that no simple guidelines could be set, since evaluating chemicals is a complex process characterized by many imponderables and often requires expert scientific judgment in each case.

But the EPA took a different course. In an effort to develop a policy for evaluating pesticides, an effort that overlooked the NCI panel's conclusion that broad guidelines in judging carcinogens were not practical, the EPA issued what it termed "Nine Principles of Carcinogenicity." In summary, these principles stated that any chemical that induces either benign or malignant tumors in animals must be considered to be a carcinogen capable of affecting man and that such a chemical must be assumed to pose a hazard even at extremely low levels of exposure. EPA applied these principles (which, because they are not fundamental truths, laws or doctrines, might better be called "propositions") to the pesticides, aldrin and dieldrin, which at high levels cause liver tumors in mice. The agency termed these substances "imminent hazards" and banned them, despite the fact that these agricultural chemicals did not cause tumors in other animals and had no carcinogenic effect on workers who for many years had been exposed to the chemicals at levels many hundreds of times that of the general population.

At the same time, OSHA was considering how to carry out its legal mandate, the protection of workers in the workplace, particularly in terms of possible exposure to occupational carcinogens. During its first years OSHA (which was created in 1970) was primarily concerned with such mishaps as falling off ladders and crushing fingers in machinery. The carcinogen matter was a relatively new one for them. Indeed, the agency was under increasing criticism, some internal and blatantly self-serving, for having regulated only a handful of chemicals as carcinogens. In an effort to increase its ability to move more quickly against possible cancer-causing chemicals in the workplace, OSHA, in late 1977, issued a proposal abandoning its previous substance-by-substance approach to the regulation of carcinogens and establishing a standard fill-in-the-blank type schema. Specifically, OSHA now proposes that a chemical be identified as a "confirmed carcinogen" if it increases the incidence of tumors or decreases latency periods between
The Politics of Cancer

exposure and onset of tumors — malignant or benign — in either humans or two mammalian species, or one animal species if the test is replicated or considered by OSHA scientists to be convincing.

While at first glance, the OSHA regulation may appear to have more flexibility than the Delaney Clause, it, too, places the label "carcinogen" on any chemical that increases the incidence of any type of tumor, in any animal, in any dose, possibly by any route of administration (including skin application or injection). In the sense that it assumes that any type of tumor, malignant or benign, is cancer, it is even more inflexible than the Delaney Clause.

While these OSHA regulations would apply only to the workplace, they could, in effect, set a national standard for the definition and regulation of carcinogens. If they are approved as scientifically valid, they could very well become part of the regulatory apparatus of all health-related agencies, thus being applied to chemicals in the air, water, cosmetics, drugs, and food.

A National Cancer Policy

As the various regulatory agencies were pondering their own individual cancer policies, four of these regulatory agencies charged with protecting workers and consumers from carcinogenic substances began to develop what they hoped would be a national cancer policy. The EPA, CPSC, FDA and OSHA developed their proposal under the Interagency Regulatory Liaison Group (IRLG), which was set up by President Carter to coordinate regulatory activity. The report of this interagency group resembles OSHA's proposal in that it relies heavily on animal tests and accepts as a major premise that cancer studies involving mice, rats or other mammals are valid methods for judging a compound's potential effects upon people and that there is currently no reliable way to predict a threshold below which human population exposure to a carcinogen has no effect on cancer risk. But the IRLG document did show some insights that the policies of the individual agencies did not. Specifically, the IRLG paper stresses risk assessment, estimating the degree of risk involved in exposure to a given chemical rather than labeling all potentially harmful substances as "carcinogens." This is significantly different from grouping all potentially carci-
nogenic substances as carcinogens and regulating them all in the same manner. There is approximately a million-fold difference between the cancer-causing activity of aflatoxin (a 'proven animal carcinogen in a number of species') on one hand and the disputed carcinogenic potential of saccharin on the other.

It is very difficult to criticize any program aimed at cancer prevention. We all agree that reasonable and effective methods should be employed to reduce the public's risk of suffering from this dreaded disease. But the Delaney Clause, the EPA "Principles," the OSHA regulations and even the new inter-agency proposal seem to be so intent on preventing cancer at any cost that they have overlooked some obvious and sometimes disturbing scientific realities.

First, all three regulatory approaches make the assumption that most cancers are caused by potentially avoidable exposures to chemical carcinogens. The Delaney Clause assumes these chemicals are likely to be food additives. The EPA Principles assume that they take the form of carcinogenic pesticides. The OSHA regulations assume that the offending chemicals are in the workplace, injuring workers and then possibly escaping to pollute our air and water supply.

But as has already been pointed out, the pieces of the cancer puzzle which have been assembled to date do not support these assumptions.

Indeed, an examination of the causes of human malignancies suggests that the combined FDA, EPA and OSHA efforts to remove cancer-causing agents from our food, water, air and workplace would only have the potential for reducing our cancer mortality by between 0 and 5 percent.

Second, all three regulations are, to varying degrees, based on a double standard, one that demands action against a man-made chemical, while no action is required to eliminate similar hazards caused by naturally-occurring substances. The Delaney Clause is specific in this regard; its legislative impact is limited to chemicals added to food. The EPA principles and OSHA guidelines are ambiguous but appear to be only concerned with "artificial" agricultural and occupational chemicals. As a result, a useful artificial sweetener like saccharin may be banned on the grounds that it induces tumors in Canadian rats while there is strong scientific evidence that egg yolk, egg white, selenium, caffeine, lactose, maltose and vitamin A — which will not be banned — are carcinogenic in at least one species of mammalian
The Politics of Cancer

test animals.
Third, all three individual regulations are inflexible, requiring regulatory action on the basis of animal experimentations, assuming that laboratory animals are excellent predictors of the cancer-causing potential of a chemical in man. Indeed, proponents of all these regulations contend that all chemicals that cause cancer in man cause cancer in animals; the inference being, then, that mice are little men.”

While it is true that most — but not all — known human carcinogens are cancer-causing agents in laboratory animals, the opposite is not true — not all animal carcinogens are known human carcinogens. Drugs such as sodium penicillin and phenobarbital, known animal carcinogens, have no known cancer-causing effect on humans. If the philosophy of the Delaney-OSHA-EPA regulations were applied to the oral contraceptive — which contains synthetic estrogen — the Pill would never have been approved, because all estrogens, natural or otherwise, have carcinogenic properties.

The fact that the OSHA regulations, unlike the Delaney Clause, assume that the appearance of benign as well as malignant animal tumors indicates a carcinogenic potential for man is even less scientifically tolerable. While most authorities believe that the appearance of benign tumors should be a warning, there is no reason to immediately classify them as "cancerous."

There is no doubt that animal experimentation plays a critical role in evaluating chemical safety. Some of the most important medical discoveries had their beginnings in animal experimentation. We are not suggesting that we should rely solely on evidence of human experience in judging a substance's safety. Epidemiology does have its limitations, primarily that it takes five, ten, twenty or more years for some human carcinogens to reveal their deadly characteristics. But we simply cannot be guided by laws that assume that the laboratory animal is an infallible predictor for man. Animal experiments need to be interpreted and put in proper perspective.

Possible individual species or strain susceptibility must be taken into account — as well as other unique circumstances that may be responsible for whatever positive results appear. It is known, for instance, that animals differ from humans in their reactions to various chemicals. Morphine has a directly opposite
effect on the cat than it does on human beings. It is a very useful analgesic drug for man, but when it is given to a cat, the animal becomes restless and belligerent.

Ensuring a Sound Basis for Prohibition

If a food additive or other industrial or environmental chemical, when ingested by a group of rats, leads to an increased incidence of malignant tumors of the bladder, liver, or other organ, the results are worth noting. But that observation is not in itself a sound basis for condemnation or prohibition. Instead, such an observation should stimulate similar tests on other animals. When the results of a series of different tests on different animals are in, the scientific decision-making process should begin. Were the results consistent? Did the chemical have a carcinogenic effect in more than one species? Certainly, one study detecting cancer in animals should not negate a dozen others reporting no cancer. What about a dose-response relationship? Did the incidence of tumors increase as the dosage of the chemical was increased? Does the chemical being evaluated have any characteristic that might lead one to suspect it is carcinogenic? Are there specific factors that promote or inhibit the carcinogenic effect of this substance in a laboratory animal? Is there any human epidemiological evidence available on the substance which would support or fail to support the laboratory findings? Years of safe use by humans should generally carry more weight than one limited animal evaluation. Does the chemical perform an important function? Are there alternatives? What would be the cost of banning or severely regulating it? The answers to some, if not all, of these questions may provide a basis for sound, scientific decision-making. There can be no set criteria for judging carcinogenic activity, but there can be a consistent and scientific method of analysis. The data provided by laboratory experimentation should provide but one input into a complex evaluation procedure.

Fourth, the OSHA regulations, like the Delaney Clause and EPA Principles before them, are unrealistic and, indeed, anachronistic in that they assume that if a large amount of a substance induces cancer in animals or humans, even trace amounts — truly minute quantities — could be carcinogenic, too, and thus should be eliminated from the environment. With our sophisticated means of detecting minute levels of a
The Politics of Cancer

substance, the zero tolerance principle is particularly inappropriate. The process of producing cancer in the most sensitive species at any dose level by whatever route and then assuming that trace amounts of that chemical might cause cancer in man, perhaps despite human evidence to the contrary, is nothing short of ridiculous.

By assuming that any chemical at any dose that induces any type of tumor in any animal is a potential cancer threat for humans and by setting standards which will ban that chemical or require expensive, superfluous restrictions, our government carcinogen policy will, in effect, be saying, "If there is even the slightest possibility, no matter how hypothetical and no matter what the cost of regulating procedures may be, take action."

Stopping the technology at even the hint of a problem is going to be very costly indeed.

As is always the case, the major costs of regulation are hidden ones, manifesting themselves in higher taxes, higher prices in the marketplace, reduced availability of supplies and services, and, in this case, increased dependence on other countries to supply us with goods that we can no longer make. Very often these costs simply show up in nickel and dime price hikes on common products and become indistinguishable in the overall spiral of inflation. What is clear, however, it that the regulatory steps now being proposed by OSHA are going to be even more expensive and are going to affect every one of us.

If applied literally to all chemicals in our environment, the OSHA standards might demand rigid protective gear for those who make their living frying eggs (as mentioned earlier, both whites and yolks are animal carcinogens) and could lead to the disappearance of major industries and materials we now take for granted, for example, the dry cleaning industry (with its dependence on perchloroethylene), cosmetics (one hair-coloring ingredient, 2,4-DAA, has been found to cause tumors in rodents, which would make it an unacceptable material for the workplace), foods (continued testing of additives and pesticides will inevitably lead to more and more isolated studies noting animal cancers), everyday products (perhaps among them insulation materials, because they have traces of asbestos, plastic bottles because of a speck of vinyl chloride monomer, and gasoline because it has more than a trace of benzene).

But it is very likely that the cancer standards won't be
applied literally because that would only make the government look more foolish than it already does and lead to more jokes, like the one about a substance called W-A-T-E-R being banned because an FDA researcher put his head in it for 20 minutes and died. It is unlikely that the regulations will be applied to the point that we shall destroy ourselves in the process. Instead of arousing the ire of Mr. and Ms. America, or risking losing the support of labor union leaders who begin to question whether they want to pay for this higher degree of safety by having fewer jobs available, the regulatory efforts will likely be focused, as they have been in the past, on areas where the impact will be more subtle, more indirect, although certainly not less costly.

The Cancer War: An Expensive Failure

It seems clear that the federal attempt to protect us from cancer, as reflected in the Delaney-EPA-OSHA-type regulations, is going to be a very expensive failure. These regulations focus a great deal of time, attention, and resources on environmental factors that contribute little to the nation's cancer burden. Obviously, we need to test our food additives to make sure that we are keeping hazardous materials out of our food supply. Highly toxic and/or carcinogenic materials should be also carefully supervised in the workplace. We realize that industry does not always voluntarily monitor itself. Some of the smaller chemical industries have been callously irresponsible about human exposure to known cancer-causing agents.

But an enormous, highly restrictive, inflexible, and expensive government regulatory system is not necessary. Because we have experienced tragedy in the past as a result of conditions that were extreme in their promiscuous-exposure to carcinogens, we do not now need to go to the other extreme, purchasing a far higher degree of safety than is necessary and instituting measures that will raise our taxes and the prices of goods and services without saving even one additional life. There are means by which we can accomplish the same goal: reducing the very small number of known chemical cancer hazards that may still exist in our environment by means of a less generalized, more focused approach, one that acknowledges degrees of risk and seeks on a case-by-case basis the counsel of the country's leading scientists, lawmakers, industry leaders, and consumer representatives.
Instead of seeking a risk-free environment, we should be moving toward the identification of acceptable levels of risk. In doing so, we would not be saying, “If you want this product, X number of workers will develop cancer” (which, indeed, is exactly the type of trade-off we willingly make using automobiles, airplanes, and swimming pools). It is possible for us to set levels of chemical exposure which according to all scientific evidence do not significantly raise anyone’s disease potentiality.

While concerns and government regulatory efforts are now focused on the possible link between technological development, environmental chemicals, and cancer, it is clear that the United States does not have a unique cancer pattern and that, with the exception of lung cancer, there is no cancer epidemic. Air and water pollution, modern food technology, and “industry” are not at the root of our cancer problem. The parts of the cancer causation puzzle now assembled point directly to harmful aspects of our individual habits, particularly cigarette smoking and dietary excesses.

Yet, popular wisdom prevails and new laws, regulations, and bannings are being proposed. And popular wisdom will continue to prevail unless there is an increased public awareness about the disastrous impact regulatory decisions based on misinformation can have.

In recent years, the few scientists who have stepped forward to report the facts about chemicals, cancer, the environment, and health have been met with skepticism and antagonism. Critics often label them apologists for the food or chemical industries, paid for issuing these unorthodox views. As a result, an unrealistic dichotomy has resulted between the self-appointed “consumer” groups who condemn the cancer-causing impact of industry and its chemicals and the much-maligned group collectively known as “industry,” which understandably is speaking (or not speaking) in its own defense.

In reality, however, neither of these groups represents the basic interests of the American consumer on questions relating to cancer and the environment.

Traditional consumerists, who have successfully called for bans on DDT, cyclamates, TRIS, Red Dye #2, and other chemicals and who are now turning their guns to saccharin, nitrite, hairdyes, and hamburgers, appear to be demanding safety at any price, no matter what a ban on a chemical might
do to availability and price tags and no matter how small or hypothetical the benefits of such a ban might be. "Industry," on the other hand, is comprised of business people who are quite legitimately seeking profits. The costs of regulations are simply passed on to the consumer, and industry always can come up with new products to sell. To go to an improbable extreme, if the chemical industry were put out of business, firms could always regroup to sell organic food, water purifiers, or air masks for city dwellers. In the long run, it is the consumer who has the most to lose in the chemicalphobia debate.

If modern-day chemicals cause cancer (and by chemicals we mean our pharmaceuticals, processed foods, and the other products of technology that make our life easier) then that would be another question. But in most cases no such cause-and-effect relationship exists, and we may soon find ourselves without some very basic, useful items, while we spend more of each dollar in taxes to pay the regulators—all this without preventing even one case of human cancer. This is an enormous price tag for nothing.

Cancer is a major public health problem in the United States, the second leading cause of death. It is a problem that demands research attention. But our "war" on cancer will be lost before it begins if we continue to misidentify the enemy.

We would be wise to look before we take a large leap backwards, assessing what costs are involved in such a move. For example, in addition to dealing with the economic burden of government regulation, by accepting a sweeping, uniform carcinogen policy, we will be paying yet another indirect and very significant cost. By investing such a large portion of our tax dollars in programs that appear to have no payoff in terms of cancer prevention, we will be detracting attention from the real war on cancer, one that might provide us, for example, with the formula for a safer cigarette, a better understanding of how diet and disease may be linked, and more complete information on the viral causes of some cancers. In this sense, government regulation may prove to be cancer's ally, leading us to wonder if our regulatory bodies themselves might be well-advised to post a label, "Warning: This agency may be harmful to your economic and physical health."
Unnecessary

BY ANITA JOHNSON

Do We Need to Poison Ourselves?

EXPOSURE TO TOXIC CHEMICALS is endurable when important benefits are provided. But many hazardous chemicals provide consumers with trivial benefits or no benefits at all. Moreover, countless consumer products are put on the market in spite of ignorance of their benefits and of their true effects.

Drugs

Consumers of over-the-counter drugs, for instance, are likely to be exposed to witches' brews of untested ingredients, many unnecessary for any medicinal purpose. The best-selling cold medicines contain a variety of unproven ingredients. The value of two of the three medicated ingredients in Contac, advertised at a cost of at least $10 million a year, are unknown by the manufacturer. Three out of four of Coricidin Cough Medicine's three ingredients are unproven, according to the Food and Drug Administration (FDA). Oratene, with $20 million in annual advertising, has two unproven ingredients out of four. Vick's cough syrup has five of nine. In addition to these ingredients, cough and cold medicines bear a plethora of dyes, perfumes, flavors and sweeteners, texturizers, vehicles and preservatives which the manufacturers add for cosmetic reasons and which are not on the label.

The case of chloroform illustrates the folly of using these untested unnecessary ingredients. Until 1976, chloroform was widely added to cough medicines, toothpastes, and mouthwashes to provide a pungent flavor. There had been suggestions for thirty years that chloroform caused cancer, but the manufacturers were not particularly curious about this possibility. In 1972 the National Cancer Institute, at the taxpayers' expense, initiated animal studies, which showed that the substance caused cancer in mice and rats. Like the cold Lax dyes, chloroform is a member of a bad family.

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(531)
Chemicals

the ubiquitous hydrocarbons, many of
whose members have caused cancer in
animal studies and in humans. Members
of this one family include vinyl chloride,
its chlorinated ethers, dichloromethyl
one, dibutyl phthalate, and triethylene,
or anilino- and anilino- and diethylyl
ether. These have all led to the
majority of human cancer studies in
vivo. But there are other anions as
well, such as chotrototyl ether, dichloro-
ethylether, and the like, which are
solvents in many of the products which
could have been used to manufacture
cigarettes. Inhaled coffee is another
product which formerly contained the
carcinogen paraffin. In 1950 Wyeth's
Ceracol, Parke Davis's Mithem, and
other cough medicines such as
Pettus. In addition, Merck are also
bombarded with public criticism over
prescriptions for antibiotics for the
treatment of patients with obesity. The
recent surge in incipient obesity,
due to sedentary lifestyles, has led to
the development of new drugs such as
progestins and the like. 

Consumers are also bombarded with
unsolicited voice-prospectives in their
dailies. For example, doctors frequently
prescribe antibiotics for the
common cold, a disease which is treatable
by avoiding bacteria. Antibiotics
affect the gut flora and may produce such
effects as life threatening diarrhea and
should be prescribed only for very
special kinds of infections such as
stomach ulcers. Another example is
amphetamines, which are prescribed for
anorexia nervosa and obesity. These
effects are more significant than the
beneficial, and the fact that these drugs
cause cancer of the stomach, with the
alcoholism-potentiated, is well-known.

Food Additives

Saccharin

Saccharin is a good example of an
unnecessary chemical exposure. Although
it has been on the market for decades,
one benefit since then has been demonstrated.
From the available evidence there is no indication
that saccharin is a carcinogen. Animal
studies have shown that these animals fed
artificially sweetened drinks make
up for the lower sweetness in the drink by eating more white bread. In fact, one
and studies have shown that saccharin
lowers blood sugar, which is significant
because lowered blood sugar is not
triggers for appetite. In fact, lowered blood sugar has also been noted in
animals subjected to starvation, at which
time the body begins to use fat as a source
of energy. There is evidence that this
behavior is also seen in saccharin-exposed
animals, and that saccharin makes it harder to diet. A
National Institute of Health study of
saccharin in 1973 concluded: "The data
on the efficacy of saccharin or its salts
for the treatment of patients with obesity,
dental caries, coronary artery disease,
and even diabetes have not yet produced a clear picture of the usefulness
in the drug."

The fact that a number of prominent
diabetes experts believe that saccharin
has no special place in the diabetic's
regimen indicates that saccharin for
diabetes, as it is used, is a custom,
not an absolute necessity. The American Diabetes
Association has taken the position
that low-calorie food can be made
appealing without artificial sweeteners
by using natural condiments such as
ginger and ground coriander. 

The FDA determined in March that
saccharin is a carcinogen. The
determination was made when the results of a
Canadian study became known. This
study was the first of at least eleven
studies in which saccharin produced
cancer in one study at doses as low as
the equivalent of 1.6 bottles of diet
soda per day. These studies have been
followed by several human studies, with
the same results. The ban triggered a
widespread outcry, and Congress delayed
its implementation for 18 months. The
uncertainty was the result of a public yet
unable to scrutinize critically the
common products on the market, to separate out
the pr,....
The FDA is required by law to prevent the addition of any cancer-causing chemicals to all foods processed or sold in the U.S.

"...which means that they are no longer considered by FDA as generally recognized as safe (GRAS). Not only have they been added to foods for many years, but they are also now known to cause cancer in some people in very small amounts. Since they are able to penetrate the DNA of a cell in minute doses and initiate a mutation which is passed on to the cell's progeny, they can cause cancer...

In addition, many dyes and pigments are not considered safe by other authorities in the pharmaceutical industry, such as the Food and Drug Administration (FDA), in their usual concentrations and in the usual types of foods.

The Delaney Clause, which forbids the addition to food of any chemical which causes cancer when fed to animals, has been the subject of much discussion. This clause is intended to ensure that food additives are safe for human consumption. However, the Delaney Clause has not been effective in preventing the use of cancer-causing chemicals in food. In fact, many of the additives currently used in food are known to cause cancer in animals.

Industry frequently cites the use of animal studies on the basis of the Delaney Clause, arguing that these studies are conducted with the goal of detecting cancer in animals. However, the Delaney Clause is not intended to prevent the use of cancer-causing chemicals in food, but rather to ensure that they are not present in food at levels that may cause cancer in humans.

Public exposure to food additives can be enormous. Based on FDA calculations, a twelve-year-old child may have taken as much as 300 pounds of food in one day, while the average adult may have consumed as much as 10 pounds of food in one day.

While the Delaney Clause is intended to prevent the use of cancer-causing chemicals in food, it is not always effective in preventing their use. In some cases, the Delaney Clause has been applied too broadly, leading to the ban of chemicals that are not actually cancer-causing. In other cases, the Delaney Clause has been applied too narrowly, leading to the failure to ban chemicals that are known to cause cancer in humans.

The Delaney Clause is intended to prevent the use of cancer-causing chemicals in food, but it has not been effective in achieving this goal. In fact, the Delaney Clause has been ineffective in preventing the use of cancer-causing chemicals in food, and has been a major source of controversy and debate.
In a recent event, proper labeling will help consumers to protect themselves and will encourage consumers to shift to less complicated products. This labeling of cosmetic ingredients is an evolution of those in a natural based ingredient without any compromising natural benefits.

and also products, among others. This finding would not be particularly striking for a ban due to the fact that FDA studies had previously concluded that 2,4-D does not cause cancer or a chronic course of hormone and other forms known to cause the early 20s. In order to protect, consumers should work the National 50% of the food that has been added to cosmetic products, although some have significantly higher rates than others. However, this study has not been published or presented in any scientific literature. The Food and Drug Administration, in consultation with the National Cancer Institute, is investigating the growth of certain kinds of bacteria and that the use of 2,4-D does not cause cancer. This is an ongoing study and may be suspended. The theory that anything that kills bacteria must be beneficial to everyone. In fact, it is highly possible that 2,4-D would never be a special class of篙mestic ingredients since 1958 when the first required safety testing began.

Labeling

On the other hand, consumers are considering the cost of labeling products that are not regulated by government agencies. To a certain extent, proper labeling will help consumers to protect themselves and will encourage consumers to shift to less complicated products. The value of ingredient labeling, of course, is not something that can be measured by those who have never used such products. Many foods are not regulated by law, but the final additives included among these are alcohol, alcoholics, which frequently contain a large number of unstable chemicals. This labeling is not labeled nor are the many ingredients in products in such as flavor and dye.

Patient information or prescriptive information is not a separate class of ingredient, although many states require it. However, at present time, the law requires detailed product information on prescriptive drugs, but at the time this document was completed, there was no instruction on the label that this information about the product is in all cases of a chemical with.

The National Cancer Institute has received complaints of animal reactions to several other substances which have dye ingredients are being marketed without labeling by the manufacturers.

Herbalism is a chemical which actually provided the economic supply until 1977. Herbalism contains the growth of certain kinds of bacteria and, as such, it was added to practically everything from beer to meat to soap as a preservative. The theory that anything that kills bacteria must be beneficial to everyone. In fact, it is highly possible that 2,4-D would never be a special class of篙mestic ingredients since 1958 when the first required safety testing began.

In conclusion, whether currently killing or not, the label on a product should not be used as a way to protect consumers. Instead, the label on a product should be used as a way to inform consumers of the ingredients that they are using and how they are using them.

In conclusion, whether currently killing or not, the label on a product should not be used as a way to protect consumers. Instead, the label on a product should be used as a way to inform consumers of the ingredients that they are using and how they are using them.
for the benefit of the doctor and the patient. If physician received information on the prescribing status of drugs, it would be expected to improve patient care. If a physician could view or read guidelines on the prescribing status of drugs, it would be expected to improve patient care.

In addition, patient education programs would be necessary to take into account the prescribing status of drugs. This information could be included in patient education programs to help improve patient care and to improve patient satisfaction.

The pharmacist or the pharmacist's representative is responsible for ensuring that the patient is provided with the appropriate information. This information should be provided in a clear and concise manner. It should be easy to understand and should be easily accessible. The pharmacist should also ensure that the patient is aware of the risks and benefits of the drug.

To improve patient care, it is necessary to provide the pharmacist with the appropriate information. This information should be provided in a clear and concise manner. It should be easy to understand and should be easily accessible. The pharmacist should also ensure that the patient is aware of the risks and benefits of the drug. This information should be provided in a clear and concise manner. It should be easy to understand and should be easily accessible. The pharmacist should also ensure that the patient is aware of the risks and benefits of the drug.
manufacturing labels for use of chemicals entering the plant so that workers cannot hear the identity of what they handle. Full disclosure of hazards will help individual workers to make more informed judgments about their jobs and their work practices and will undoubtedly increase labor union interest in occupational health.

Licensing of hazardous substances is not a realistic alternative to a ban for this reason. Management is not obligated to ensure that all substances stored are the least hazardous if it means the cost of getting more hazardous substitutes. The need to use the cost of labor is usually not an issue unless the plant can sequester a sizable portion of its work force in a separate area or has hazardous and other plants dangerous to labor.

Licensing of a substance limited to help when the experiments of consumer products that have been tested and are widely recognized as the least harmful. A wide variety of hazardous substances which are not under severe threat are listed in this report for which no exposure is expected. For example, the use of hazardous labels has been the performance of experiments that are necessary to prevent where an exposure is not made of the product substance. The use of labels has been thoroughly tested and proved safe for the public.

For a number of years the chemical and biological laboratories with their toxic and bioassays all groups of workers' health are not adequately described. This approach presents a real threat to the public. There is no reason to imagine that a licensing system will be effective in this regard. The development of the licensing system is the only way to ensure that the substance is not hazardous to the public. This has been done in the past.
Although up to 90 percent of human cancer, according to some scientists, is environmentally caused and controllable, Federal efforts to protect the public from cancer-causing chemicals have not been very effective.

Many chemicals cause cancer in animals, but Federal agencies have trouble determining which also pose a cancer threat for humans because:

- there are no generally accepted principles concerning environmental causes of cancer (see p. 17),
- there are no uniform minimum guidelines for testing (see p. 17),
- test data are not always complete or appropriate (see p. 19), and
- scientists cannot accurately predict human response to chemicals on the basis of animal test results (see p. 20).

The Director of the National Cancer Institute is responsible for directing Federal efforts and should, with the cooperation of other involved Federal agencies, develop a uniform Federal policy for identifying and regulating cancer-causing chemicals.

The policy should at least cover:

- the information needed to regulate cancer-causing chemicals,
- which chemicals should be tested in animals,
- how tests should be conducted,
- how results should be evaluated.
--how human risk can be assessed from animal studies, and
--what factors other than public health should agencies consider. (See p. 38.)

Although the Department of Health, Education, and Welfare agrees that a Federal policy is needed, it does not agree that a formal effort, headed by the Director of the Institute, is necessary. GAO believes a Federal policy can only be developed with the active support of every involved Federal agency, and the Institute Director, as head of the National Cancer Program, should coordinate these efforts. (See'p. 35.)

GAO is also recommending that the Food and Drug Administration have all approved and proposed food additives tested for their cancer-causing potential because it had not been requiring data from such tests when the additives were unintentionally added to the food in amounts less than 1 or 2 parts per million. The Department disagrees, saying the risk of cancer is remote and the costs for testing would be substantial. (See pp., 12 and 37.)

EXTEND FEDERAL AUTHORITY TO CIGARETTES

Tobacco and tobacco products are on the Institute's list of known human carcinogens; since 1964 the Surgeon General has reported to the Congress on the relationship between smoking and cancer.

For the past 2 years the Secretary of Health, Education, and Welfare has recommended that the Congress give the executive branch the authority to control hazardous ingredients--such as tar and nicotine--in cigarettes.

GAO is suggesting that the Congress

--request the Department to prepare a study showing the available options for regulating tobacco and tobacco products and the impact each option would have on the rising U.S. lung cancer rate and then
--consider giving the Department or some other appropriate agency the specific authority to regulate tobacco and tobacco products. (See p. 38.)

BURDEN OF PROOF

The Government can control cancer-causing chemicals, but an important factor in achieving public protection is whether action is taken before or after the chemical gets into commercial use and the environment.

The Government requires only the manufacturers of pesticides, drugs, and food and color additives to prove their products' safety before marketing them. The Government must prove the health hazards of other products, air and water pollutants, and occupational hazards before initiating action.

The proposed toxic substances legislation would make manufacturers prove a chemical's safety before it is marketed rather than having the Government prove that it poses a hazard after it is marketed. GAO believes this legislation would improve Federal efforts to protect the public from cancer-causing chemicals. (See p. 38.)
CHAPTER 1
INTRODUCTION

Cancer is the uncontrolled growth of cells. 1/ About 1,000 Americans die every day with the 100 or more diseases called cancer. Cancer causes over 16 percent of all U.S. deaths, making it the second largest killer (after cardiovascular diseases). Estimates of cancer's annual cost to the Nation run as high as $15 billion, of which some $3 to $5 billion represents direct care and treatment costs; the balance is loss of earning power and productivity.

Cancer mortality in the United States ranks somewhere in the middle of the worldwide range, but the rank of mortality from specific types of cancer varies markedly. Compared with other nations, the U.S. white population has the lowest mortality from stomach cancer and close to the highest from cancers of the colon and female breast. As shown in the table on page 3, the incidence rates of various cancers in the United States are expected to fluctuate between 1970 and 2000, including an 84-percent decrease in the incidence of stomach cancer and a 179-percent increase in lung cancer. The table also suggests some of the possible causes and means of preventing various cancers.

Available evidence suggests that environmental agents and social practices are largely responsible for variations in the occurrence of cancer in different populations. Although the extent to which man-made environmental chemicals are responsible for U.S. cancer rates is not precisely known, some scientists claim that external factors cause as much as 90 percent of all human cancer. National Cancer Institute (NCI) officials pointed out that this high estimate includes voluntary exposures to such carcinogens as cigarette smoke, which appears to be responsible for about 40 percent of all cancer in white males. NCI officials added that cancer attributable to occupational exposure and exposure to natural carcinogens is included in the 90-percent value.

NCI, 1 of the 11 National Institutes of Health, aims at reducing the occurrence of the major types of cancer in the United States to the level of the lowest ranking country for

1/More technically, cancer is a disease process characterized by the development of host-derived tissues which grow irreversibly in a manner uncoordinated with that of normal tissues and organs, which invade adjacent structures, which 

spread, and which persist after the stimuli are withdrawn.
that type. Such a reduction would cut U.S. deaths from cancer by one-third.

Seven Federal agencies have principal authority for identifying and/or regulating cancer-causing chemicals (/carcinogens/) or the products in which they appear.

---NCI.
---National Institute of Environmental Health Sciences (NIEHS).
---National Institute for Occupational Safety and Health (NIOSH).
---Food and Drug Administration (FDA).
---Environmental Protection Agency (EPA).
---Occupational Safety and Health Administration (OSHA).

Their roles and responsibilities are discussed in chapter 2. Despite this wide base, no single agency or official has assumed a leadership role, and as a result, many unresolved issues have hampered effective public protection from carcinogens. This report discusses the impact of several of those issues, including

---what chemicals are tested,
---how tests are designed,
---how results are communicated, and
---what agencies consider when deciding on regulatory action.

This report is concerned with Federal agencies' efforts to protect the public from carcinogens. Other GAO reports dealing with more general effects of chemicals and other environmental factors are listed in appendix IV.

1/Throughout this report, the term "chemicals" will be used to refer to individual chemicals, compounds, and mixtures, unless otherwise noted.
### Cancer Incidence, Expected Numbers, 1970-2000

<table>
<thead>
<tr>
<th>Site</th>
<th>New cases (incidence)</th>
<th>Deaths 1970</th>
<th>Deaths 1980</th>
<th>Percent change in rate</th>
<th>Major causation</th>
<th>Years of prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung</td>
<td>11,000</td>
<td>295,000</td>
<td>62,000</td>
<td>76</td>
<td>Tobacco smoke:</td>
<td>Stop smoking.</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Nitrogen.</td>
<td>Reduce pollution.</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Large and small bowel</td>
<td>92,000</td>
<td>134,000</td>
<td>44,000</td>
<td>11</td>
<td>Intestinal flora?</td>
<td>Identify susceptibles and eliminate exposure.</td>
</tr>
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<td></td>
</tr>
<tr>
<td>Pancreas</td>
<td>20,000</td>
<td>35,000</td>
<td>18,000</td>
<td>18</td>
<td>Diet? Virus? Other insults?</td>
<td>Identify etiology. Identify susceptibles. Identify etiology. Identify susceptibles.</td>
</tr>
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<tr>
<td>Prostate</td>
<td>51,000</td>
<td>18,000</td>
<td>17,000</td>
<td>11</td>
<td>Hormones? Diet?</td>
<td>Identify etiology. Identify susceptibles. Identify etiology. Identify susceptibles.</td>
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<tr>
<td>Stomach</td>
<td>21,000</td>
<td>4,500</td>
<td>15,000</td>
<td>86</td>
<td>Diet. Poor socioeconomic conditions.</td>
<td>Diet modifications. Social and economic modifications. Identify susceptibles. Identify etiology. Identify susceptibles.</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Non-melanotic skin</td>
<td>378,000</td>
<td>585,000</td>
<td>5,000</td>
<td>20</td>
<td>Actinic rays. Genetic.</td>
<td>Limit radiation exposure. Identify susceptibles. Identify susceptibles.</td>
</tr>
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<td></td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>242,000</td>
<td>408,000</td>
<td>75,000</td>
<td>30</td>
<td>Multiple.</td>
<td>Identify extrinsic and intrinsic factors and modify them.</td>
</tr>
</tbody>
</table>

*Based on data from Third National Cancer Survey, 1969-70. Cases in which the disease was confined to the site of origin without invading neighboring tissues (in situ) have been excluded.

*Projected change in age-adjusted incidence rates (year 1980 compared to 1970), assuming the trend in rates noted from 1947 to 1969 continues to the year 2000.

Source: National Cancer Institute, Division of Cancer Cause and Prevention, Annual Program Review Document for Fiscal Year 1974.
CHAPTER 2
FEDERAL RESPONSIBILITY

The Federal Government attempts to protect the public from carcinogens through research and regulation. NCI sponsors most of the Government's research on cancer cause and prevention; NIEHS, NIOSH, and some of the regulatory agencies also conduct or sponsor such research. EPA is responsible for clean air and water and safe pesticides; OSHA sets and enforces standards to protect workers from safety and health hazards, including hazardous chemicals, in workplaces; FDA is responsible for the safety of foods, food and color additives, drugs, medical devices, and cosmetics; and CPSC has jurisdiction over every consumer product not covered by any other agency except those specifically excluded by the Consumer Product Safety Act.

Several other Federal agencies help to protect the public from carcinogens. Their activities, however, are generally initiated as a result of some other action taken by one of the principal organizations. Appendix V contains more information on these agencies.

RESEARCH AND REGULATORY AGENCIES

NCI--The National Institutes of Health attempt to improve the health of all Americans by sponsoring biomedical research activities. NCI is the largest institute, with appropriations for fiscal year 1976 of about $743 million. The National Cancer Act of 1971 (42 U.S.C. 282) was passed to strengthen NCI, mainly through increased authority and funding authorizations, to more effectively combat cancer. Among other things, the act authorized NCI's director to plan and develop an expanded, intensified, and coordinated cancer research program, encompassing programs of NCI, related programs of other research institutes, and other Federal and non-Federal programs. The National Cancer Program's ultimate goal is to develop the means for eliminating human cancer.

NCI established a research program on the causes of cancer in 1961, although it had previously supported such research. A more formal program dealing with chemical carcinogens (as opposed to other possible causes of cancer, such as viruses) was begun in 1968, and today NCI sponsors research to find out what causes cancer; who is likely to get cancer; how to study the causes of cancer; why, how, and where cells become cancerous; and what we can do to prevent cancer. In fiscal year 1974, NCI reported that it spent about $100 million researching environmental causes of cancer, of which
$9.5 million was spent on animal testing of suspected chemicals. The latter amount dropped to about $9.3 million in fiscal year 1975.

NIH--NIH is also part of the National Institutes of Health. Its mission is to (1) identify the chemical, physical, and biological factors in the environment that can adversely affect people, (2) contribute to an understanding of the mechanisms and manifestations of human diseases produced by these agents, and (3) provide the scientific basis for developing control measures by other agencies. NIH is particularly concerned with the effects of low levels of chemicals over long periods of time.

NIH officials said they generally avoided cancer research because of NCI's established role. Although NIH does not routinely test chemicals to determine their cancer-causing ability, it funded over 40 studies during fiscal year 1974 that dealt in some way with the carcinogenic effects of certain chemicals. For example, one study involved the effect of various environmental chemicals on lung cancer in hamsters.

NIOSH--Under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651), NIOSH conducts and sponsors research and reviews literature to develop criteria for protecting workers from occupational safety and health hazards. A major NIOSH responsibility is to provide OSHA with proposals and supporting data (criteria documents) for new or improved occupational safety and health standards. In fiscal year 1974 NIOSH funded about 225 research projects (contracts, grants, and interagency agreements) at a cost of about $16.3 million; of these only 4 dealt specifically with occupational carcinogenesis. According to the Department of Health, Education, and Welfare (HEW), NIOSH has increased its efforts in occupational carcinogenesis research and in fiscal year 1976 will spend about $7 million.

FDA--The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) gives FDA authority to protect Americans from foods that are not pure, wholesome, and safe to eat; from drugs and therapeutic devices that are not safe and effective when used as intended; and from cosmetics that are not safe or made from appropriate ingredients.

The law is designed to protect consumers by requiring manufacturers to prove the safety of drugs, food additives, and color additives before they can be marketed. Food additives must be "generally recognized as safe" or manufacturers must scientifically prove their safety for their intended use.
to FDA's satisfaction before marketing them. FDA checks to see that residues of pesticide chemicals in foods do not exceed tolerance levels set by EPA.

Cancer is a specific health effect for FDA to consider when judging the safety of food or color additives. The Delaney Clause, a 1958 amendment to the Federal Food, Drug, and Cosmetic Act, requires FDA to ban the use of a food additive when:

"it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal."

A 1960 amendment applied the language of the Delaney Clause to color additives used in foods, drugs, or cosmetics. Further amendments in 1962 allow carcinogenic chemicals to be used in animal feeds but only if no residue of the chemical can be found by an approved method in food products taken from the animal and if the additive does not adversely affect the animal.

FDA and EPA jointly sponsor the National Center for Toxicological Research to study the biological effects of potentially toxic environmental chemicals. The Center's principal mission is to develop better methods to evaluate the degree of toxicity of chemicals.

EPA--EPA was established in 1970 to centralize Federal activities for, among other things, controlling pesticides, air and water pollution, and drinking water quality.

The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135) requires pesticide manufacturers to prove the safety of their products to EPA before selling them. If a pesticide remains in or on a food product, EPA has to set a tolerance for the pesticide. If the pesticide is a carcinogen, EPA must set a tolerance or exempt the pesticide from the tolerance requirement.

The Federal Water Pollution Control Act (33 U.S.C. 1251) requires EPA to publish a list of toxic water pollutants and set limits for their discharge into waterways. The act also requires EPA to publish water quality criteria which would

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1/Tolerance levels are the maximum levels of pesticides that may legally remain in food.
provide the basis for State water quality standards. The recently enacted Safe Drinking Water Act (Public Law 93-523) requires EPA to set drinking water standards to protect the public health and provide an aesthetic water supply. In setting the standards, EPA must consider recommendations from the National Academy of Sciences on the maximum level of contaminants that EPA should allow in drinking water.

The Clean Air Act (42 U.S.C. 1857) authorizes EPA to develop air pollutant standards in seven categories, including primary ambient air quality (to protect the public health), secondary ambient air quality (to protect the public welfare), and hazardous air pollutants (to prevent increased death or illness). EPA can require manufacturers of fuels or fuel additives to conduct tests to assess the chemical's carcinogenic potential.

EPA also has the authority to set standards for protecting the general environment from radioactive materials. The Nuclear Regulatory Commission and the Energy Research and Development Administration are primarily responsible for developing, implementing, and enforcing radiation standards for individual nuclear facilities.

EPA research is conducted through grants, contracts, and agreements with several sources as well as through its own laboratories. In fiscal year 1975 it spent $170 million for research and development of pollution processes, effects, and control technology. The research is not usually concerned specifically with carcinogenesis but with the whole range of possible adverse health effects from the environment.


In addition to the new responsibility under the 1972 act, CPSC assumed responsibility for several existing consumer protection statutes, including the Federal Hazardous Substances Act (15 U.S.C. 1261). Under its general authority, CPSC can perform research necessary to regulate carcinogens in consumer products. CPSC also has the authority to ban or regulate the marketing of consumer products which can cause personal injury or illness.

Specifically excluded from CPSC's authority under the Consumer Product Safety Act are (1) articles not normally considered consumer products, (2) tobacco and tobacco products, and (3) certain products, such as drugs, pesticides, and motor vehicles, regulated under other Federal laws.
In fiscal year 1975 CPSC awarded 104 contracts for about $6 million. An official of CPSC's Bureau of Biomedical Sciences said that five of the contracts, costing about $1.1 million, related in some way to carcinogens and consumer products. Although CPSC emphasizes hazards and injuries rather than illnesses, one of the agency's objectives is to develop methods for testing carcinogens in consumer products.

OSHA—OSHA sets and enforces occupational safety and health standards which pertain to a wide range of areas, such as farm vehicles and a chemical worker's exposure to a carcinogen. OSHA cannot ban production or use of hazardous chemicals. OSHA can protect a worker from exposure to them. The Secretary of Labor can, through order of the U.S. district courts, restrain employers from exposing employees to imminent dangers.

BURDEN OF PROOF

Several sources indicate that almost 2 million chemical compounds exist today and that about 250,000 new compounds are created annually. About 300 to 500 new compounds, some of which may be carcinogenic, get into the environment and into commercial use each year, and for most of them no Federal authority requires that they be proved safe before they are used.

Protecting the public from carcinogens depends greatly on (1) where the burden of proving safety rests and (2) whether the proof must be established before the public can be exposed. Before manufacturers can begin marketing drugs, pesticides, and food and color additives, they must prove such products are safe. The burden of proof remains with the manufacturers even after they receive initial Federal approval. For example, FDA needs only to gather information indicating an association between a marketed drug and an adverse reaction; the manufacturer retains the burden of proving the drug's safety in light of the new information.

In contrast, the burden of proving the health hazards of chemicals in other products rests with the Government. Because manufacturers can market these products without proving their safety, the public can be exposed to such chemicals before the Government can prove their harm. EPA must prove which chemicals already in the air and water are health hazards; FDA must prove that chemicals in cosmetics are injurious to health; OSHA must prove what levels of chemical exposure in workplaces threaten workers' health; and CPSC must prove the health hazard of chemicals used in consumer products.
An exception to the general burden of proof rule may be when an agency is petitioned to regulate carcinogenic chemicals, in which case the burden of proof rests with the petitioners. For example, in December 1975 CPSC was petitioned to regulate certain fluorocarbons in consumer products because of a potential increased risk of skin cancer. CPSC denied the petition because the petitioners had not proved the health hazard of the fluorocarbons.

As a result, the public may be exposed to certain chemicals for a long time before the government regulates them because of their carcinogenicity. For example, workers had been exposed to beta-naphthylamine for more than 50 years by February 1974, when OSHA regulated it because of its carcinogenicity.

Pending and Suggested Legislation

The proposed Toxic Substances Control Act (S. 3149), passed by the Senate on March 26, 1976, states that adequate data should be developed with respect to chemical substances and mixtures concerning their effect on human health and the environment and that such data development should be the responsibility of those who manufacture or process such substances. The Senate version would require manufacturers of new chemicals to notify EPA of the existing data concerning environmental or health effects of the new chemical at least 90 days before first manufacturing it. Additionally, if EPA determines that new or existing chemicals may present an unreasonable risk to health or the environment, or if EPA lacks sufficient data to judge their environmental or health effects, it may require the manufacturer to make safety tests. Such tests may be made to detect the chemical's cancer-causing potential, at EPA's discretion. The act would not apply to pesticides, drugs, or food and color additives which now receive premarket safety testing. As of May 27, 1976, the House Interstate and Foreign Commerce Committee had not passed this bill.

The Surgeon General's report on the health consequences of smoking identifies cigarette smoking as the major cause of lung cancer. About 72,000 people died of lung cancer in the United States in 1973. On June 27, 1974, the Secretary of HEW recommended that the Congress consider legislation to set maximum permissible levels for hazardous ingredients--such as tar and nicotine--in cigarettes. HEW officials told us, however, that as of April 1, 1976, HEW had not introduced such legislation but that two bills dealing with this subject had been introduced--S. 2248, which would require the Federal Trade Commission to establish acceptable levels of tar and

...
nicotine in cigarettes; and S. 2902, which would tax cigarettes based on their tar and nicotine content and use these tax revenues for increased support of biomedical research.

CONCLUSIONS

The Congress has given NCI, NIOSH, and NIEHS broad authority to conduct or sponsor research to identify carcinogens. NCI has done most of the research. The regulatory agencies do little research on their own to identify carcinogens, but manufacturers of drugs, pesticides, and food and color additives must do research to prove their products' safety before these products can be marketed.

For chemicals that reach the public through other products and through the environment, however, the Government must initiate a regulatory action to remove them from the market. Cancer-causing chemicals can be controlled—either by safety testing before the chemical is marketed or by Government testing and regulation after it is marketed.

The Congress is considering toxic substances legislation to require premarket safety testing of chemicals which may present an unreasonable risk to health or the environment. Enactment of the Toxic Substances Control Act could shift the burden of proving a new chemical's safety to the manufacturer by requiring such proof before the chemical could be marketed. Enactment, we believe, would improve public protection from carcinogens.

Because tobacco and tobacco smoke are known human carcinogens (see app. VI), the Congress should request H.E.W to prepare a study showing the available options to regulate tobacco and tobacco products and the impact each option would have on the rising U.S. lung cancer rate. The Congress should then consider, as the Surgeon General has recommended, giving H.E.W or some other appropriate agency the specific authority to regulate tobacco and tobacco products.
CHAPTER 3
NEED FOR A FEDERAL POLICY CONCERNING CARCINOGENS

Federal agencies have problems accepting and applying the results of animal tests to people because (1) NCI has only recently developed minimum testing guidelines for determining a chemical's carcinogenicity and other agencies have not officially adopted them as a basis for carcinogenicity testing and (2) there are no scientific principles to help Federal agencies apply animal test results to humans. As a result, some carcinogens are not regulated at all while others are regulated differently by the different regulatory agencies. All agencies responsible for protecting the public from carcinogens should, we believe, cooperate to develop a uniform policy for identifying and regulating carcinogenic chemicals and the products in which they appear. The policy should also deal with such issues as under what conditions regulatory agencies will allow public exposure to carcinogens.

EFFECTIVENESS OF PREMARKET AND POSTMARKET TESTING

Premarket testing

Although some legislation discussed in chapter 2 is intended to assure the safety of all pesticides, drugs, and food and color additives before they appear in commercial use, not all chemicals used in these products have received the kind of long-term tests that experts agree are needed to detect any cancer-causing potential.

Before requiring manufacturers to conduct long-term animal tests for drugs, FDA considers the type of exposure people will get (one-time dose or prolonged use) and the number of people expected to be exposed.

The Federal Fungicide, Insecticide, and Rodenticide Act requires manufacturers to test and prove to EPA that their pesticides are not harmful to human health. Since 1963, when the Department of Agriculture administered the act, manufacturers of pesticides which leave residues on foods have been required by the administering agency to conduct long-term tests to detect carcinogenic potential. In safety evaluations for 30 randomly selected pesticides with tolerances for residues on foods, we found that, of the 36 chemicals used in those pesticides, 7 did not receive
the appropriate long-term testing. 1/ EPA officials said required safety data may not be available because (1) the pesticide was approved before 1963, (2) later EPA reviews were inadequate, or (3) the data could have been submitted but later lost during moves or reorganization.

Unintentional food additives

As discussed on page 6, the Federal Food, Drug, and Cosmetic Act requires that manufacturers of food additives prove their products' safety to FDA and that FDA disapprove any food additive that, when properly tested, is shown to cause cancer in animals or humans. The act covers both intentional and unintentional food additives. According to the legislative history of the act, examples of these additives are "substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food."

In discussing the concept of safety in regulating food additives, a Senate report on 1958 amendments to the act (S. Rept. 2422, 85th Congress) stated:

"Since the scientific investigation and the other relevant data to be taken into consideration by the Secretary [of HEW] include information with respect to possible cancer causing characteristics of a proposed additive, the public will be protected from possible harm on this count."

Although FDA's Deputy Chief Counsel advised us that the Federal Food, Drug, and Cosmetic Act requires manufacturers of food additives to test for carcinogenicity, FDA's Associate Chief Counsel for Foods advised us that the act only requires that safety be assured before FDA approval.

According to officials in FDA's Division of Food and Color Additives, all intentional food additives must receive long-term tests to detect carcinogenicity before FDA will approve them. Intentional additives are to (1) improve nutritional value, (2) maintain freshness, (3) improve aesthetic appeal, or (4) aid in processing.

Unintentional additives are used mainly in packaging foods and, according to the FDA officials, receive long-term testing only when the consumer would be exposed to more than 1 or 2 parts per million of the additive in the food unless FDA had valid reasons to suspect that the additive might be carcinogenic. FDA officials explained that the long-term tests were very expensive, and because virtually none of the unintentional additives migrate from the packaging material to the food, the amount of the additive which may be ingested is virtually nil. FDA's principle in this regard is the higher the anticipated human exposure, the greater the amount of toxicological data required to assure human safety.

One official said that FDA had approved about 10,000 unintentional food additives, but he could not readily determine how many of the 10,000 had not received long-term testing. We noted that FDA has approved a few suspected carcinogens for adhesives that are used for packaging, transporting, and holding food.

In commenting on our report (see app. I), HEW stated that, although extending carcinogenicity testing to indirect food additives that have only remote possibilities of risk might be reassuring, it does not foresee any benefit to the public great enough to justify the substantial costs of such a policy.

We noted, however, that an April 1970 report to the Surgeon General by the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens recommended that:

- No level of exposure of a chemical carcinogen should be considered toxicologically insignificant for humans.

- No chemical substance should be assumed safe for human consumption without proper negative lifetime biological assays of adequate size.

Under this view, FDA would be unable to assure the safety of food additives that do not receive long-term testing.

Postmarketing testing

Scientists believe that most cancer is caused by chemicals already in the environment. As discussed on page 8, the Government must initiate regulatory action to control potentially carcinogenic chemicals that appear as air or water pollutants, as occupational health hazards, or in consumer products.
Although several Federal agencies conduct and sponsor some long-term chemical testing, except for NCI they do not routinely test large numbers of existing chemicals for carcinogenicity. NCI's tests take about 3 years from initial chemical selection to final reporting. NCI spends from $150,000 to $205,000 to test each chemical, and at its fiscal year 1975 funding level it can add about 50 to 60 chemicals to its testing program each year.

IDENTIFICATION OF CARCINOGENS

Many chemicals have been tested for their carcinogenicity in animals, but Federal agencies and non-Federal organizations have trouble identifying which chemicals cause cancer in humans.

NCI

NCI sponsors research to determine whether chemicals cause cancer. At January 1, 1975, NCI had 550 chemicals in its test program. NCI also reviews the scientific literature to identify carcinogens. It has compiled a list of 36 chemicals or chemical compounds (see app. VII) which definitely cause cancer in humans. NCI said that the scientific community generally accepted these chemicals as definitely being human carcinogens, yet the public can be exposed to at least 32 of the 36 substances. At our request, an NCI staff member classified the exposure hazard of the 36 substances into the following 6 categories. (See app. VII.)

- Controlled or restricted use; protection requires technical surveillance 15
- Voluntary; personal choice by the user 3
- Poorly controlled 14
- Prescribed by physician 1
- Used in laboratory only 2
- No longer produced in significant quantities 1

Total: 36

Although the NCI staff member stated that the use of 15 of the known human carcinogens is controlled or restricted by regulatory agencies, the public is not, we believe, adequately protected from some of these chemicals because Federal regulations neither ban their use nor cover all means of public exposure. Many cancer experts---including the 1970 ad hoc committee of the Surgeon General---agree that a safe level of a carcinogen cannot be established and that any exposure may cause cancer. Two human carcinogens which the NCI staff member classifies as being controlled or restricted---asbestos and benzidine---are discussed in more detail on pages 23 to 25.
The chief of NCI's carcinogen bioassay and program resources branch stated that, of all chemicals tested by NCI contractors between 1962 and 1973, 214 were carcinogenic in animals. The public is exposed to some of these chemicals.

An NCI official said that the traditional method of releasing test results is through publication in scientific journals and through symposia but that this method has worked poorly. NCI is initiating a technical reporting series that would contain certain information on each chemical's exposure, use, and production, as well as a detailed explanation of test procedures and results. Chapter 4 contains a detailed discussion of NCI's role in identifying carcinogens.

Public Health Service

The Public Health Service—a part of HEW which includes the National Institutes of Health, FDA, NIOSH, and several other operating agencies—publishes general information on any animal carcinogenicity experiments of which it is aware. An NCI official said that the publications contained 6,000 chemicals. Although the Public Health Service does not indicate whether a chemical is a carcinogen but merely recaps information provided in published studies, NCI officials advised us that about 1,000 of the 6,000 have been reported in the literature to cause cancer in animals; many of these reports, according to NCI, appear to be based on inadequate data.

NIOSH

NIOSH conducts and sponsors research and reviews existing research literature to develop criteria for OSHA standards. NIOSH has developed and published a list of all known toxic substances. In its 1975 edition, NIOSH reported that information was included on the carcinogenicity of 1,500 chemicals.

World Health Organization

The International Agency for Research on Cancer, a part of the World Health Organization, publishes monographs on its evaluation of the carcinogenic risk of chemicals but makes no recommendations for preventive measures.

In March 1975 the agency reported that, of 196 compounds evaluated, 151 (77 percent) were carcinogenic. Of the 151, 17 were associated with human cancer, 93 were definitely carcinogenic in animals, and 41 had a limited carcinogenic effect on animals.
The type of exposure to the 17 human carcinogens was occupational for 14, medicinal for 2, and dietary for 1. In addition, some of the 93 chemicals found to be definitely carcinogenic in animals are produced in very large quantities.

Regulatory agencies

At the time of our review, the regulatory agencies--FDA, EPA, OSHA, and CPSC--did not maintain lists of carcinogens but had from time to time regulated chemicals because of their carcinogenicity. For example, from 1950 to 1974 FDA banned 14 food and color additives because of a finding or suspicion of carcinogenicity. In 1973 EPA published a list of toxic water pollutants and included benzidine because it was a carcinogen. When EPA proposed drinking water guidelines in 1974, it listed toxic chemicals, including arsenic and chromium, which it acknowledged as suspected carcinogens. In 1974 OSHA regulated the use of 14 chemicals 1/ in the workplace and CPSC banned the use of vinyl chloride in self-pressurized containers because the chemicals were carcinogenic. The regulatory agencies have taken or proposed action on several other carcinogens as well.

By November 1975 OSHA had developed a priority list of 220 chemicals to be used in its standard development activities; of the 220, OSHA indicated that 50 were suspected carcinogens. An OSHA official stated that OSHA wanted NIOSH to use this list in developing criteria documents.

PROBLEMS IN IDENTIFYING HUMAN CARCINOGENS

As previously stated, NCI considers that at least 1,000 chemicals have been reported to cause cancer in animals. Federal agencies have trouble determining which chemicals also pose carcinogenic threats for people. Some of the problems are that:

--Federal agencies have not been able adopt a set of general principles concerning environmental carcinogenesis.

1/On December 17, 1974, the U.S Circuit Court of Appeals for the Third Circuit vacated the standards for 1 of the 14 chemicals (4, 4'-methylene bis(2-chloroaniline) because OSHA made a procedural error in formulating the standard. The court also vacated the standards of the other 13 chemicals as they applied to research laboratories.
NCI has only recently developed minimum testing guidelines which other agencies have not yet officially adopted as a basis for carcinogenicity testing. When experimental data are available, they may not be as complete or appropriate as the agencies would like. The limited state of the art does not allow scientists to accurately predict human response to chemicals on the basis of animal test results.

In addition, even though Federal agencies believe a chemical to be carcinogenic, legislation and court decisions may require them to consider factors other than public health when deciding whether and how to regulate carcinogenic chemicals.

Principles of carcinogenesis

The April 1970 report to the Surgeon General by the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens discussed the problems of environmental exposures to chemicals and the scientific criteria for evaluating carcinogenic hazards. The report, which is not HEW policy, deals with evaluating animal test results, problems in establishing a safe level of exposure, need for proper lifetime tests, and the principle of a zero tolerance for all exposures to chemical carcinogens. Several cancer experts restated some of these principles during administrative hearings on EPA's efforts to ban two carcinogenic pesticides--aldrin and dieldrin.

Representatives from six agencies met in August 1974 to discuss several areas concerning environmental carcinogenesis. According to the EPA representative, Federal agencies had a growing need to agree on a national policy, particularly in terms of risk-benefit considerations. As of April 1, 1976, however, no such policy had been developed. (See p. 32.)

Most recently, a subcommittee of the National Cancer Advisory Board is considering the general criteria for assessing the evidence for carcinogenicity of chemical substances, and NCI has chartered a new committee to review, evaluate, and interpret carcinogenicity data generated by the NCI testing program.

Minimum test guidelines

Because testing suspected carcinogenic chemicals on humans is neither ethical nor practical, scientists use animals. Experience with laboratory animals has shown that nearly all
557

chemicals that are carcinogenic in people are also carcinogenic in animals. The way a test is designed—the number of animals and dose levels used, the length of the test, and other laboratory conditions—can directly affect the validity of the results and their value to regulatory agencies.

The more animals tested, the more statistically sensitive are the results. Similarly, the more species used, the greater is the assurance that the chemical, and not some other factor, caused the cancer. Also, the more test dose levels administered, the better a scientist can estimate the relationship between the dose and the animal response. Finally, the tests should be conducted over the animal's lifetime to better approximate human exposure.

NCI has developed standard testing guidelines to be used by commercial labs under NCI contracts to test environmental chemicals. NCI officials hope that these guidelines, issued in January 1975, will (1) make research results more comparable and more applicable to humans, (2) increase the tests' sensitivity, and (3) provide better data on which regulatory agencies can act. In addition to prescribing animal care standards, the guidelines call for at least 2 doses to be given to 50 animals of each sex and each of 2 species.

NCI has shared these guidelines with other Federal agencies and at least two of them—EPA and NIOSH—have provided for consideration of these guidelines in some of their test procedures. None of the agencies, however, has officially adopted the guidelines as a basis for carcinogenicity testing. Some agency officials even question the need for such guidelines, stating that each test should be designed individually. NCI believes that the guidelines describe many features which are common to all well-designed and properly conducted long-term animal studies and which need to be considered whenever a carcinogen test is planned or undertaken. Chapter 4 discusses some of NCI's problems in designing tests for use by regulatory agencies.

Before the NCI guidelines were developed, Federal agencies had no common guidelines for testing chemicals for their carcinogenicity. EPA had proposed guidelines for testing pesticides which called for 2 species, 3 dose levels, and between 25 to 50 animals of each sex and species per dose level. The National Academy of Sciences, under contract to EPA, recommended 2 rodent species, tested at several dose levels, with 40 to 50 animals of each sex surviving the highest dose. An international cancer group recommended at least two species (one of which should be a nonrodent mammal), one
dose level 1/ (the highest dose tolerated by the animals), and enough animals to yield reasonably significant results. An EPA advisory committee suggested two rodent species tested at several dose levels, including one which would yield the most tumors, but did not say how many animals should be used.

Past regulatory actions have been based on results of research conducted under a wide variety of protocols. For example, the animal studies which conclusively linked vinyl chloride to a rare form of liver cancer included three species and seven dose levels. EPA on the other hand, proposing to limit the amount of benzidine in water, cited several studies to establish the carcinogenicity in animals and humans, but relied on an animal study which included only one species and one dose level through a route of administration (injection) not normally experienced by the public. 2/

Incomplete and inappropriate data

In some cases, the experimental data available to the regulatory agency is not as complete or appropriate as necessary. For example, the first link between vinyl chloride and cancer came in 1970 when a scientist reported tumors in rats exposed to extremely high doses of the chemical. Although these results were statistically valid, they were not viewed with alarm because the concentration of vinyl chloride was near the explosive limit and was not likely to be found in industrial situations. Similarly, a U.S. court of appeals denied EPA's proposed ban on dumping asbestos into the drinking water of Lake Superior because EPA could not prove that asbestos causes cancer when ingested. The carcinogenicity of inhaled asbestos has been documented for about 40 years.

Many chemicals have been reported to cause tumors in test animals, but regulatory agencies are hesitant to base any action on a single test. The 1970 report to the Surgeon General recommended that the test designs provide for reproducibility of results.

1/The international group considered it advisable to test more than one dose level.

2/As of May 27, 1976, this proposal was still pending. See page 24 for more information on EPA's proposed benzidine standard.
A critical problem in regulating carcinogens is trying to predict the human risk of exposure to small levels of chemicals solely on the basis of results of animal tests. The limited state of the art restricts scientifically sound regulation.

Conventionally, toxicologists have applied "safety factors" to animal test results and have assumed that an animal's reaction would not differ from a person's reaction by more than that factor. NCI's associate director for carcinogenesis has questioned whether this safety procedure can be applied to cancer risks because of the differences between cancer and other diseases.

The validity of tests on laboratory animals is most easily accepted when people are exposed to the chemical in the same way the test animals were. However, people are exposed to practically all chemicals at such low levels and for such long periods that an impractically large number of animals is needed to produce statistically valid results under those conditions. To further complicate the matter, a person's reaction to a chemical may be different than an animal's in terms of absorption, distribution, and storage, metabolism, excretion, and reabsorption, arrival at the site of action, and reaction with the biological receptor. One analysis of the state of the art for extrapolating results of animal tests to people concludes that there is a basis for comparing the median mouse to the median rat to the median dog to the median person. But the report warns of the greater difficulties in comparing the median animal to the not-so-average person.

At congressional hearings held in 1971 on "Chemicals and the Future of Man," concern was expressed about unduly frightening the public about adverse health effects from chemicals which had been commonplace. A House Appropriations Committee report gave some examples of how much of a banned substance a human would have to consume to receive amounts comparable to those given to experimental animals. The purpose of the examples, all of which dealt with carcinogenic food additives banned by FDA, was to translate abstract scientific studies into their real-life equivalents. According to the Committee's report:

--An adult would have to drink from 38 to 552 bottles of soft drink each day to get a comparable amount of cyclamate that caused cancer in mice and rats.
A person would have to drink 250 quarts of vermouth each day to get a comparable amount of oil of calamin that caused cancer in rats.

A person would have to drink 613 bottles of root-beer-flavored soda or eat 220 pounds of hard candy each day to get an amount of aflatoxin comparable to that which caused cancer in rats.

Factors other than public health

The 1970 report to the Surgeon General stated:

"Any substance which is shown conclusively to cause tumors in animals should be considered carcinogenic and therefore a potential cancer hazard for man. * * * [and] no level of exposure to a chemical carcinogen should be considered toxicologically insignificant for man. For carcinogenic agents 'a safe level for man' cannot be established by application of our present knowledge."

Strictly applying this criteria, any chemical that causes cancer in animals would be presumed to cause cancer in people, regardless of level of exposure. But in some cases, laws require regulatory agencies to consider more than the carcinogenic risks of a chemical. When considering whether to approve a drug for marketing, FDA weighs its benefits against any safety risks. For example, some drugs used to treat cancer have also been shown experimentally to cause cancer. Certain drugs used to treat severe heart conditions are also carcinogenic. But FDA has determined that the immediate benefits from those drugs outweigh the potential risks.

Likewise, EPA considers the benefits and dangers to the public health and welfare from the use of pesticides. The Federal Environmental Pesticide Control Act of 1972 (7 U.S.C. 136) defines the "unreasonable adverse effects on the environment" of a pesticide as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."

Since January 28, 1975, the Office of Management and Budget has required that agencies of the executive branch consider the inflationary impact of major legislative and regulatory proposals.

In revising its permanent standard for vinyl chloride, OSHA decided that no detectable level should be allowed in the workplace. After receiving industry views on the costs of compliance and a consultant's report of the economic
impact of the proposed standard, OSHA raised the permissible level to 1 part per million. OSHA did not claim, however, that 1 part per million was a safe level of exposure to vinyl chloride.

Regulatory agencies also consider the practicality of their proposed actions, including the state of the art of analytical and detection equipment. When EPA developed a standard for asbestos in the air, an important consideration was the lack of satisfactory methods of measuring asbestos emissions. As a result, the asbestos standard was not written in terms of numerical values; instead, it limited visible emissions and required certain manufacturing techniques to reduce those emissions.

Federal agencies should consider these factors, when properly authorized and documented, in deciding on regulatory action against carcinogens. It is important for the public record that the documentation show the impact of the regulation on the public health, as well as on the other factors considered.

DIFFERENCES IN PUBLIC EXPOSURE TO CARCINOGENS

If a carcinogenic chemical is not banned, people may be exposed to it. Despite differences in the degree of such exposure, scientists have not proved that any exposure is harmless. Therefore, the public faces some risk of getting cancer when carcinogenic chemicals are not banned.

In its comments on this report (see app. I), HEW stated that, although it may be true that any exposure to a chemical carcinogen will cause cancer within the exposed population, the risk or probability that cancer will occur may very well be related to exposure levels. HEW said that, when exposure cannot be completely eliminated or the benefit is deemed to outweigh the risk from exposure, efforts must be made to estimate the upper limits of risk from specific levels of exposure using the best evidence obtainable by applying current research tools. HEW also recognized that current animal test procedures do not provide a quantitative assessment of the hazard to exposed human populations which would be required to resolve certain regulatory needs and questions.

We selected two chemicals that NCI has concluded to be known human carcinogens--asbestos and benzidine--to determine how the public is being protected from them. We found varying degrees of regulation over the two chemicals for various reasons.
Asbestos

Asbestos refers to a family of hydrated silicates that, when crushed or processed, separate into flexible fibers. Only six of the many asbestos minerals are of commercial importance.

Asbestos is used in over 3,000 products, and in 1972 over 800,000 tons were used in the United States. The regulatory agencies reviewed all consider asbestos to be carcinogenic, but they regulate it differently.

On June 7, 1972, OSHA specified a numerical standard allowing some asbestos in the workplace. When NIOSH recommended the standard to OSHA, it conceded that the standard was based on the health hazards of asbestosis—a type of lung impairment—and not cancer, because there was insufficient information to set a standard to prevent lung cancer unless the standard was zero. This is consistent with NCI's belief that no level of exposure to a carcinogen should be considered safe for humans. However, on January 29, 1974, OSHA required that workers' exposure to 14 other chemicals it considered to be carcinogens be reduced to the maximum extent practical.

In October 1975 OSHA proposed lowering the permissible level of asbestos in most workplaces by 90 percent, recognizing the cancer risk of asbestos in the workplace and the technological and economic factors which, OSHA reasoned, had prevented such a regulation. If enacted, the new regulation would allow up to 0.5 fibers of asbestos per cubic centimeter of air in the workplace, averaged over an 8-hour work period.

On April 6, 1973, EPA developed a standard for asbestos in the air. The asbestos standard was not written in terms of numerical values, as is the OSHA standard for asbestos, but instead it limited visible emissions and required certain manufacturing techniques to reduce those emissions. An important consideration in the EPA standard was the lack of satisfactory methods of measuring asbestos emissions. Therefore, the standard was not based on a "safe" level of emission.

In January 1972 EPA tried to ban the dumping of asbestos into the drinking water of Lake Superior because asbestos was a carcinogen. A U.S. court of appeals denied this ban, however, because EPA could not prove asbestos causes cancer when ingested, although the carcinogenicity of inhaled asbestos has been documented for 40 years.

On September 28, 1973, FDA proposed several regulations to restrict the use of asbestos filters for drug manufacturing and to prohibit the use of asbestos in the manufacture of medical devices.
Asbestos is a mineral that is known for its heat resistance and insulation properties. It was widely used in various industries due to its durability and cost-effectiveness. However, the health risks associated with asbestos exposure became evident, particularly in the context of building materials, where it was used in the form of asbestos-cement pipes, roof shingles, and insulation. The use of asbestos in consumer products was also a concern, especially concerning the potential for inhalation or ingestion of asbestos fibers.

In March 1975, the FDA decided to delay any final regulations because it could not prove that asbestos was present in these substances or that ingested asbestos caused cancer. The FDA did, however, regulate the use of asbestos filters for manufacturing drugs used for injection in humans. CPSIC also noted that asbestos is in a number of consumer products, but it has not identified specific products. CPSIC does not plan to regulate the use of asbestos in consumer products until considerable research is completed in the area.

The Government is studying whether ingested asbestos can cause cancer. Representatives from several federal agencies developed a test protocol, and on June 10, 1975, NIEHS awarded two contracts for lifetime ingestion studies in rats and hamsters. The studies are to run for 4 years at an estimated total cost of about $2.9 million.

Benzenidne

Benzenidne occurs as white or slightly reddish crystals or leaflets or as a crystalline powder. Its domestic marketable production in 1972 was 1.5 million pounds. One source lists 361 dyes derived from benzenidne and its salts. In addition, it appeared as a contaminant in workplaces before 1974 and as a water pollutant. The suspicion that benzenidne-induced bladder cancer in workers was reported before 1940.

OSHA recognized both the animal and human carcinogenicity of benzenidne and included it as 1 of the 14 chemicals it regulated in January 1974. Under these regulations, workers can only handle benzenidne in a closed system—where benzenidne is not released into the work environment.

EPA recognized the potential for increased water pollution from benzenidne and listed it as a toxic water pollutant in July 1973. In December of that year, it proposed an effluent standard to limit the discharge of benzenidne into navigable waters.

EPA's proposed standard would have allowed each user of benzenidne to dump up to 1 pound a day into the water. The amount each user could dump would depend on the characteristics of the waterway but not on the number of users dumping into that waterway. The method used to derive that standard was designed to determine a level of discharge which
would result in an "acceptable level of risk" to people. The actual standard was derived by extrapolating animal test data using what EPA called conservative statistical methods. The method defined "acceptable level of risk" as less than one case of tumor induction per million people exposed over an entire generation to drinking water from supplies derived from waters contaminated with the maximum permitted concentration of benzidine. NCI's associate director for carcinogenesis commented on the specifics of EPA's supporting arguments for the standard, concluding that:

"... an extremely inadequate, poorly documented experiment (carried out a quarter of a century ago) was used, without any attempt to further investigate its meaning, as a basis for the estimate of exposures to a large human population to one of the most effective presently known human carcinogens."

The NCI official referred to more recent NCI-supported studies, cited but not used by EPA to develop the proposed standard, which would have resulted in a lower standard for benzidine discharge.

Although EPA had not issued final regulations for benzidine as of May 27, 1976, it has been considering changing the proposed acceptable limit. Nevertheless, EPA maintains that:

"... extrapolation methods should provide reasonable assurance that the true carcinogenic risk at the level identified in the standard will not be greater than the risk calculated at that level."

CONCLUSIONS

The public is being exposed to carcinogenic chemicals. In addition, new chemicals which may be carcinogenic are entering the environment because in some cases there is no premarket testing and in other cases the premarket testing that is done is insufficient. For example, not all premarket testing of food additives has included appropriate long-term tests that cancer experts agree are necessary to determine a chemical's carcinogenicity.

Even if all chemicals receive long-term tests, agencies may have problems accepting and applying the results of those tests to people because (1) NCI has only recently developed tissue test guidelines for determining a chemical's carcinogenicity, and most agencies have not officially adopted them as a basis for declaring a chemical's carcinogenicity and (2) there are no
scientific principles to help Federal agencies apply animal test results to humans. The appropriate Federal agencies should cooperate to resolve these issues in a manner consistent with the best available scientific knowledge.

As a result of the problems agencies face in identifying carcinogenic chemicals, some are not regulated at all while others receive inconsistent regulation. A uniform Federal policy on how to identify and regulate carcinogens is needed. Some of the issues which we believe should be included in such a policy are the

-- information needed to protect the public,
-- chemicals that should be tested,
-- test guidelines that should be followed,
-- way test results should be evaluated,
-- feasibility of allowing exposure to carcinogens which would result in "acceptable levels of risk" for the public, and
-- factors other than public health that should be considered.
CHAPTER 4
NCI'S PROGRAM FOR TESTING CHEMICALS

NCI is the only Federal agency that routinely tests large numbers of chemicals for carcinogenicity. Until recently, NCI's efforts had not given regulatory agencies much of the scientific data necessary to control or eliminate chemical carcinogens because (1) chemicals NCI tested were not always of the highest priority, (2) regulatory agencies did not agree on what type of data they needed to make decisions, and (3) NCI only recently developed a formal system to advise regulatory agencies on the carcinogenicity of chemicals tested.

The Congress, through the National Cancer Act of 1971, intended that the Director of NCI assume a leadership role in the Federal Government's efforts against cancer and coordinate other Federal and non-Federal programs. Recently, the NCI Director has been trying to involve the major Federal agencies in a coordinated program for identifying and regulating carcinogens.

THE CARCINOGENESIS PROGRAM

At the request of the National Advisory Cancer Council, NCI's principal advisory group, NCI developed a formal carcinogenesis program in 1968. This program evolved from other NCI activities that had been operating since 1961. The program is now composed of five coordinated approaches:

-- Identifying and characterizing population groups at risk for different cancers.
-- Identifying carcinogenic activity of selected chemicals by animal testing.
-- Developing and selecting biological models for animal testing, for the characterization of carcinogenic processes, and for correlation with people.
-- Identifying processes required for carcinogenic action of selected chemicals at target points for corrective measures in people.
-- Developing, applying, and evaluating corrective measures for people and the environment.

NCI stated that in fiscal year 1974 it spent about $100 million on environmental carcinogenesis; of that about $16 million was for the carcinogenesis program, including
$9.5 million for animal testing contracts. In fiscal year 1975, NCI spent about $44.5 million for the carcinogenesis program, including about $9.3 million for animal testing contracts. Animal testing takes about 3 to 4 years from start to finish and costs from $150,000 to $205,000 for each chemical. On the basis of fiscal year 1975 funding, NCI can only add about 50 to 60 chemicals to the program each year.

CHEMICAL SELECTION

In view of NCI's fiscal constraints and the universe of untested chemicals, some of the chemicals being tested for carcinogenicity are of questionable priority because their production or use is limited or the public exposure is minimal. For example, in October 1971 an NCI contractor began testing Dulcin under a project designed to test chemicals commonly used in commerce and industry for their carcinogenicity. According to the contract, NCI hoped that the regulatory agencies would use the data to eventually eliminate those chemicals found to be carcinogenic. Dulcin is a non-nutritive artificial sweetener which FDA banned in 1950 because it caused liver tumors in rats. An NCI official explained that it is being tested to see if its carcinogenic effect can be inhibited by another chemical, arginine glutamate.

Another NCI contractor began to test Amiben, an herbicide, in December 1971. The contractor stated that the test required more of the chemical than the manufacturer normally produced in a year. NCI officials said that Amiben is a possible future replacement for existing herbicides.

Another NCI contractor is testing plant extracts and fractions, which are used as herbal folk remedies by geographically and culturally restricted societies, such as those found in South Africa, the island of Curacao, and some areas of South Carolina.

According to NCI officials, the carcinogenesis program as a whole has many needs for bioassay which may result in materials with limited human exposure being animal tested. As an example, they cited studies to establish how a chemical reacts in humans which frequently require testing substances which do not exist as such in the environment.

Selecting chemicals to test now involves a formalized system with input from several sources, including NCI, other Federal agencies, contractors, and other interested non-Federal groups. A committee reviews all the relevant data about a suggested chemical before deciding whether it should be tested. It does not, however, rank chemicals according to any priority. Because of the newness of the system, we did not evaluate its effectiveness.
NCI TEST DESIGNS

NCI should conduct its animal tests so that the appropriate regulatory agency can use the results to protect the public from carcinogens. As discussed in chapter 3, the regulatory agencies have not agreed on a set of standards, or minimum guidelines, for testing suspected carcinogenic chemicals. NCI officials believe that their animal testing guidelines, also discussed in chapter 3, will provide a scientific base for regulatory action on suspected carcinogens.

Other NCI officials stated that regulatory agencies might need more indepth and extensive studies to support regulatory action. One NCI official explained that the NCI testing program is merely a screening process to identify suspected carcinogens. He explained that NCI would have to spend twice as much time and money to make the types of animal tests that the regulatory agencies indicated would be needed. For example, NCI would have to test more dose levels to identify (1) any dose-response relationships and (2) what happens to the chemical in the body in terms of absorption, excretion, and metabolism.

Short-term testing

Proper animal testing of suspected carcinogens requires considerably more resources than NCI has made available. Therefore, researchers have become interested in using tissue culture to develop in vitro models to screen selected chemicals. According to NCI officials, such procedures, compared to current animal testing, should require less time and money; require only small samples of test chemicals; and be as reliable, sensitive, and practical.

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1/Literally, "within a glass," in this context referring to tests in which animal or human serum is extracted and grown in tissue culture, where it is exposed to test substances (viruses, chemicals). If carcinogenic, the substance will kill the cells or cause them to grow abnormally.
Other types of short-term tests are being considered to aid in identifying carcinogens. FDA uses in vitro testing to determine potential adverse effects of vaccines. FDA stated that it has found good correlation between in vitro and animal tests when using viruses but not chemicals. NCI has assigned high priority to studying these short-term test systems. It hopes that a battery of tests can be developed and validated by 1980.

In addition to supplementing the animal tests, NCI hopes the short-term tests can soon be used as "prescreens" to help select chemicals for the animal tests.

**DISSEMINATION OF INFORMATION**

When the animal tests are completed, NCI does not evaluate the human cancer risk of the chemicals tested. Rather, NCI scientists usually view their role as that of providing hard data from the experiments and letting others draw their own conclusions.

As a result of our discussions with NCI officials in July 1974 concerning dissemination of research results to regulatory agencies, NCI developed a "memorandum of alert" to notify the agencies of positive carcinogenic findings before the conclusive test results are available. In March 1975 this was used to notify EPA, FDA, and NIOSH of the carcinogenic hazards of trichloroethylene, a chemical used mainly as a degreasing agent in the metal industry and as a solvent and dry cleaning agent in the clothing industry. It is also used to extract certain substances from foods; for example, to remove caffeine to produce decaffeinated coffee. More than 600 million pounds of the chemical are produced in the United States each year; as of June 1, 1975, none of the involved regulatory agencies had acted on the "memorandum of alert" to further regulate the chemical because they did not have conclusive results.

1/These include an in vivo-in vitro test in which pregnant animals are injected with test chemicals, the embryo is removed, and the embryo cells are grown in culture. If the cells become malignant, they are reimplanted in another animal to develop into tumors. Another short-term test being considered is a mutagenicity screen, by which a chemical's ability to induce genetic change can be easily determined. Because mutagenicity and carcinogenicity may be closely related, researchers hope this screen will detect carcinogens as easily as mutagens.
According to an NCI official, the normal method of releasing test results in journals or at symposia had created problems. NCI has therefore proposed a technical reporting series to contain comprehensive information on each chemical's exposure, use, and production, as well as a detailed explanation of test procedures and results. NCI issued such a report on trichloroethylene in February 1976.

**NCI Coordination Efforts**

Section 407 of the National Cancer Act of 1971 requires the NCI director to develop a cancer research program that would be coordinated with related programs of the other research institutes and other Federal and non-Federal programs. With regard to cancer-causing chemicals, NCI has (1) sponsored the Interagency Collaborative Group on Environmental Carcinogenesis, an informal group of middle-management officials of several federal agencies, (2) participated in HEW's Committee to Coordinate Toxicology and Related Programs, (3) met with the heads of five other agencies concerned with environmental and chemical carcinogenesis, and (4) organized a formal Interagency Coordinating Committee for the National Cancer Program. NCI has also provided general advice to the Congress; other Federal agencies; and representatives of industry, consumer groups, the news media, and the public on cancer-causing substances.

These efforts have been useful but have failed to bring about a uniform Federal policy on chemical carcinogens or achieve the degree of consistency that would give all segments of the public the same protection from carcinogens. As shown in chapter 3, workers' exposure to asbestos and benzidine is controlled, but the public may be exposed to the chemicals in consumer products, the air, or the water.

**Interagency Collaborative Group on Environmental Carcinogenesis**

This group was set up in January 1973 to serve as a technical discussion group of operating-level agency officials. An NCI official serves as chairman. The group represents 18 agencies but is not chartered, has no authority, and does not make recommendations to the agencies.

**HEW Committee to Coordinate Toxicology and Related Programs**

HEW's Assistant Secretary for Health set up this group in July 1971 to provide for information exchange, coordination, resource-sharing, and advice-giving by HEW agencies conducting toxicological research. The Committee, which
has nine member agencies, is headed by the NIEHS Director and has addressed a variety of issues, some relating to carcinogenicity.

Group of six agency heads

NCI convened this group in August 1974 to discuss problem areas of environmental and chemical carcinogenesis. The following agencies were represented: NCI, NIOSH, FDA, EPA, the National Center for Toxicological Research, and the Center for Disease Control (an HEW agency responsible for providing leadership and direction in the prevention and control of diseases). At that meeting, the agency heads decided to let EPA develop a national policy statement on environmental carcinogens. As of April 1, 1976, a policy statement had not been developed (although one had been drafted), and the group had not met again.

Interagency Coordinating Committee for the National Cancer Program

This group was chartered in December 1974 to assist the NCI Director in coordinating Federal cancer research programs by (1) providing for information exchange, (2) reviewing information systems, (3) preventing unnecessary duplication of effort, and (4) promoting joint-funded projects. It consists of 18 members—9 from within HEW and 9 from other Federal agencies, including FDA, the National Center for Toxicological Research, NIOSH, and EPA. As of April 1, 1976, its only meeting, held on November 10, 1975, had been a briefing by NCI personnel on all NCI activities.

Conclusions

Because NCI is the only Federal agency that routinely tests large numbers of chemicals for their carcinogenic potential and because of its large commitment of time and money to each chemical being tested, it should be certain that the most important chemicals in terms of use, production, and exposure are tested first. NCI has recognized this problem and established a new chemical selection process which became operational during our review.

We recognize the other aspects of NCI's carcinogenesis program and the need to answer basic questions on cancer causation, but the routine testing of suspected chemicals to determine their carcinogenicity is a distinct and necessary NCI function.

1/EPA was represented by two senior science advisors.
The key to the set of guidelines a lab will follow when testing for a chemical's carcinogenicity should be the minimum requirements of the agency responsible for regulating that chemical. But because the regulatory agencies have not agreed on a set of standards or minimum testing guidelines, research agencies cannot be sure that the regulatory agencies will act on their results.

NCI should conform its testing guidelines, to the extent possible, to the needs of the regulatory agencies.
CHAPTER 5
CONCLUSIONS, AGENCY COMMENTS AND OUR EVALUATION,
RECOMMENDATIONS, AND MATTERS FOR CONSIDERATION
BY THE CONGRESS

The Congress has given the Federal regulatory system
the authority to protect the public from any proven carcino-
gen. In some cases, such as those involving pesticides,
that authority is exercised before the carcinogens can be
marketed; in other cases, such as those involving air or
water pollutants, the Government acts after the carcinogen
is in the environment.

Unfortunately, the Federal regulatory system has only
achieved partial success because (1) Federal agencies have
not developed a uniform policy on how to identify carcino-
gens, (2) most regulatory actions can be taken only after
the carcinogens are in the environment or commercial use,
and (3) Federal interagency coordination has not achieved
agreement among the agencies charged with the identifica-
tion and control of public exposure to carcinogens.

The regulatory agencies which approve chemicals as
safe on the basis of manufacturers' tests do not require
that all chemicals be tested for carcinogenicity. There-
fine, some commonly used food and color additives, drugs,
and pesticides may be carcinogens.

Although many chemicals are considered as potential
human carcinogens because of their effects on animals,
regulatory agencies are usually hesitant to remove them
from the environment or even to limit their use. Much of
this caution results from the lack of agreement among Fed-
eral agencies as to what findings should be considered valid
indicators of human carcinogenicity. Federal agencies also
have to be aware of economic, social, and other effects of
their regulatory actions against chemical carcinogens.

Responsibility for identifying carcinogens and provid-
ing the scientific basis for their regulation rests mainly
with NCI, although NIEHS, FDA, NIOSH, and EPA sponsor some
animal testing. NCI's activities have been not only to
identify carcinogens but also to answer many basic questions
about how and why chemicals cause cancer. NCI's carcino-
genesis program has selected some chemicals of questionable
priority for testing.
The regulatory agencies themselves are not certain of the types of animal tests or general carcinogenesis principles they will accept. Because so many Federal agencies are involved in carcinogenesis research and regulation and because no overall Federal policy on these matters exists, Federal agencies have not consistently regulated known or suspected carcinogens or adequately acted on all means of public exposure to known carcinogens.

Public exposure to cancer-causing chemicals can be controlled--either by safety testing before the chemical is marketed or by Government testing and regulation after it is marketed. The problem has been to develop a system to select chemicals, properly test them in animals, evaluate the results in terms of people, and finally develop and implement regulations to protect the public.

If a carcinogenic chemical is not banned, people may be exposed to it. The exposure may be limited, but scientists have not proved that any exposure is harmless. Therefore, the public faces some risk of getting cancer when carcinogenic chemicals are not banned.

AGENCY COMMENTS AND OUR EVALUATION

In notifying HEW of our findings and conclusions, we proposed that the NCI Director, as head of the National Cancer Program:

---Provide leadership and coordination with other involved Federal agencies to establish a policy regarding the identification and regulation of carcinogens.

---Resolve the current issues, including (1) the information needed to protect the public from carcinogens, (2) the chemicals that should be tested, (3) the test guidelines that should be followed, and (4) the way results should be evaluated and used.

---Periodically reevaluate the policy, considering advances in technology, changes in legislation, changes in social and economic climates, judicial rulings, and other relevant matters.

We also proposed that FDA have all approved and proposed food additives tested for carcinogenicity.

HEW generally disagreed with these proposals, stating that its Public Health Service has made important progress toward protecting the public from carcinogens since our review.
Set Federal policy

Although HEW agreed that a Federal policy on carcinogenesis is greatly needed, it disagreed that the NCI Director should set policy for regulatory agencies. HEW stated that NCI's major future challenge will be developing a procedural framework which meets the needs of the national program involving identification, risk evaluation, and prevention strategies for chemical carcinogens. HEW cited several interagency activities involving NCI staff that it believes promote better understanding of interagency concerns, which it hopes will lead to a more uniform Federal policy on regulating chemical carcinogens.

Although we did not intend that NCI unilaterally set regulatory policies or policies for other research agencies, we did intend that it be the focal point for seeing that a policy is established and that it more actively coordinate all Federal policies dealing with carcinogens so that these policies reflect the latest scientific advancements and afford maximum protection to the public. We believe that this role is in line with the NCI Director's responsibilities legislated by the National Cancer Act of 1971.

HEW stated that interagency activity will lead to a more uniform Federal policy on carcinogens but, as discussed on pages 31 and 32, past NCI coordination efforts have failed to bring about a uniform Federal policy. We believe that the Director of NCI should be made specifically responsible for developing a policy and that every agency with a role in protecting the public from carcinogens should be involved in developing that policy. Without an overall policy, there is no assurance that carcinogens will be consistently regulated by all agencies.

Resolve current issues

HEW stated that NCI is working to resolve the above-mentioned issues by establishing a committee to evaluate data from its testing program, continually reviewing its procedures for selecting chemicals for testing, and developing minimum test guidelines for NCI and regulatory agencies. HEW stated that NCI will not and should not tell regulatory agencies how to use the test results.

According to its charter, NCI's data evaluation committee will be limited to reviewing for NCI's Director data from NCI's carcinogenesis program. The National Cancer Advisory Board subcommittee discussed on page 17 is developing general criteria for NCI's use in evaluating a chemical's carcinogenicity. We believe that these matters—the questions
of what is tested, how the tests are performed, and how the results are evaluated—must be addressed and agreed upon by all agencies. For each agency to independently develop test guidelines and its own procedures for evaluating test results to determine whether a chemical is a carcinogen and, the extent of regulation needed does not, in our opinion, provide for effective and consistent protection of the public. We believe that these issues are among the most important that must be resolved by a Federal policy.

Reevaluate the policy

Although HEW stated that NCI constantly reevaluates its policies, it did not comment on whether NCI should reevaluate a Federal policy once it is established. We continue to believe that responsibility for establishing and reevaluating the policy should rest with the Director of NCI.

Carcinogenicity testing of food additives

HEW stated that the Federal Food, Drug, and Cosmetic Act requires only that a food additive’s safety be assured before FDA clearance. We agree with this statement but we do not agree that FDA can assure safety for unintentional additives when the additive migrates to the food and leaves a residue of less than 1 or 2 parts per million. In these cases, FDA usually does not require carcinogenicity tests. HEW also stated that, although extending carcinogenicity testing to unintentional food additives that have only remote possibilities of risk might be reassuring, it did not foresee any benefit to the public great enough to justify the substantial costs of such a policy.

Because the Delaney Clause implies that food additives that cause cancer in animals or humans are, per se, unsafe, we believe that the act intended FDA to consider cancer in assessing safety. According to the Surgeon General’s Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens (see p. 13), no level of exposure to a carcinogen should be considered toxicologically insignificant and no chemical should be considered safe for humans unless proper lifetime animal tests are negative. Based on these criteria, we do not believe that FDA can assure that all food additives are safe unless the additives receive carcinogenicity testing. To have the data necessary to assure safety, we believe FDA should require manufacturers to test all proposed food additives for carcinogenicity. Therefore, we believe that FDA should reconsider its policy of not requiring all food additives to be tested for carcinogenicity.
OSHA and BHA also reviewed this report and had only technical comments. (See apps. II and III.)

RECOMMENDATIONS TO THE SECRETARY OF HEW

We recommend that the Secretary require the NCI Director, as head of the National Cancer Program, to set a Federal policy on carcinogens. The policy, which should be developed with the cooperation, advice, and support of other involved Federal agencies, should address the scientific issues which have hampered effective public protection from carcinogens, including the

- information needed to protect the public;
- chemicals that should be tested,
- test guidelines that should be followed,
- way test results should be evaluated,
- feasibility of allowing exposure to carcinogens which would result in "acceptable levels of risk" for the public, and
- factors other than public health that should be considered.

We recommend that the NCI Director periodically re-evaluate this policy, considering advances in technology, changes in legislation, changes in social and economic climates, judicial rulings, and other relevant matters. We also recommend that the Secretary require FDA to have all approved and proposed food additives tested for carcinogenicity.

MATTERS FOR CONSIDERATION BY THE CONGRESS

Because tobacco and tobacco smoke are known human carcinogens (see app. VI), the Congress should request HEW to prepare a study showing the available options to regulate tobacco and tobacco products and the impact each option would have on the rising U.S. lung cancer rate. The Congress should then consider, as the Surgeon General has recommended, giving HEW or some other appropriate agency the specific authority to regulate tobacco and tobacco products.

The toxic substances legislation as introduced would require manufacturers to prove a chemical's safety before it is marketed rather than requiring the Government to prove
that it poses a hazard after it is marketed. The Congress should also consider whether this change would, as we believe, improve Federal efforts to protect the public from carcinogens.

The Congress should especially emphasize its oversight responsibility for those Federal agencies and programs which would be affected by a Federal policy on carcinogens. Among the public issues that could be covered by such a policy would be whether the Government will allow people to risk getting cancer from these chemicals and, if so, how the Government will determine that risk in the absence of adequate scientific data.
We reviewed the activities of the major Federal agencies responsible for identifying potential cancer-causing chemicals and protecting the public from them. We also contacted officials of other Federal agencies involved in protecting the public from carcinogens. (See app. V.)

At the research agencies—NCI, NIOSH, and NIEHS—we reviewed ongoing and recently completed activities to find out what was being tested, how it was being tested, and what was being done with the results. At the regulatory agencies—FDA, EPA, OSHA, and CPSC—we reviewed their efforts to implement research findings to find out what information they used, what factors they considered, and how timely their actions were in regulating carcinogens.
March 17, 1976

Mr. Gregory J. Ahart  
Director, Manpower and Welfare Division  
United States General Accounting Office  
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "Observations on Federal Efforts to Protect the Public from Cancer-Causing Chemicals." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

John H. Young  
Assistant Secretary, Comptroller

Enclosure
COMMENT OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE ON THE COMPTROLLER GENERAL'S DRAFT REPORT TO THE CONGRESS OF THE UNITED STATES ENTITLED "OBSERVATIONS ON FEDERAL EFFORTS TO PROTECT THE PUBLIC FROM CANCER-CAUSING CHEMICALS"—B-164031(2)

General Comments

Although the report contends that Federal efforts to protect the public from carcinogens have achieved only partial success, we feel that PHS has made important progress toward this goal since the time of the GAO review. Beginning in fiscal year 1975, NIOSH greatly increased its efforts in occupational carcinogenesis. For fiscal year 1976, NIOSH has programmed approximately $7 million in this area. Also, all PHS agencies concerned with carcinogenesis have taken the initiative to coordinate their efforts in this field.

Those directing the Federal efforts toward controlling the exposure of the public to carcinogenic materials must recognize that while it may be true that any exposure to a chemical carcinogen will cause cancer within the exposed population, the risk or probability that cancer will occur may very well be related to exposure levels. In those instances where exposure cannot be completely eliminated, or where the benefit is deemed to outweigh the risk from exposure, it is extremely important that efforts be made to estimate the upper limits of risk from specific levels of exposure using the best evidence that can be assembled through application of current research tools. It is anticipated that additional basic research on the cellular and molecular mechanisms of carcinogenesis will provide additional, fundamental information required for improving the quality of these estimates. As pointed out by the National Cancer Advisory Board (NCAB) Subcommittee on Environmental Carcinogenesis, the NCI should, and does, foster the development and validation of new and innovative analytic and bioassay techniques to meet the above needs.

We feel that epidemiologic investigations represent an essential component in cancer control. Constant vigilance must be maintained over the cancer rates among populations to detect trends which may indicate possible environmental etiology of cancer. These trends must be further investigated to identify the most likely agent or combination of agents which may be responsible. The separate efforts of the various health agencies such as CDC, through NIOSH and the Bureau of Epidemiology, and NIH, through NCI, are actively coordinated by the Assistant Secretary for Health through such committees as the Committee to Coordinate...
Toxicology and Related Programs. Also represented as observers on these committees are other Federal agencies such as EPA and the Department of Defense.

**GAO Recommendation**

That the Secretary of HEW require the NCI Director, as the head of the National Cancer Program, to provide leadership and coordination with other involved Federal agencies to set policies regarding the identification and regulation of carcinogens.

**Department Comment**

We do not concur. The Director of the NCI is fully cognizant of his responsibility for providing leadership in the direction and coordination of Federal efforts in carcinogenesis and is not only firmly committed to this end but is already providing appropriate leadership and coordination. However, we do not believe that his role does or should include setting regulatory policies. Appropriately, setting such policies is within the purview of the appropriate regulatory agencies. The Director, NCI, concentrates on setting policy on scientific matters and advising the regulatory agencies on scientific and public health needs.

Within NCI, the establishment of the requisite procedural framework combining formal and informal arrangements at policy and working levels throughout the institute has received the highest priority and is now functional. Recent examples include the Interagency Coordinating Committee for the National Cancer Plan; the NCAB Subcommittee on Environmental Carcinogenesis, which is endeavoring to develop criteria for assessing carcinogenicity; and the NCI Committee for the Review and Evaluation of Carcinogenic Data, a newly approved advisory committee which will evaluate carcinogenic data on a case-by-case basis as required based on need and priority. These activities are not intended to preempt or preclude specific undertakings, such as the NCI Temporary Committee to Evaluate Data on the Carcinogenicity of Cyclamates or the less formal effort involving NIOSH, NCTR, NCI, and industry to develop a protocol satisfactory for the evaluation of alpha and beta naphthylamines, or NCI's participation in the evaluation of current studies of diethylstilbestrol with NCTR, NIEHS, and FDA. The need for these specific undertakings will continue to exist, but the major challenge for the future will be the development of a procedural framework which meets the needs of the national program involving identification, risk evaluation, and prevention strategies for chemical carcinogens.

In the area of occupational carcinogenesis, NIOSH has the leadership role in applied research and criteria for standard development. Efforts are underway to accomplish a coordinated NIOSH-NCI approach.
Because things such as benefit, risk factors, mechanisms of occurrence in human, public needs and desires not all potentially carcinogenic materials can be regulated or controlled in identical fashion. Nonetheless, PHS recognizes the need for a Federal policy on carcinogens and has given it the highest priority. However, establishing such a policy will take time. Reprogramming, now in progress, restructurings, additional training of personnel, and the establishment of functional interlocking management systems among the agencies. PHS has taken initiative in this direction as evidenced by its growing participation in many interagency functions. Such participation includes NCI staff membership on (1) the DHEW Committee to Coordinate Toxicology and Related Programs (CCTR), including the chairmanships of CCTRP subcommittees; (2) FDA advisory committees; (3) the Science Advisory Board of NCTR including board subcommittees; and (4) the Science Advisory Board of EPA. It also includes the establishment of Interagency Collaborative Group on Environmental Carcinogenesis in collaboration with the Council on Environmental Quality to coordinate Federal efforts in the conduct of a prototype epidemiologic-demographic study of cancer etiology. Members of NCI, FDA, EPA, NIOSH, OSHA, and CPSC serve as advisors, consultants, and co-project officers on projects of mutual interest. These interactions promote better understanding of interagency concerns which we hope will lead to a more uniform Federal policy on the regulation of chemical carcinogens.

GAO Recommendations

That the NCI Director use the authority conferred by the National Cancer Act of 1971 to resolve the current issues, including (1) the information needed to protect the public from carcinogens, (2) the chemicals that should be tested, (3) the test guidelines that should be followed, and (4) the way results should be evaluated and used.

Department Comments

We partially concur in these recommendations. The Director, NCI, has taken steps to assure that information on potentially carcinogenic materials is made public at the earliest possible time. The mechanism for accomplishing this is the newly formed NCI Committee for the Review and Evaluation of Carcinogenic Data. Appropriate NCI officials will keep the committee informed of research results on testing suspected or potentially carcinogenic materials. The committee will hold public meetings at which information on suspected carcinogens will be discussed. After the completion of its meetings on a particular material, the committee will advise the Director, NCI, on what steps should be taken for distributing appropriate information to the public.

The NCI procedures used for selecting chemicals for testing are continually reviewed. The enactment by the Congress of the proposed Toxic
Substances Control Act (TSCA) (HR 76-64) with the amendment proposed by the Administration could affect the procedures used for selecting chemicals through providing a mechanism and fixing responsibilities for the screening of compounds. Future NCI activities in carcinogenesis testing may, in large part, be predicated on the provision of the proposed TSCA. The NCI is working closely with EPA and other Federal agencies (including FDA, NIOSH, and OSHA) in protocol development as it relates to possible requirements for industry testing.

The NCI has developed minimum test guidelines that have been at least partly adopted by regulatory agencies. However, these are only test guidelines, not specific protocols.

The Director, NCI, has used his authority to establish the NCI Committee on the Review and Evaluation of Carcinogenic Data which, on a case-by-case basis, will evaluate data and render advice on the use of such data. However, the NCI Director will not and should not direct the regulatory agencies on what use they will make of such data. He will provide them advice and data but they must make the appropriate decisions.

GAO Recommendation

The NCI Director should periodically reevaluate the policies, considering advances in technology, changes in legislation, changes in social and economic climates, judicial rulings, and other relevant matters.

Department Comments

We concur. The NCI is constantly reevaluating its policies based on factors such as those cited by GAO.
GAO Recommendation

That the Secretary require FDA to have all approved and proposed food additives tested for carcinogenicity.

Department Comment

We do not concur. The report misinterpreted the Delaney Clause of the Federal Food, Drug, and Cosmetic Act as requiring that all food additives, both direct and indirect, be tested specifically for carcinogenicity. The Associate General Counsel for Foods did not advise the auditors that Section 409 of the Act requires testing for carcinogenicity in every instance. The law requires only that safety be assured prior to FDA clearance. The Delaney Clause applies only where "the additive in appropriate laboratory tests indicates a potential of inducing cancer," in which case the Commissioner requires "further testing (to) show that the additive would not produce cancer."

In determining the safety of the anticipated usage or presence of a compound in the food supply, FDA follows the principle that the higher the anticipated human exposure, the greater the amount of toxicological data required to assure human safety. This principle is directly applied in evaluating the safety of indirect food additives. Any packaging ingredient which has been demonstrated to be capable of migrating to food where the anticipated residue in food may be as much as or higher than 1 ppm usually leads the FDA to require a full-scale toxicological review including lifetime feeding studies to investigate the potential for chronic toxicity and carcinogenicity of the compound in question. Below this level, but where there is still anticipated migration, 90-day feeding studies are required at the minimum for toxicological evaluations of safety. If there are valid reasons to suspect that the migrant may be
APPENDIX I

Carcinogenic, even under these insignificant levels of migration, judgment is applied as to whether or not lifetime carcinogenicity studies would be required or whether the substance should be treated as a suspect carcinogen and prohibited from usage.

Although it might be reassuring to extend carcinogenicity testing to indirect food additives that have only remote possibilities of risk, we do not foresee any significant benefit to the public to justify the substantial costs of such a policy.

GAO Recommendation

That, if, for any reason, the Consumer Product Safety Commission does not regulate high-tar cigarettes, the Congress may wish to request HEW to prepare a study for congressional consideration showing (1) the different options available to regulate tobacco and tobacco products and (2) the impact each option would have on the rising lung cancer rate in the United States.

Department Comments

The report places great emphasis on the need to clarify, by congressional action, governmental authority to control hazardous agents associated with cigarette smoking. The NCAB addressed this in a resolution to the President, dated November 27, 1974, in which the board recommended that limits be set for tar and nicotine content in cigarettes. Also, the Division of Cancer Cause and Prevention, NCI, recognizing the magnitude of the disease burden imposed by cigarette smoking, initiated a smoking and health program in 1970 with the objective of developing a less hazardous cigarette. These efforts are considered complementary to those leading to regulatory control of hazardous agents associated with cigarette smoking.

GAO note: Deleted comments relate to matters discussed in the draft report but omitted from the final report.
January 15, 1976

Mr. Gregory J. Ahart
Director
Manpower and Welfare Division
U. S. General Accounting Office
Washington, D. C. 20548

Dear Mr. Ahart:

This is in response to your letter of November 21, 1975, requesting comments on the proposed report entitled, "Observations on Federal Efforts to Protect the Public From Cancer-Causing Chemicals".

There are no recommendations to the Secretary of Labor in this report. Enclosed are specific comments on portions of the report for your consideration during preparation of the final report. [See GAO note.]

Thank you for this opportunity to review the proposed report and to furnish you with our comments.

Sincerely,

FRED G. CLARK
Assistant Secretary for Administration and Management

Enclosure

"GAO note: These general and technical comments have been incorporated into the final report and are not included here."
January 20, 1976

Mr. Henry Eschwege
Director, Resources and Economic Development Division
U. S. General Accounting Office
Washington, DC 20548

Dear Mr. Eschwege:

We received copies of the General Accounting Office's proposed report entitled, "Observation on Federal Efforts to Protect the Public from Cancer-Causing Chemicals" as transmitted with your letter of November 21.

In general, we feel that this is a balanced and accurate report of the National Cancer Institute's carcinogenesis bioassay program, and the relationship of this program to EPA and other Federal regulatory agencies.

I appreciate the opportunity you have given EPA to review and comment on this draft report prior to its publication.

Sincerely yours,

Alvin L. Alm
Assistant Administrator for Planning and Management
APPENDIX IV

GAO REPORTS DEALING WITH GENERAL EFFECTS OF CHEMICALS AND OTHER ENVIRONMENTAL FACTORS

1. "Use of Cancer-Causing Drugs in Food-Producing Animals May Pose Public Health Hazard: The Case of Nitrofurans" (report to the Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce, HGO-76-85, Feb. 25, 1976) discusses the lack of FDA action to determine whether residues of nitrofurans were present in food taken from treated animals.

2. "Need to Establish the Safety of Color Additive FD&C Red No. 2" (report to Senator Gaylord Nelson, N60-76-40, Oct. 20, 1975) questions FDA's failure to resolve safety questions of a color additive which had been used for 15 years.

3. "Federal Pesticide Registration Program: Is it Protecting the Public and the Environment Adequately from Pesticide Hazards?" (report to the Congress, RED-76-42, Dec. 6, 1975) criticizes EPA's implementation of the federal laws regulating pesticides, including the one that requires testing of proposed pesticides.


5. "Improved Federal and State Programs Needed to Insure the Purity and Safety of Drinking Water in the United States" (report to the Congress, B-166506, Nov. 15, 1973) deals with the chemical quality of certain water systems, concludes that potentially dangerous drinking water has been delivered to some consumers, and makes appropriate recommendations to EPA and HEW.

7. "Supervision over Investigational Use of Selected Drugs" (report to the Subcommittee on Reorganization, Research, and International Organizations, Senate Committee on Government Operations, B-164031(2), July 23, 1973) discusses, among other things, FDA's handling of proposed drugs which had caused cancer in animals.

8. "Environmental Protection Agency Efforts to Remove Hazardous Pesticides from the Channels of Trade" (report to the Congress, B-13192, Apr. 26, 1973) discusses EPA's suspension and cancellation procedures for hazardous pesticides.
SECONDARY AGENCIES INVOLVED IN CARCINOGEN REGULATION

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service—monitors the quality of meat, poultry, and egg products under standards set and enforced by EPA and FDA.

Agricultural Research Service—performs various research relating to carcinogens, including tests on meat, poultry, and egg product samples provided by the Animal and Plant Health Inspection Service and research involving mycotoxins.

DEPARTMENT OF COMMERCE

National Bureau of Standards—develops and evaluates measurement methods so that regulatory standards may be accurately quantified and enforced. The Bureau's Programmatic Center for Consumer Product Safety provides technical assistance to CPSC under a working agreement between the two agencies.

DEPARTMENT OF DEFENSE

Biomedical Laboratory, Edgewood Arsenal conducts short-term and some long-term toxicological studies which are generally not designed to identify unknown environmental carcinogens.

HEW

National Clearinghouse for Smoking and Health—develops and disseminates data relating to smoking and health, develops information systems for such data, and conducts research on the behavioral aspects of smoking.

DEPARTMENT OF THE INTERIOR

Mining Enforcement and Safety Administration—develops and enforces health and safety standards for coal and non-coal mining operations; follows standards developed by the American Conference of Governmental Industrial Hygienists.

Bureau of Mines—conducts research on mine health and safety, including the engineering aspect of safety, primarily developing technology to implement the health standards.
APPENDIX V

Fish and Wildlife Service—conducts research concerning the safe use of chemicals to control wildlife populations and conducts a pesticide monitoring program. Enforcement powers for use or nonuse of certain chemicals are limited to Interior-held lands.

DEPARTMENT OF TRANSPORTATION

Office of Hazardous Materials—regulates the interstate shipment of hazardous materials. None of its regulations are directed specifically toward regulating hazardous materials because of their carcinogenicity.

Federal Aviation Administration—regulates aerial application of pesticides under standards set by EPA and conducts some toxicological research involving such objectives as the effects of certain chemicals on a pilot's ability to safely operate his aircraft.

INDEPENDENT AGENCIES AND ORGANIZATIONS

Energy Research and Development Administration—conducts long-term research to assess the risks associated with radiation and energy-related effluents.

National Academy of Sciences—National Research Council, Committee on Toxicology, Advisory Center on Toxicology, provides expert opinion to sponsoring agencies on toxicological problems and other related areas, such as carcinogen classification and testing. The research is conducted through literature searches and not actual experimentation.

National Science Foundation—conducts research regarding the effects of contaminants on ecosystems, participating in such programs as Research Applied to National Needs, International Biological Program, and International Decade of Ocean Exploration.

Smithsonian Institution—Registry of Tumors in Lower Animals collects, records, and disseminates information regarding tumors in lower animals but conducts no toxicological research.

World Health Organization—International Agency for Research on Cancer provides expert opinions on carcinogenesis which are published in technical reports and monographs evaluating the carcinogenic risk of chemicals to people.
APPENDIX VI

NCI LIST OF KNOWN HUMAN CARCINOGENS

1. beta-naphthylamine 19. tars
2. benzidine 20. pitches
3. 4-aminobiphenyl 21. asphalts
4. 4-nitrobiphenyl 22. cutting oils
5. clornaphazine (bis-2-chloroethyl-2-naphthylamine) 23. shale-oils
6. mustard gas (bis-chloroethyl sulphide) 24. creosote oils
7. nickel carbonyl 25. high boiling petroleum oils
8. diethylstilbestrol 26. coke oven effluents
9. bis (chloromethyl) ether 27. various combustion products
10. vinyl chloride 28. betel nut (chewing)
11. aflatoxin 29. radium (note a)
12. asbestos 30. thorotrast (note a)
13. arsenicals 31. uranium ores (radon and radon daughters)
14. chromates 32. other radioactive materials (note a)
15. estrogenic compounds 33. auramine (note b)
16. tobacco 34. magenta (note b)
17. tobacco smoke 35. isopropyl oil
18. soots 36. wood dust (note b)

a/Carcinogenicity due to radiation.

b/Manufacturing exposure to these materials has been related to cancer induction; the materials themselves may not be carcinogenic.

The chemical substances and mixtures that have been found to cause cancer in humans are listed above. For hundreds of other substances which have been tested in the laboratory, there is evidence of carcinogenicity in rodents. In some instances the evidence is strong; in others it is barely fragmentary.
APPENDIX VII

MEMORANDUM

TO: Supervisory GAO Auditor
General Accounting Office

FROM: Chemist, Office of the Associate Director for
Carcinogenesis, CDPH, NCI

DATE: September 17, 1975

SUBJECT: Classification of the Exposure Hazard Presented by Thirty-Six Chemicals and Mixtures

1. The thirty-six substances, which are on the list of Individual Chemicals and Mixtures that Have Been Found to Cause Cancer in Man by Direct Observation of Exposed Populations, can be separated into five categories. These classifications give some indication of the level of exposure threat which exists for the American population or some segment of the general population. The five classifications are:

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
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<tbody>
<tr>
<td>I</td>
<td>Controlled or restricted usage. Protection of the population requires technical surveillance.</td>
</tr>
<tr>
<td>II</td>
<td>Recognized as carcinogenic. Exposure is largely voluntary.</td>
</tr>
<tr>
<td>III</td>
<td>Implicated in human carcinogenesis by epidemiological evidence. Exposure is poorly controlled in spite of carcinogenesis hazard.</td>
</tr>
<tr>
<td>IV</td>
<td>Prescribed by physicians or endogenous.</td>
</tr>
<tr>
<td>V</td>
<td>Utilized in laboratory only.</td>
</tr>
</tbody>
</table>

2. The compounds and mixtures are categorized as follows:

Category I

- β-naphthylamine
- benzidine
- 4-aminobiphenyl
- 4-nitrophenol
- nickel carbonyl
- diethylstilbestrol
- vinyl chloride

Category II

- aflatoxin
- asbestos
- arsenicals
- radium
- thorotrast
- uranium ores (radon and radon daughters)
- other radioactive materials

(count 15)
APPENDIX VII

Category II
- tobacco
- tobacco smoke
- betel nut (chewing)
- (count 3)

Category III
- chromates
- soots
- tar
- pitches
- asphalts
- cutting oils
- shale oils
- creosote oils
- high boiling petroleum oils
- coke oven effluents
- various combustion products
- wood dust
- arsenine
- naphthene
- (count 14)

Category IV
- estrogenic compounds
- (count 1)

Category V
- chloromephazaine (bis-2-chloroethyl-2-naphthylamine)
- mustard gas (bis-chloroethyl sulphide)
- (count 2)

Isopropyl oil is no longer produced in significant quantities.

Charles P. Wyman
Charles R. Warner, Ph.D.
Chemist, Office of the Associate
Director for Carcinogenesis
Division of Cancer Cause & Prevention
APPENDIX VIII

PRINCIPAL OFFICIALS RESPONSIBLE FOR
ACTIVITIES DISCUSSED IN THIS REPORT

<table>
<thead>
<tr>
<th>Official</th>
<th>Date appointed</th>
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</thead>
<tbody>
<tr>
<td>SECRETARY OF HEW: David Mathews</td>
<td>Aug. 1975</td>
</tr>
<tr>
<td>ASSISTANT SECRETARY FOR HEALTH: Theodore Cooper</td>
<td>May 1975</td>
</tr>
<tr>
<td>SURGEON GENERAL: Paul S. Ehrlich (acting)</td>
<td>Jan. 1933</td>
</tr>
<tr>
<td>DIRECTOR, NIH: Donald S. Fredrickson</td>
<td>July 1975</td>
</tr>
<tr>
<td>DIRECTOR, NCI: Frank J. Rauscher, Jr.</td>
<td>May 1972</td>
</tr>
<tr>
<td>DIRECTOR, NIEHS: David P. Rall</td>
<td>Mar. 1971</td>
</tr>
<tr>
<td>COMMISSIONER, FDA: Alexander M. Schmidt</td>
<td>July 1973</td>
</tr>
<tr>
<td>DIRECTOR, NIOSH: John F. Pinkle</td>
<td>May 1975</td>
</tr>
<tr>
<td>SECRETARY OF LABOR: W. J. Usery, Jr.</td>
<td>Feb. 1976</td>
</tr>
<tr>
<td>ASSISTANT SECRETARY FOR OCCUPATIONAL SAFETY AND HEALTH: Morton Cbrn</td>
<td>Nov. 1975</td>
</tr>
<tr>
<td>ADMINISTRATOR, EPA: Russell E/1 Train</td>
<td>Sept. 1973</td>
</tr>
<tr>
<td>CHAIRMAN, CPSC: Richard O. Simpson</td>
<td>May 1973</td>
</tr>
</tbody>
</table>
Public Policy

Chemicals and cancer

"Chemicals" and "cancer" are two words that most chemists hate to see juxtaposed. They believe, with justification, that the public at large interprets chemicals in this case as industrial chemicals only and so gets the impression that the chemical industry is responsible directly for most of the cancer problems in this country. Of course, this is far from being the case. As chemists point out repeatedly, everything is chemical, whether man-made or natural. Also, they stress that most cancers are related to overall environmental factors and to the wrong life-for instance, smoking and the food we eat, and not to exposure to industrial chemicals.

However, the fact remains that a few industrial chemicals have been shown to cause cancer in humans. And a growing number are suspected of doing so. Hence, the issue of the relationship between cancer and man-made chemicals is a serious and increasing one for chemical makers as well as for both the research community as it seeks ways to detect carcinogens early and for a host of government agencies as they strive for well-founded protocols to contain or eliminate cancer hazards.

In this special presentation, C&EN offers two views of the issue of chemicals and cancer-one from government, one from industry. They were given at different times and at different forums, hence they are not meant to rebut each other. Indeed, there is a spirit of agreement between them. But they do represent somewhat different perspectives of what needs to be done.

Barbara Hackman Franklin has been a commissioner for the Consumer Product Safety Commission since 1973. She is serving a seven-year term. She calls for greater government involvement in the cancer issue, believing that the current efforts of government, industry, and others are "akin to 30 different acts being performed simultaneously at a three-ring circus that lacks a ringmaster." She apparently sees President Carter as filling the ringmaster role by "providing the leadership for a strong, sustained, and coordinated national commitment to bring the hazards down to size and to help reduce the confusion and uncertainty over cancer and chemicals."

John P. Schmits is assistant general counsel for Du Pont. He calls for setting acceptable exposure levels for chemicals. For each chemical this would be the level at which it could be reasonable to predict that no one would be likely to get cancer or another chronic illness. He thinks that the legislative basis for such an approach has been set by passage of the Toxic Substances Control Act and that success now depends on the development of balanced regulations.

Commissioner Franklin is a 1963 graduate of the State University. In 1964 she became one of the first women to receive a master's degree from Harvard Business School. She moved to Washington, D.C., in 1971, working for two years as the White House staff where she was charged with launching a program to recruit women to fill policy-making positions in the federal government. She earlier had worked for Singer Co. and for First National City Bank in New York City.

Schmits joined Du Pont in 1955 in the firm's Washington, D.C., law office. He assumed his present position as assistant general counsel in 1972. He graduated from Cornell University in 1953 with a chemical engineering degree. He earned a J.D. degree from Georgetown University law school in 1956.

The Franklin presentation was given last month in Los Angeles at a meeting of the Town Hall of California. Schmits presented his views late last year at the National Symposium on Chronic Hazards.

Cancer control: a bigger role for government

Barbara Hackman Franklin, Consumer Product Safety Commission

The little-understood, thorny dilemma of chemicals and cancer may have a devastating impact on millions of people. It is a problem increasingly central to idiosyncrasies. My contention is that we must find more rational, responsible ways to deal with the hazards at the outset short order.

In a real-life twist to what was science fiction, some substances are now identified as potential hazards not only to the environment but to human life as well. The rallying cry is cancer. The old saw that probably occurs more abroad and less in the minds of the American people than any other disease, with good reason. In the U.S., cancer is the second leading cause of death. Among all developed nations, it ranks number two. This year in the U.S. alone, some 900,000 new cases will be diagnosed.

Looking ahead, the situation may be no better. Indeed, it may worsen, because of the long incubation period of the disease and its inclination to strike middle-aged and older Americans, our fastest growing population. Expectations are that we must deal with high incidence rates for years to come, even if cures (such as those developed for many victims of Hodgkin's disease and childhood leukemia) were announced today. Eventually, according to the American Cancer Society, one in every four of us will develop cancer, and about two thirds of those who get it are likely to die.

With this as background, it is understandable why, as a nation, we must make the best possible efforts to get at the root causes and cures and to insist on better diagnosis, treatment, and rehabilitation. Three successive Presidents and Congress have recognized the importance of this work. They have booked, for example, the budget of the National Cancer Institute, the "Pentagon" of this effort, from $180 million in 1970 to $810 million this year.

It is an expensive proposition. The program is big. But the stakes are high, too. And like many areas of public health and safety that seem to cost a lot and rely heavily on research, controversy mounts in direct proportion to the rate at which conclusive answers and miraculous cures seem outside our grasp.

One controversy is whether the strategy aimed more at cures than at prevention is impeded, in view of accumulating evidence...
It was the 1959 cranberry scare that first aroused the public consciousness about environmental hazards. Others followed. Congressional hearings over passage of the new Toxic Substances Control Act sparked some of the current debate. But for many Amercians, it was the proposed ban on saccharin early this year that brought the message home. With President Carter's recent signing of legislation to delay the ban pending the outcome of further testing, I believe we should expect even more public attention.

Developments along this line are changing the thrust of the battle against cancer. The developers are sending scientists scurrying back to their labs and making back to law libraries. They are proposing Congressional hearings and regulatory proposals in the Federal Register in a hurry, and are filling the nation's newspapers columns and airwaves.

What are environmental factors? They include smoking, alcohol consumption, diet, exposure to radiation—and a range of chemicals and other substances. What does this mean? It means that more and more, the concern is over potentially dangerous substances in the air we breathe, the food we eat, the products we use and the manufacturing processes we employ upon. And, more and more, a target of the concern is children.

Cranberry scare was the first of many.
For all the agencies, the $64,000 question is what does it take to achieve public protection? There are other questions. Should there be consistency in the ways agencies move from research to results to regulation? Or will this always lead down to a case-by-case situation within the framework of each agency's laws? How do we resolve delays in the regulatory process yet assure a solid basis for regulation, meaningful public participation, and adequate due process? And another question: the federal agencies snap cut beneficial thinking altogether, as some suggest. Simply banning a substance may be the one quick way out now—but it certainly is not an adequate or acceptable answer over the long term. For example, in the case of saccharin for people who are diabetic or obese, the risks of cancer? And what about the questions that such an answer raises? Are they equally or more dangerous? Finally, what about the impact of a ban on businesses and their employees? My point is that banning a specific substance may indeed be the proper approach. But other factors must be weighed—before decisions are made so that we don't dreadfully shortchange the public health and safety or cause unnecessary economic upheaval.

That's the battle of the tests. As a nation, we're short on tests and testing protocols that are reliable, fast, and cheap. Some short-term testing is being used but there is no test or out of government is certain just yet how conclusive it is as a basis for regulation. As a result, each agency has its own testing guidelines and criteria. And the consequences can be costly. As companies try to develop new chemicals on the theory that safety should be tested in the lab and not on the environment, they find no uniform position on the scientific, federal, or business communities on what tests should be conducted and how the results should be interpreted. This is especially true when two or more agencies are focusing on the same chemical—or, as in the case of Fyrol, the same test is used but conflicting results emerge. Another issue is threshold levels of exposure—in other words, which threshold of cancer? The threshold may have no adverse effects on human health. If there were scientific certainty or even consensus on these levels, there would be no need to consider the approach of any agency. And even if they were—decisions making for regulators and businesses would be easier. But such is not the case, and the mere suggestion of it sends many of our scientific friends up the wall. One result is the approach of each agency differs, depending on the specific substances and the provisions of the particular law which apply.

The proposed bill, for example, in accordance with a specific provision of the Delaney clause, which triggers an automatic ban. The Delaney clause is a provision of the Consumer Product Safety Commission, that a substance presents an "unreasonable risk" of injury or death, effective course of action needed

Where do we go from here? I only wish I could plot an effective course of action which would make sense for industry, government, and most of all, for consumers—those who must feel increasingly confused or cynical—and frankly, I'm hard pressed to blame them.

At the moment, products whose benefits consumers have enjoyed, sometimes for years, are hedged at hazards that may be perceived under threat. At the same time, they are beset by conflicting news reports that there is absolutely no cause for concern. Is nothing safe any more? Are we victims of overgeneralization by the media? Regulatory overkill or undertkill? Industrial or consumer?. Is this the necessary price we pay for living in a highly industrialized society? Is it right that we may not allow any other single individual, agency, company, or public interest group has conclusive evidence to all of these questions. The answers are clear. They are much too complex and interdependent and their impact irreversible to expect that the answers are the sole prerogative of any one person, organization, or profession. But the questions are general, and they underscore the urgency and seriousness of the challenges of chemicals and cancer before us. Fundamentally, this stirs at the heart of my major concern. It is that we in government seem to be talking too much to ourselves and too little with industry and consumers, whose knowledge and resources may differ—or may be the same. The point is that we're not sure. Industry is riding along in its own course—without full consideration of the attitudes and information of others. It's akin to 30 different acts being performed simultaneously at a three-ring circus which lacks a director.

There is yet another. How do we explain that the chemical problems and cancer are truly shared and that it serves the broad public interest to face them squarely. So it goes with the solutions, if they are to be sound, equitable, and lasting. They too, must reflect information and involvement from many sources and in the final analysis, consensus and compromise—albeit though these words may seem to some.

This is why, in many public forums, I have called for wide, open, and frank discussion of the causes and costs of cancer. It is essential that all segments of the public be more adequately informed and actively concerned and involved. Not just when cancer strikes a family member or friend. But just in reaction to a specific regulatory proposal. Not just when writing a check to support cancer research and related activities, as important as all of these are.

President Carter must spearhead effort

The concern must go much deeper, and the public consciousness and understanding must be raised proportionately. This is why, I repeatedly urged President Carter to provide the leadership for a strong, sustained, and coordinated national commitment to bring the hazards down to zero and to help reduce the confusion and uncertainty over cancer and chemicals. With vigorous support from the White House, I believe we can achieve it—and head off the possibility of a government snafu.

The first major step needed was the request, President Carter—to ask the interagency group to conduct a study and make recommendations. But much more must be done. The next step urgently needed is serious discussion with the scientific, academic, and medical communities, business community, and the public and the federal agencies themselves—beginning now. Together, we must explore the issues and support sound strategies to deal with them.

If this is why I will continue to urge formulation of a national policy on carcinogens with the weight of the White House behind it. Again, government must take the lead responsibility but the policy must reflect the diverse concerns of the public. A policy developed in concert with the public should reflect—a reflection that everybody will know—the posture and program of the federal government in this area and the guiding principles behind it. At a minimum, I believe a policy must address issues including these: information needed to regulate cancer-causing chemicals, the tests that should be used, how the results should be interpreted, and the basis other than public health that should be taken into account.
Chronic health hazards: a national challenge

John F. Schmidt, Du Pont

Chronic health hazards are of concern to me, my company, the industry, and the nation. Twenty-five years ago, two or three chemicals were known to cause cancer in man. Today, the Occupational Safety & Health Administration regulates 17 solvent or plastic sheet or a solvent. From a policy perspective, the need to control carcinogens and cancer is not the reason called for. With this issue, the time and resources are used to solve the real problem. When we see a need for action, we often say, "What about the ethical instrument that mechanized this? If we can't control what we see, we can't control what we don't see. For our lives, it is ethical to control and protect our health, not only to do what we can see, but also to do what we can't see." When we see our limit to resources, and makes positive progress toward a clean and healthy environment.

Today, I would like to:
1. Prevent a perspective to chronic health hazards.
2. Discuss the central issue, particularly acceptable risk.
3. Demonstrate the possibility to how we might deal with these issues.

Because it is so personal to each of us, the question of chronic illness, particularly cancer, is one that is difficult to view in perspective. The deep concern for these issues leads us to react emotionally rather than rationally. To manage chronic health hazards effectively, we must be willing to let go of the notion that we can control every aspect of our lives. It is not only possible, but it is essential, to understand that a national challenge.

In summary, health hazards are a national problem resulting from a variety of sources, which industrial chemicals are only a part. Let me hasten to add that because of the human suffering involved, industrial chronic health hazards are a major concern to industry. However, industrial hazards are far from being the principal cause of chronic illness. Why then the focus on industry? This builds on the second theme of the focus on chronic health hazards, a chemical and a naturally occurring carcinogen. Our first and growing fear of environmental quality in the environment as an ever increasing problem.

Second, chemicals and other chemical chronic health hazards are not necessarily "good" or "bad." Almost everything in nature involves chemicals. The chemical "good" or "bad" is determined by what we do with it. To change from one, man-made product to another is no change from natural to synthetic products. It is not a change from natural to synthetic chemicals. It is a change from one way to another in which we deal with chemicals, which are essential to our lives.

For example, nickel and selenium in some forms are highly toxic in certain conditions. We would die without them. We are prone to consider a certain chemical a "good" chemical because we need it. We need clout that serve the people that have been involved, industrial chronic health hazards. In one case we can say, "We need to take the lead in putting the brakes on the Harvard-Cornell study that 50 to 60% of cancers are environmentally caused. We cannot distinguish between smoking and diet, and other means of environmental causes. The major cause of environmental cancer is smoking and diet. Reliable experts estimate that 5% or less of cancer is environmentally related. This number includes known hazards such as asbestos, benzene, and others not well controlled.
the level while further data are gathered may provide reason-

able assurance of safety and acceptable uncertainty. In-

other words, control to the lowest level feasible is inap-

propriate, until as an interim measure. With a potent car-

cinogen, for which no-effect level has not been established,

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cinogen, for which no-effect level has not been established,

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propriate, until as an interim measure. With a potent car-

cinogen, for which no-effect level has not been established,
Thus, I agree with safety analysts that our approach for regulating chemical hazards is the workplace. But ultimately, hazards must be evaluated on a product by product basis. Furthermore, we must determine that, whether adequate protective controls, engineered controls, or personal protective equipment are used, should be used. In order to reduce the rate of occupational illnesses, we must continue the efforts of the Health and Safety Committee.

In the past, the Chemical Education Act has provided the basis for adequate regulation. With the passage of the Toxic Substances Control Act, which was generally supported by industry, the basis has been provided. We can all thank Congress for its efforts that made that legislation possible. Now, success of its implementation will depend critically on adequate regulation.

An Interagency Regulatory Liaison Group, representing the Consumer Product Safety Commission, the Environmental Protection Agency, the Food & Drug Administration, and OTA has been formed to provide a mechanism to enhance our efforts in this area. In addition, risk assessment, regulation should be based on a scientific and risk management approach. One group called the Toxic Substances Control Act (TSCA) has been formed to provide a mechanism to enhance our efforts in this area.

In the past, the Chemical Education Act has provided the basis for adequate regulation. With the passage of the Toxic Substances Control Act, which was generally supported by industry, the basis has been provided. We can all thank Congress for its efforts that made that legislation possible. Now, success of its implementation will depend critically on adequate regulation.

An Interagency Regulatory Liaison Group, representing the Consumer Product Safety Commission, the Environmental Protection Agency, the Food & Drug Administration, and OTA has been formed to provide a mechanism to enhance our efforts in this area.

First, I propose a review of data from federal agencies in order to determine whether additional data is needed. At the moment, we must ask whether the freedom of manipulation required of employees is a valid one. It is not possible to prove that one could not prove, nor is it possible to prove, that some unique and sensitive person could not be regulated.

Second, there should be full disclosure of all significant hazards to all those who may need to act on that information, including employees, customers, the government, and others. Existing authority under TSCA provides an adequate statutory base to require industry to notify the government of potential health and safety data.

Third, workplace concentrations of suspected animal or human carcinogens should be limited to levels that would not exceed the lowest feasible level considering effective exposure. The physical form of the material, its registered or expected dose and its chemical data. The level of control should be used to control existing data and apply a safety factor. For example, in some cases the acceptable exposure concentration might be 10 times the observed no-effect concentration in a suitable animal study.

The level and duration of control, while the means thereof, should be the product of scientific judgment. The means of control should be a practical combination of engineering controls and personal protective equipment. The basis for sound regulation has been provided.

The condition precedent to sound regulation is an adequate and balanced legislative base. With the passage of the Toxic Substances Control Act, which was generally supported by industry, the basis has been provided. We can all thank Congress for its efforts that made that legislation possible. Now, success of its implementation will depend critically on adequate regulation.

An Interagency Regulatory Liaison Group, representing the Consumer Product Safety Commission, the Environmental Protection Agency, the Food & Drug Administration, and OTA has been formed to provide a mechanism to enhance our efforts in this area.
BIBLIOGRAPHY


Page 111

Contents.—Background.—Consumer problems and the advocacy concept.—Pending legislation.—Agency powers.


Cites failings of various laws designed to protect the consumer.


"Article focuses on the key provisions of the Act which are important to the accomplishment of its goals. The analysis scrutinizes the underlying policy decisions supporting the legislative approach, the lack of clarity in the statutory language, and the problems posed by the regulatory response to the legislation. Finally, within this framework, this article assesses the viability of the Act as a vehicle for achieving its stated objectives. Finds much of the Act "obscure in purpose and effect."


Former Chairman of the Consumer Product Safety Commission (CPSC) examines new initiatives for product hazard data collection, the definition of defect for the purpose of tort liability versus the purpose of reporting to the CPSC, the confidentiality of manufacturers' reports and how the effects of compliance and noncompliance with CPSC actions relate to product liability.


"Congress has been cold-shouldering the movement's favorite bills, including some supported by Jimmy Carter. But consumerists continue to get action in the states and cities."


Discusses efforts to quantify the belief that consumer dissatisfaction is growing. Concludes there are potential benefits to encouraging more complaints by the use of telephone hotlines, questionnaires inserted in packages and other improved communications devices. But regardless of the effect of such encouragement, it is clear that consumer complaints cannot be allowed to serve as the sole source of information about consumer dissatisfaction.

The author, an FTC commissioner, suggests some limitations on the use of cost-benefit analysis in a speech surveying some of the Commission's recent activities.


Interview with the Assistant Secretary of Agriculture for Food and Consumer Services ranges over a number of consumer issues.


In this Sept. 1977 speech the author argues that government regulation has left the consumer less well off than he would be if competitive markets were allowed to function unimpeded.


Article surveys the broad range of civil and criminal sanctions currently available to most state enforcement agencies for consumer protection and recommends coordinated civil and criminal penalties.


"A growing number of companies have overcome their paranoia and are beginning to realize bottom-line benefits from listening more carefully to consumer concerns." Ms. Haney describes the expanding role of consumer affairs professionals in business and offers recommendations on how a company might initiate a consumer program or improve an existing one.


"This paper . . . deal[s] broadly with the question of how government regulation of consumer products can be controlled to prevent either indifference to genuine problems or unnecessary overregulation. It . . . briefly examine[s] the rationale for and mechanisms of government regulation and review[s] possible ways of achieving control of agencies in order to assure balanced regulatory activities."


"The adverse impact of imports on American jobs has been amply demonstrated, but the impact on American consumers is just beginning to surface. For a great many items in the family budget, the price advantage of imports has disappeared; many products have serious safety hazards;"
"the quality of well-known brand items made partly or wholly abroad is now questionable."

"Some recent reverses have produced dire predictions on the future of the consumer movement. But those who think—or hope—the movement is dead are wrong, because the nation has an underlying public demand for consumer reforms. Consumer concerns may keep changing, as they've done before, but there will be no let-up. In fact, recent surveys indicate the U.S. public is far ahead of many government and business leaders in understanding the need for consumer protection."

Discusses ways businesses can educate consumers and concludes that businesses, not the public school systems, should educate consumers about their products. It meeting their responsibility, they will receive many benefits—including bigger profits.

KF1610.M65 1978 343.7307

Protecting the consumer interest: private initiative and public response.
HC110.C63F77 381.3

658.408

The article develops the thesis that "consumer-protection regulation should aim at improving market performance by enhancing seller's stake in goodwill, rather than improving the quality of particular products or product information. This calls for a strategy combining, in differing proportions according to market characteristics, elements of disclosure, property rights in trustworthiness, and competition."

"The purpose of this article is to examine the balance of warrant- or consumer interests under the (Magnuson-Moss Warranty) Act in order to determine its potential impact on the marketplace."

"In recent months, with its redirected political might, business has helped kill important consumer legislation. How is business doing it? From the top, the corporate chief executive officers use their influence; from the bottom, the grassroots businessmen and women use their numbers. In the middle are the legislators—pressured from both directions."


"Nine years of carefully coordinated efforts by a business coalition had the desired effect despite a major push by consumer interests."


"Our goal [is] . . . to provide a forum where those parties most involved in consumerism can come and tell Congress what they believe are priority issues."


"To establish an agency for consumer protection in order to secure within the Federal Government effective protection and representation of the interests of consumers, and for other purposes."


At head of title: 94th Cong., 1st sess. Committee print.


"Serial no. 95-170"
B. DEBATE PROPOSITION ONE—RESOLVED THAT THE FEDERAL GOVERNMENT SHOULD
INITIATE AND ENFORCE SAFETY GUARANTEES ON CONSUMER GOODS

Rick, Thomas, and Roger E. Kasperson. Pitfalls of hazard management: the CPSC experiment. Environment, v. 20, Oct. 1978: 30-42. The authors critically evaluate the Consumer Product Safety Commission in the areas of setting priorities, "chronic hazard" management, agency independence, and public participation. Two lessons drawn are that there is "a pressing need for the classification of hazards and for a defensible assignment of priorities" and that "little is known about how to give the public an effective voice in bureaucratic decisions."

Former chairman of the Consumer Product Safety Commission (CPSC) examines new initiatives for product hazard data collection, the definition of defect for the purpose of tort liability versus the purpose of reporting to the CPSC, the confidentiality of manufacturers' reports and how the effect of compliance and noncompliance with CPSC actions relates to product liability.


Discusses new regulatory techniques that allow alternative solutions and less burdensome ways of meeting regulatory goals in air pollution, worker safety, product safety and other areas.


"Susan B. King, the commission's new head, believes in government regulation, and she is determined to improve her agency's reputation." Contains excerpts from an Oct. 17 interview.


Article reviews the administration of product safety legislation by the Consumer Product Safety Commission. Notes problems of undue delay in enforcement and an insufficient number of standards. Suggests combining the remedial powers under the various product safety acts.


The author evaluates the Commission's performance, examining both the sources of Commission's regulatory problems and the extent to which recent amendments to the Consumer Product Safety Act will ameliorate these problems. Alternative approaches to the regulation of consumer product safety are suggested. Finds that "the outlook for more than marginal improvement in performance on the part of the Commission is not great."


While it is still too early to evaluate conclusively the new wave of consumer product safety regulation, the evidence thus far indicates that serious resource misallocation is taking place and is likely to continue. The regulators of product safety tend to rely solely on direct controls (product bans and standards) and to be concerned with the benefits only, as measured in the number of lives saved and accidents avoided.

They ignore, often intentionally, the costs of their controls. "Unless this 'safety imperative' approach to regulation is changed,
the problems of resource misallocation will multiply over time as regulatory controls are extended to several additional product classes.

Examines activities of some U.S. agencies with product recall powers (the NHTSA, EPA, FTC, CPSC, FDA and others). Believes that requirements imposed on manufacturers have become too onerous, and that the incentives to avoid accidents should be distributed "more sensibly" between consumer and manufacturer.

Article says that "the pendulum of products liability law has swung too far in favor of the plaintiffs and against the manufacturers and sellers." The author discusses the legislative reforms he believes are necessary to restore the proper balance to the law of products liability including placing more responsibility on the user or consumer of the product.

This paper deals broadly with the question of how government regulation of consumer products can be controlled to prevent either indifference to genuine problems or unnecessary overregulation. It briefly examines the rationale for and mechanisms of government regulation and review possible ways of achieving control of agencies in order to assure balanced regulatory activities.


Critiques the Consumer Product Safety Commission (CPSC) and its unaggressive approach to reducing death and injury to consumers resulting from unsafe products. Specifically cites the CPSC's lack of action in formulating regulations and guidelines for the use of asbestos in products.

Indicates that business must consider instituting a well-defined program to make certain that all echelons in the business are aware of the new concept of strict liability, recent decisions of the courts, the Consumer Product Safety Act, consumer attitudes, and the potential impact of all of this on their business.

Li, L. "The government is getting tougher on product safety, and liability suit awards are soaring. One expert sees the number of product recalls growing at a 10% to 15% annual clip."


"Comment proposes "a blueprint for a model trade association whose testing activities would receive a limited antitrust exemption. Such an exemption would assure the relatively efficient flow of product-quality information while protecting the consumers' interest in competitive markets."


"Author explores the underlying concept of risk and consumer safety and the decision-making process which leads to determining the nature and magnitude of the risk."


"Examines the benefits and costs of various regulatory programs dealing with safety, health, and the environment. The case studies collected were inspired by efforts of the Ford administration's Council on Wage and Price Stability to determine whether proposed regulations are worthwhile."


"Comment illustrates the complexities of establishing a uniform export policy, examines how various statutes regulating drugs, pesticides, chemicals, and consumer products affect exports of domestically banned products, contends that the present approach is inadequate, and outlines the scope of..."
U.S. responsibility to provide safeguards to the purchasers of U.S. products. Suggests a policy "which would reduce the risk of hazardous exports while permitting each nation to make its own informed decision on domestic health and environmental standards.'

Smith, Betty F., and Rachel Dardis. "Cost benefit analysis of consumer product safety standards." Journal of consumer affairs, 11, summer 1977: 34-46. This paper investigates the role of cost-benefit analysis in evaluating consumer product safety standards and argues that such analysis to an evaluation of flammability standards for children's sleepwear. Cost-benefit ratios ranged from 0.62 to 0.89, showing that the standard provided 100% protection.


At head of title: 95th Cong., 1st sess. Committee print.
Partial contents.—The independent status of the regulatory commissions.—Coordination of regulatory programs.—Food regulation.—Transportation regulation.—Banking regulation.—Antitrust enforcement.—Energy regulation.—Health and safety regulation.

Also issued as 95th Cong., 2d sess. Senate. Document no. 95-91.


C. DEBATE PROPOSITION TWO—RESOLVED THAT, THE FEDERAL GOVERNMENT SHOULD ESTABLISH UNIFORM STANDARDS FOR THE REGULATION OF COMMERCIAL ADVERTISING


Brengle, John E. Access of the poor to basic economic needs; a new concern in freedom of speech decisions. Indiana law journal, v. 54, fall 1978: 83-94.

"The Supreme Court has recently expanded the right of consumers to receive relevant product information by ruling that 'commercial speech,' information that concerns only financial transactions, is protected by the First Amendment." Comment examines the ways in which the Court's concern for the poor's access to basic needs has been evidenced in the professional advertising cases and how it may affect future decisions.


Discusses the relationship between advertising, concentration, and profitability. Also examines the role of advertising in informing consumers about the existence of individual producers and the prices of their products.
Can't get enough of that sugar crisp: the First Amendment right to advertise to children. New York University law review, v. 54, June 1979: 581-599. Comment "examines the proposed ban on children's advertising in light of recent developments in the constitutional doctrine of commercial speech. It concludes that the proposed regulations are overly broad and, therefore, unconstitutional."

Examines "the naive and dangerous attitudes that permit consumer fraud, false advertising, and a host of other 'clean crimes,' from tax, stock, and securities fraud to embezzlement and bribery."

Focuses on the debate between advertisers and public-interest groups on the issue of TV advertising aimed at children. Argues that "the battle is so unequal that federal regulatory agencies have a responsibility to act on behalf of the interests of children and parents."

"The Federal Trade Commission is trying to decide how much protection children need from the advertisements they see on television. Critics say the ads for sugary cereals and other products shouldn't be shown to children, but the industry says the critics are off base. The FTC may decide this month what it will do about the complaints."

Article sketches some findings on the impact of television advertising; examines how the FCC (via the fairness doctrine) and the FTC (via deceptive advertising regulation) "could provide for the effective presentation of contrasting points of view on controversial issues implicitly or explicitly raised by television product advertising, could ensure that the implicit messages of such advertisements are delivered fairly and without deception, and could counter the adverse effects of such advertising; and considers constitutional limits on regulatory action."

Article proposes a bifurcated approach to commercial speech cases: a relatively lenient test (the O'Brien test) should be used for State regulation based on the contractual nature of the speech (e.g. misrepresentation), but in other cases, as where State regulation restricts the flow of information, the general First Amendment speech tests should apply.

"The antagonism between the advertising industry and the Federal Trade Commission is increasing as members of the industry are balking at
the commission's latest regulation "tactics." Advertisers call it overregulation and say the situation has reached the point of warfare.


Kramer contends that not only the words but also the "sensory experience" projected by ads should be examined for misleading impressions. Liebeler agrees that deceptiveness should be eliminated, but feels that much of Kramer's argument is based on disapproval of consumer spending decisions rather than on deceptive ads.


Focusing on the New England area, considers the impact of the recent Supreme Court decision which "struck down rules banning advertising by lawyers." Discusses deliberations by the Massachusetts Supreme Judicial Court on whether electronic media-radio and television-advertising will be permitted.


"The author reports on the legal status of commercial speech, from the Supreme Court's 1942 ruling in the Chrestensen case, to the 1975 Bigelow decision. The report indicates confusion and inconsistency in the courts, marked by rulings which have ranged from acknowledging no constitutional protection, to those according full First Amendment protection."


"Argues that "when lawyer advertising leads to lower prices, it need not result in a loss of quality. In fact, quality may be enhanced.""


"Sketches the controversies concerning the effect of advertising on consumer preferences and whether advertising confers monopoly power on the seller. Doubts the value of government regulation of advertising, since "everything that makes a 'socially optimum' advertising policy difficult for the responsible firm would also create difficulties for government regulation.""

Metzger, Michael B., and Barry S. Roberts. The new commercial speech doctrine. MSU business topics, v. 27, spring 1979: 17-23.

"Examines legal cases regarding advertising and finds "the advent of commercial speech doctrine extending the protection of the First Amendment's freedom of speech to previously unprotected advertising language.""

Says that for the soft-drink industry "concentration is now high, entry into the national market has stopped completely, and consumer prices for soft drinks are substantially above the competitive level. Large-scale advertising has once more taken its toll, converting what might have been a highly competitive American industry into a tightly oligopolistic one that serves the public poorly."


Article "examines the economic and legal justifications for ad regulation, suggests the contours of a consumer-oriented regulatory program, and assesses recent departures from traditional ad regulation by the Federal Trade Commission."


Article surveys recent Supreme Court decisions which "have eliminated the doctrine that commercial speech is wholly outside the protection of the First Amendment (in other words, that it is really 'nonspeech'), and in its place have established the principle that speech that does no more than propose a commercial transaction is entitled to a 'lesser degree' of constitutional protection. . . . Although this modified doctrine is well-suited to commercial speech, its appropriateness for other areas is highly questionable."


Article discusses the Federal Trade Commission's requirement of a "reasonable basis" of substantiation for claims made in advertisements. Critiques the case-by-case approach of the Commission and concludes that "it is hard to devise an effective advertisement immune from some risk of an FTC 'reasonable basis' complaint; it is hard to mount an effective defense when such a complaint is issued; and it is hard to negotiate a settlement."


Maintains that the regulation of advertising is not in fact designed to maximize the economic well-being of consumers.

616
Contend that the "court ruling in two cases that commercial advertising has First Amendment protection is in conflict with actions of agencies on behalf of consumers."


"Serial no. 96-69"


D. DEBATE PROPOSITION THREE—RESOLVED THAT, THE FEDERAL GOVERNMENT SHOULD ESTABLISH UNIFORM STANDARDS FOR TESTING AND MARKETING ALL PRODUCTS WITH POTENTIALLY CARCINOGENIC EFFECTS ON HUMANS


Gives background on the Delaney Clauses in the Federal Food, Drug, and Cosmetic Act, which require the FDA to test specifically for carcinogens. Discusses other criteria and procedures that the FDA uses to regulate carcinogens in food, drugs, and cosmetics.


The main flame retardant in children’s pajamas is a mutagen and should not be used.

"Federal agencies are divided on quantification; OSTP [Office of Science and Technology Policy] proposes a centralization of authority."


"After years of interagency rivalries, five federal agencies have negotiated a battle plan for the war on cancer that is aimed at eliminating inconsistencies in the way the government regulates cancer-causing substances in the environment, the workplace and the market. The five-agency agreement also paves the way for a period of rapid growth in such regulation."


"Should potentially hazardous food additives be permitted on the market if they provide other kinds of health benefits? Should economic considerations enter into decisions to order additives off the market? These are some of the questions that the Food and Drug Administration and Congress are asking as they review the nation's food laws."


"It is now clear... that most, if not all cancers have environmental causes and can in principle be prevented. The identification of environmental hazards and clarification of the mechanisms through which they cause disease are thus among the highest priorities in cancer research."


"Presents two views of the relationship between cancer and chemicals; one from a member of the Consumer Product Safety Commission and the other from an executive of Du Pont Corporation."


"When setting priorities for safety evaluation of food ingredients, two broad overlapping areas of concern must be recognized: (1) the total universe of chemicals in man's environment of which food ingredients are a small and relatively well-defined segment, and (2) the relative potential hazard of the individual food ingredients."


Hutt, Peter Barton. Unresolved issues in the conflict between individual freedom and government control of food safety. Food drug cosmetic law journal, v. 33, Oct. 1978: 558-589. Contends that our current no-risk food safety policy is unattainable because carcinogens pervade our entire food supply. Concludes that Congress and the FDA must begin to formulate new food safety policy and outlines related legal considerations. Discusses sources of food safety data and the need for consistent rules to guide regulatory decisions. Urges the participation of qualified scientists and the general public in food policy formulation.

Kirschten, Dick. The new war on cancer—Carter team seeks causes, not cures. National Journal, v. 9, Aug. 6, 1977: 1220-1225. Describes the Carter Administration's efforts to coordinate the activities of agencies regulating toxic substances. The backgrounds of Carter appointees to enforcement and research positions are outlined.

Lijinsky, William. How nitrosamines cause cancer. New Scientist, v. 73, Jan. 27, 1977: 216-217. By systematically modifying the molecular structure of nitrosamines it is proving possible to pin down chemically the cancer-inducing activity of these important environmental contaminants.


O'Connor, Charles A. and Stephen C. Woodward. Filling gaps in chemical carcinogenesis: a defensive research program. Chemical times & trends, v. 3, Oct. 1979: 10-13, 48-53. To date federal agencies have regulated the majority of suspect chemical carcinogens based not upon human but upon animal data. Avoiding human exposure to carcinogens by identifying them first in experimental animals, of course, is the ideal. Yet it assumes what is still at issue, namely, whether experimental data is a reliable predictor of human carcinogenicity.
are food additives overregulated? food drug cosmetic law journal, v. 31, nov. 1976: 627-635.

describes "the plethora of regulations applicable to food safety and the relative roles of the fda and congress."

Regulatory aspects of carcinogenesis and food additives: the Delaney case.
(ecotoxicology and environmental quality, 2d v.)


Rorvik, david m. cancer and cancer research. new york, alicia patterson foundation, 1977. 28 p.

Article discusses the politics of cancer research, including the problems Linus pauling has had with the national cancer institute over the use of vitamin C in cancer research.

Presents a critical look at American cancer research, especially as it applies to environmental and occupational health.

The controller general comments on the "GAO's work in reviewing Federal policies for regulating cancer causing chemicals in our environment," and reviews the tobacco-smoking controversy.


"serial no. 95-8"


"serial no. 95-118"


Report concludes that saccharin is a carcinogen, based on the evidence of "a significant increase in the incidence of bladder cancer in rats" fed high levels of saccharin, which "leads to the conclusion that saccharin is a potential cause of cancer in humans.

605


"Industry as represented by an American Industrial Health Council paper faults the logic and the methodology of a recent government study which attempts to estimate future cancer deaths from present and past worksite exposures."
HOW TO SECURE ADDITIONAL MATERIAL ON CONSUMER PROTECTION

A. GENERAL INDEXES

To update or expand this compilation the debater may wish to consult such indexes as Readers' Guide to Periodical Literature and Magazine Index (a microfilm publication), guides to general and non-technical periodicals; Bulletin of the Public Affairs' Information Service, a subject list of books, pamphlets, government publications, reports of research organizations, and periodical articles; Social Sciences Index, an index to selected English language journals; Index to Legal Periodicals for law journal articles; Vertical File Index, a list of free and inexpensive pamphlets, leaflets, and mimeographed materials; and the Journal of Economic Literature and Index to Business Periodicals, indexes to economics and business literature. The New York Times Index, the Wall Street Journal Index, and the Index to the Christian Science Monitor are relatively long-standing indexes to newspaper articles. More recently, the Bell & Howell Newspaper Indexing Center has compiled indexes for the Chicago Sun-Times, the Chicago Tribune, the Denver Post, the Detroit News, the Houston Post, the Los Angeles Times, the New Orleans Times-Picayune, the San Francisco Chronicle, and the Washington Post.

B. FEDERAL GOVERNMENT PUBLICATIONS

Some of the most valuable sources of information on consumer issues and developments are U.S. Government publications. Government publications available to the general public are listed in the Monthly Catalog of United States Government Publications. The Monthly Catalog provides an index to congressional hearings, reports, documents, and committee prints, as well as to publications of the executive departments. All material in this catalog is available for purchase, if still in print; or items might be obtained from your local library, from one of the over 1300 libraries serving as depository libraries for Government publications, or on interlibrary loan.

The Congressional Record contains the debates on the floors of Congress and inserted articles and speeches presented elsewhere. The Record is printed daily during sessions of Congress with a bi-weekly index. Bound volumes of the Record are published at the end of each Congress with a cumulative index for each session. Pagination differs between the daily and the bound editions. The Digest of Public General Bills and Resolutions, issued several times during each session, provides a summary of each public bill and resolution and its current status in the legislative process.

C. SOURCES COVERING CONGRESS AND THE EXECUTIVE BRANCH

Several periodical services regularly analyze current issues involving the Federal Government. Congressional Quarterly Weekly Report summarizes congressional activity for the preceding week and includes background information on

(623)
I. Issues before Congress. The Congressional Quarterly Almanac is an annual comprehensive review of the legislative session. The weekly National Journal covers recent congressional and executive branch developments and their impact. Congressional Digest features a pro-con discussion of one current legislative problem in each of ten issues per year. The Commerce Clearing House Congressional Index is a loose-leaf service reporting the status of pending legislation. The United States Code Congressional and Administrative News reproduces public laws, House and Senate reports of each bill that becomes law, legislative histories, and an essay section discussing issues before Congress. A further aid in finding information published by Congress is CIS Annual and its monthly updates, published by the Congressional Information Service. This publication indexes and abstracts congressional hearings, reports, documents, and committee prints. Congressional materials are indexed by subject, names of hearing witnesses, authors, affiliations of witnesses, popular names of bills and reports, and law, bill, report, and document numbers.

D. CONSUMER PERIODICALS AND NEWSLETTERS

Debaters may wish to monitor on a regular basis the following list of publications in order to be aware of the latest writing on the subject of consumer protection:

- CFA News (10 times annually), Consumer Federation of America, 1012 14th St., N.W., Washington, D.C.
- Journal of Consumer Affairs (semi-monthly), American Council on Consumer Interests, 238 Stanley Hall, University of Missouri, Columbia, Mo.
- Of Consuming Interest, Federal-State Reports, Inc., P.O. Box 986/Court House Station, Arlington, Va.
- Product Safety and Liability Reporter (weekly), Bureau of National Affairs, Inc., Washington, D.C.
E. FEDERAL AGENCIES

Below is a list of Government agencies that the debater may wish to contact for additional consumer protection information. Contact should be made with the Office of Public Information in the respective agencies.

Consumer Product Safety Commission (CPSC)
1111 18th Street, N.W.
Washington, D.C. 20207

Department of Agriculture (DOA)
The Mall, between 12th and 14th Streets, S.W.
Washington, D.C. 20250

Department of Health and Human Services (HHS)

Food and Drug Administration
3500 Fishers Lane
Rockville, Md. 20857

Office of Consumer Affairs
330 Independence Ave., S.W.
Washington, D.C. 20201

Department of Housing and Urban Development (HUD)
451 7th Street, S.W.
Washington, D.C. 20410

Department of Transportation (DOT):

Federal Aviation Administration (FAA)
800 Independence Avenue, S.W.
Washington, D.C. 20591

National Highway Traffic Safety Administration (NHTSA)
400 7th Street, S.W.
Washington, D.C. 20590

U.S. Coast Guard
400 7th Street, S.W.
Washington, D.C. 20590

Environmental Protection Agency (EPA)
401 M Street, S.W.
Washington, D.C. 20580

Federal Trade Commission (FTC)
Pennsylvania Avenue at 6th Street, N.W.
Washington, D.C. 20580

General Services Administration (GSA)
Consumer Information Center
Pueblo, Co. 81009
PUBLICATIONS RELATING TO THE
1980-81 NATIONAL HIGH SCHOOL DEBATE TOPIC

How Can the Interests of United States Consumers Best Be Protected?


Advertising for Over-the-Counter Drugs:


Staff Report and Recommendations. 1979. 313 p.

Advertising of Ophthalmic Goods and Services. Similar to the issue of Disclosure of Prescription Drug Prices, this analysis focuses on State and local restrictions in the ophthalmic field in medicine and industry, and recommends various changes to better serve the interests of the consumer. 1976. 168 p.

Advertising of Proprietary Medicines; Hearings Before the Subcommittee on Monopoly and Anti-Competitive Activities of the Select Committee on Small Business, Senate, 94th and 95th Congress, 1st Session; (All missing parts are out of print.)

Part 4, Antacids, June 6, 1973 and June 4-5, 1974. 1974. p. 153-1672. 11. 4.5m 1/2:M 46/p.4

High School Debate


Biological Effects of Electromagnetic Waves, Selected Papers of the USNC/URSI Annual Meeting, Boulder, Colorado, October 20-23, 1975;


Biological Effects of Ionizing Radiation: Pertinent Federal Laws and Regulations:

Summary. 1979. 28 p. HE 20.3002:r 11 S/N 017-040-00455-9 1.50


Bureau of Radiological Health, A Look at FDA's Program to Protect the American Consumer From Radiation. Publication looks at a Food and Drug Administration program. 1977. 18 p. HE 20.4102:r 11/13 S/N 017-015-00128-8 1.20

Cancer Rates and Risks. An accumulation of facts about cancer for physicians, medical students, teachers, and others concerned with the disease. The statistics and summaries are divided into four sections, covering cancer in the United States, distribution of various forms of cancer, factors associated with high or low cancer risks, and treatment and survival of cancer patients. 1974. 108 p. 11. HE 20.3152:r 11/974 S/N 017-042-00086-6 1.80

Cancer Testing Technology and Saccharin. This volume is important reading for those interested either in the use of saccharin or the validity of high-dose animal tests for carcinogens. 1977. 149 p. 11. Y 3.T 22/2:2 C 16 S/N 052-003-00471-3 3.25
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<th>Title</th>
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<td>Carcinogens: Control Procedures for the Safe Handling and Use of Cancer-Causing Substances in the Workplace. Publication report on 14 cancer-causing substances found in the American Workplace. Contents of publication: Pt. 1, What the employer must do; Pt. 2, What the employee must know.</td>
<td>1975</td>
<td>19</td>
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<td>Carcinogens in the Environment. Reprinted from the Sixth Annual Report of the Council on Environmental Quality, 1976. It discusses the relationship of environmental factors to cancer, focusing on chemicals introduced into the environment by our consumption patterns and way of life.</td>
<td>1976</td>
<td>42</td>
<td>$0.75</td>
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<td>Care Labeling of Textile Products and Leather Wearing Apparel: Staff Report to the Federal Trade Commission and Proposed Revised Trade Regulation Rule (16 CFR part 423.)</td>
<td>1978</td>
<td>481 p.</td>
<td>$6.75</td>
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<td>Conference on Occupational Health Experience With Uranium.</td>
<td>1975</td>
<td>476 p.</td>
<td>$5.20</td>
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Consumer Aid Series - con.

TD 8.14/21/pt.1  S/N 050-003-00226-7  $ .95

TD 8.14/21/pt.2  S/N 050-003-00227-5  $ 1.00

J 24.2/C 76/3  S/N 027-000-00062-1  $ 3.50

FT 12/C 76/5  S/N 016-000-00235-1  $ 7.50

GS 4.110:95/631  S/N 022-003-92162-1  $.80

A 1.75:355/2  S/N 001-000-02790-5  $ 1.75

Y 4.0 74/9:C 76/977  S/N 052-070-04147-1  $ 3.25

Contrary to Nature: Being an Illustrated Commentary on Some Persons and Events of Historical Importance in the Development of Knowledge Concerning Cancer. This is an impressive, well-researched book on the history of cancer and cancer research. It begins by examining two of the oldest written records of man, the Egyptian papyruses (written 3,500 years ago), which make references to "large tumours" on the body. It continues by describing important persons and events in the study of cancer during the Graeco-Roman period, the Middle Ages, and the 16th through the 20th centuries. Most of the book is devoted to progress made since World War II. This is an excellent book for anyone interested in how knowledge concerning cancer has been developed over the years. 1977. 458 p. 11. 
HE 20.3002:H 21/8  S/N 017-042-00128-5  $ 14.75

Criteria for a Recommended Standard: Occupational Exposure During the Manufacture and Formulation of Pesticides. 1978. 429 p. 11. 
HE 20.7110:P 43  S/N 017-033-00347-9  $ 6.25

Current Literature Report on the Carcinogenic Properties of Ionizing and Nonionizing Radiation: 
Volume 1, Optical Radiation. 1977. 90 p. 11. 
HE 20.7111/2:C 11/v.1  S/N 017-033-00280-1  $ 2.75

613
High School Debate

Current Literature Report, con.


Don't Be Gypped. This bulletin is designed to help the consumer avoid deceptive business practices. Also advises the consumer of help available if he has been misled, sold a shoddy product, or given poor service. 1972. 6 p. ill. N 1.3/2:8 3.50


Environmental Protection Agency and the Regulation of Pesticides, Staff Report. This is a Senate staff report that points out problems and deficiencies in EPA's pesticide programs. The introduction was written by Senator Edward Kennedy, who is a critic of the EPA in this regard, 1976, 50 p.


FDA Consumer. (Monthly except July-August and December-January which are combined issues.) Contains information written especially for consumers about Food and Drug Administration regulatory and scientific rationale, and about the safe use of products regulated by FDA. Subscription price: Domestic - $12.00 a year; Foreign - $15.00 a year. Single copy price: Domestic - $1.00 a copy; Foreign - $2.25 a copy. [FDAP] (File Code 2G)

General Services Administration Consumer Information Booklets. These booklets are designed to tell the consumer in simple language what GSA has learned in buying products for the Government. By discussing the selection, use and maintenance of various products, these booklets will help you make better informed purchases.

Automobile Batteries, Their Selection and Care. 1971, 13 p.

Food Advertising:


Household Cleaners. The household all-purpose cleaner will always absorb all of the household features needed for a well-balanced, non-abrasive finisher. It will strip away daily grime and protect the delicate surfaces, both inside and outside, of your home. 1974. 8 p. 11.

OS 2.16:12
S/N 022-000-00000-2

Household Cleaners: Buying Guide. A new publication offers comprehensive instructions on choosing the best household cleaners. This guide provides tips on selecting, purchasing, and using cleaning products, including advice on how to clean various surfaces, from countertops to floors. 1974. 16 p. 11.

OS 2.16:11
S/N 022-001-00059-1

Mixers and Blenders. This consumer information booklet provides advice on what to look for when purchasing mixers and blenders. Although brand names are not mentioned, the booklet does outline the major features available in these appliances, as well as safety, performance, and price guidelines. Also included are sections on safe use, and tips for finding the best deals. 1973. 8 p. 11.

OS 2.16:13
S/N 022-000-00077-2

Power Hand Tools. Explains safety, quality, and suitability features to look for. Sections on selecting drills, drill accessories, bolt extractors, finishers, Sanders, and metalworking tools, as well as tips for finding the best deals. Also included are sections on safe use, and tips for finding the best deals. 1973. 8 p. 11.

OS 2.16:16
S/N 022-003-00002-7

Handbook and Standard for Manufacturing Safer Consumer Products. This publication helps industry implement the Consumer Product Safety Commission’s System Standard by supplying background information regarding the rationale of its requirements as well as suggestions and ideas for its implementation. Rev. 1977. 82 p. 11.

S/N 052-011-00102-2

Health and Safety Guide for Pesticide Formulators. This booklet describes health and safety hazards and discusses proper safety practices that minimize the hazards. 1977. 102 p. 11., 3 plates.

S/N 017-033-00243-6

History of the Comstock Patent Medicine Business and Dr. Morse's Indian Root Pills. 1972. 49 p. 11.

S/N 047-000-00004-4


S/N 032-000-00227-6


S/N 029-015-00053-8


National Business Council for Consumer Affairs:


National Cancer Program, Hearings Before the Committee on Government Operations, House, 95th Congress, 1st Session:


High School Debate . . .

Perinatal Carcinogenesis. Conference was held in Tampa, Florida, January 10-21, 1976. Contents of publication: Human experience; Experimental studies on hormones; Hormonal carcinogenesis; Transplacental carcinogenesis in the nervous system; and Perinatal carcinogenesis and carcinogen bioassay procedures. 1979. 282 p. 11. Clothbound. HE 20.3162:51S/N 017-042-00139-1 $10.00

Pesticides Abstracts. (Monthly and Annual Index.) Monthly publication of the United States Environmental Agency which fosters current awareness of the major worldwide literature on effects of pesticides. Reviews more than 2,000 domestic and foreign sources. Periodicals from which articles have been abstracted are listed in each January issue. Subjects and authors of abstracted articles are cross-referenced in March, June, September, and the annual index issue. Subscription price: Domestic -$21.00 a year; Foreign - $26.25 a year. Single copy price: Domestic - $1.60 a copy; Foreign - $2.00 a copy. Annual Index: Domestic - $1.80 a copy; Foreign - $2.30 a copy. (HAPS) (File Code 2M) (P 5.9)

Pesticides Monitoring Journal. (Quarterly.) Interagency publication of the National Pesticide Monitoring Program which publishes Federal findings on pesticide levels in humans and all other elements of the environment. Includes extensive tables of monitoring data. Accepts monitoring studies from State and local governments, universities, private industry and foreign nations. Appears in March, June, September, and December; subject/author index is in March issue. Subscription price: Domestic - $7.90 a year; Foreign - $9.90 a year. Single copy price: Domestic - $2.00 a copy; Foreign - $2.50 a copy. (PMJ) (File Code 20) (P 6.7)

Population Dose and Health Impact of the Accident at the Three Mile Island Nuclear Station (A Preliminary Assessment for the Period March 28 Through April 7, 1979). This publication outlines the findings of an Ad Hoc Population Dose Assessment Group. It presents an assessment of the collective radiation dose received by the population and addresses several areas of concern about the type of radiation released, the contribution to population exposure due to beta radiation, the degree of coverage afforded by available radiation measurements, and the range of health effects that may result from the estimated collective dose. 1979. 99 p. Y 3.N 88:2 P 81 S/N 017-001-00408-1 3.75


Price of Death, A Survey Method and Consumer Guide for Funerals, Cemeteries, and Grave Markers. 1975. 16 p. IF 1.8/3 3 S/N 018-000-00185-3 1.05
High School Debate...

Procedures for Field Testing Microwave Ovens. Gives procedures for testing ovens for compliance with the microwave emission and safety interlock operation requirements of the Federal radiation safety performance standard. The manual is useful for Food and Drug Administration, State and local testing personnel. 1977. 35 p. ill. HE 20.4108: M 58 S/N 017-015-00138-5 $ 1.60

Radiation Hazard in Mining. Dealing with the occurrence of lung cancer among underground miners caused by breathing radioactive dust particles known as radon daughters. 1977. 30 p. ill. T 69.8/2:7 S/N 026-019-00025-0 1.50


Safe Handling of Radioactive Materials: Recommendations of the National Committee on Radiation Protection. 1964. 107 p. ill. C 13.11:92 S/N 003-003-00136-8 2.10


Sales, Promotion, and Product Differentiation in Two Prescription Drug Markets. This is a Bureau of Economics study of product differentiation and its relationship to brand promotion and brand sales. The study focused on two therapeutic markets for prescription drugs. It sought to determine the validity of the widely-held notion that leading brands gain and retain market dominance primarily as a result of promotional activity. 1977. 164 p. FT 1.2:0 84/2 S/N 018-000-00207-8 2.75
Survey of Compounds Which Have Been Tested for Carcinogenic Activity:
Clothbound. 2 sections, sold as a set.
HE 20.3152:C 17/66-67  S/N 017-0042-00605-5  $48.75

J 1.2:C 76/13  S/N 027-000-00672-8  4,25

HE 20.401226:56/56  S/N 017-015-00149-1  2.50

HE 20.7112/2:C 17/976  S/N 017-033-00224-0  4.50

Y 3.0 76/3:2 L 87  S/N 052-011-00120-1  4.50

Television Advertising to Children. Summarizes petitions from Action for Children's Television, and the Center for Science in the Public Interest, requesting the promulgation of a trade rule regulating television advertising of candy and other sugared products to children. 1978. 365 p.
FT 1.2:T 23/2  S/N 018-000-00228-1  6.00

Vinyl Chloride, Fact Sheet 58. 1975. 2 p.
Y 3.0 76/3:11/58  S/N 052-011-00066-6  1.75

We Want You to Know About:
HE 20.4002:C 1  S/N 017-012-00181-5  .35


FT 1.2:F 31/6/976  S/N 018-000-00199-3  .55

620