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ABSTRACT

This hearing includes testimony on contaminated strawberries in school lunches. Contaminated strawberries were determined to be the cause of an outbreak of hepatitis in the state of Michigan. In addition to statements by the committee members, testimony was given by: (1) Mary Ann Koeffe, Acting Under Secretary, Food Nutrition and Consumer Services, Department of Agriculture; (2) Lon Hatamiya, Administrator, Agricultural Marketing Service, U.S. Department of Agriculture, accompanied by Craig Beauchamp, Office of the Inspector General, U.S. Department of Agriculture; Harold Margolis, Centers for Disease Control and Prevention; and Fred Shank, Food and Drug Administration; (3) David R. Johnson, the chief executive and medical officer, Community Public Health Agency, Michigan Department of Community Health, Lansing, MI; (4) Thomas W. Schimm, a teacher and parent of a child who contracted hepatitis; and (5) Susan Doneth, a mother and member of the Safe Tables Our Priority (S.T.O.P.), Marshall, MI. An appendix contains additional material submitted for the record, including questions submitted to government agencies by committee members and a letter to the committee. (EV)

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CONTAMINATED FROZEN STRAWBERRIES IN SCHOOL LUNCHES

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ED 424 028

HEARING

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY UNITED STATES SENATE

ONE HUNDRED FIFTH CONGRESS

FIRST SESSION

ON

CONTAMINATED STRAWBERRIES IN SCHOOL LUNCHES

JUNE 5, 1997

Printed for the use of the
Committee on Agriculture, Nutrition, and Forestry



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(II)

C O N T E N T S

	Page
Statements:	
Hon. Richard G. Lugar, a U.S. Senator from Indiana	1
Prepared statement	3
Hon. Larry E. Craig, a U.S. Senator from Idaho, prepared statement	4
Hon. Spencer Abraham, a U.S. Senator from Michigan	4
Prepared statement	7
Hon. Nick Smith, a U.S. Representative from Michigan	9
Prepared Statement	10
Hon. Charles E. Grassley, a U.S. Senator from Iowa	11
Hon. Paul Coverdell, a U.S. Senator from Georgia	12
Prepared statement	12
Hon. Patrick J. Leahy, a U.S. Senator from Vermont	30
Mary Ann Keffe, Acting Under Secretary, Food Nutrition, and Consumer Services, Department of Agriculture, Washington, DC.	13
Lon Hatamiya, Administrator, Agricultural Marketing Service, U.S. Department of Agriculture; accompanied by Craig Beauchamp, Office of the Inspector General, U.S. Department of Agriculture; Harold Margolis, Centers for Disease Control and Prevention; and Fred Shank, Food and Drug Administration, Washington, DC.	15
David R. Johnson, chief executive and medical officer, Community Public Health Agency, Michigan Department of Community Health, Lansing, MI	31
Thomas W. Schimm, teacher, minister of music, Holy Cross Lutheran Church and School, Saginaw, MI	33
Susan J. Doneth, mother and member, Safe Tables Our Priority (S.T.O.P.), Marshall, MI	34

APPENDIX

Prepared Statements:	
Acting Under Secretary Mary Ann Keffe, with attachments	39
David R. Johnson	46
Thomas W. Schimm	47
Susan J. Doneth	48
Additional material submitted for the record:	
Senators' questions submitted to the witnesses and responses thereto:	
Senator Landrieu's questions submitted to the Centers for Disease Control and Prevention	52
Senator Coverdell's questions submitted to the Centers for Disease Control and Prevention	52
Senator Landrieu's questions submitted to Food and Drug Administration (FDA)	53
Senator Coverdell's questions submitted to Food and Drug Administration (FDA)	54
Letter:	
To the Senate Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, Washington, DC., from Kevin Thompson, Pennfield High School, Battle Creek, MI	56

CONTAMINATED FROZEN STRAWBERRIES IN SCHOOL LUNCHES

THURSDAY, JUNE 5, 1997

**U.S. SENATE,
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,
Washington, DC.**

The committee met, pursuant to notice, at 9:03 a.m., in room SR-328A, Russell Senate Office Building, Hon. Richard G. Lugar (Chairman of the Committee) presiding.

Present or submitting a statement: Senators Lugar, Craig Coverdell, Grassley, Leahy, and Abraham.

STATEMENT OF HON. RICHARD G. LUGAR, A U.S. SENATOR FROM INDIANA

The CHAIRMAN. This hearing of the Senate Agriculture Committee is called to order.

The committee will hear testimony this morning concerning the recent outbreak of hepatitis A that has caused approximately 250 Michigan school children to become ill. Evidence indicates that infections were most likely caused by contaminated frozen strawberries served as part of school lunches.

Broadly speaking, this committee is responsible for leadership on matters of nutrition, including the safety of our food supply. More specifically, we have jurisdiction over the Federal School Lunch and School Breakfast Programs, which make a critical contribution to the nutritional requirements of our Nation's children.

This morning's hearing will allow us to establish a record of the facts behind this case. Perhaps more important, I hope the session will give all of us direction on how to prevent a similar outbreak in the future. It was only recently that enough information on this tragedy in Michigan was unearthed to permit us to have a useful hearing.

Today, we have with us representatives of the Department of Agriculture, the Food and Drug Administration, the Centers for Disease Control and Prevention, as well as the Michigan Department of Community Health. The USDA, the Agency for which this committee has direct oversight, has generally done a commendable job in connection with the hepatitis outbreak. However, I am troubled by reports that USDA was aware beforehand that the company suspected of supplying the tainted strawberries may have broken the law regarding domestic origin of school lunch commodities, and I hope that more light can be shed on this issue by our witnesses today.

(1)

I also thank the Senators from Michigan for their leadership on this issue. Most specifically, my Colleague, Senator Spence Abraham, is with us this morning and will be testifying shortly, as will Congressman Nick Smith of Michigan.

Let me say that we are especially pleased to have with us from Michigan today parents of two students who were stricken with the hepatitis A virus and we welcome them and look forward to their testimony.

The safety of our food supply, especially food consumed by our children, is of paramount concern to all of us. We want to ensure continued public confidence in the School Lunch Program, which feeds more than 25-million children every day.

Before I recognize Senator Abraham for his testimony, I want to note for the record that in response to a letter recently sent to Donna Shalala, the Secretary of the Department of Human Services, she has responded with a letter dated May 30, 1997, and I want to quote from parts of that. It will all be made a part of the record, but portions of her answers are relevant.

The CHAIRMAN. Ms. Shalala in her letter points out that she appreciates the correspondence from Senator Harkin and myself, and then responds to questions that we asked. The first question was: "Where, when, and how were the strawberries contaminated?" She responds, "The source of the contamination is not known and may never be determined. The epidemiological investigation conducted by CDC found that consumption of frozen strawberries was associated with the illness. The investigation did not identify a single event, food handler, or contaminated water source to explain the source of the contamination of the strawberries. The CDC analysis suggests that the contamination occurred prior to the arrival of the frozen strawberries in Michigan. After the outbreak occurred, FDA staff observed the fields in Mexico where the strawberries were grown and picked. They found some deficiencies in sanitation. However, since the strawberries were picked about 1 year ago, we can only speculate about the conditions that existed in the fields at the time.

USDA had an inspector in the packing and processing plant at the time the strawberries were processed. The USDA inspector did not report any sanitation deficiencies. Most of the employees who picked and who processed the strawberries a year ago have dispersed and are not available for interviews. FDA had hoped to locate and interview employees of the processing plant about illnesses they may have had at the time the contaminated lots of strawberries were processed. However, the employees have not returned to work, since the plant has not reopened this season. We will advise you as additional information about the source of the contamination becomes available."

A second question we asked was: "How does FDA communicate with USDA about the food safety history of a packer/processor when the packer/processor is involved in a Federal contract to distribute food through the school meals program?" Her answer was, "There is a cooperative agreement between USDA's Agricultural Marketing Service and the FDA regarding inspections of food processing and packing plants. This agreement outlines the information communicated by the Agencies to each other.

When AMS has an inspector stationed at the plant, as was the case with the plant that processed the strawberries, FDA minimizes its inspections of the plant to avoid duplicative inspections. Under the agreement, AMS notifies FDA of sanitation problems or deficiencies in good manufacturing practices. FDA notifies AMS whenever FDA finds objectionable conditions in plants under AMS contract or in other food plants, and a copy of this agreement is enclosed for your convenience, and Ms. Shalala has enclosed that.”

Finally, we asked question 3: “Have all of the contaminated strawberries now been removed from the marketplace?” She responds, “The 13 lots of frozen strawberries implicated by CDC in the outbreak have been recalled from the market by the company that packed and processed them. USDA immediately notified schools that had received these lots to place the product on hold so they would not be served in the Lunch Program. The company began a recall of these 13 lots on March 29, 1997. FDA verified that the recall of these implicated lots is complete. The company also its distributors to voluntarily withdraw the remainder of the strawberries processed in 1996 from the market. It is important to note that the recall of the 13 lots does not raise any concerns about this year’s harvest of strawberries, nor is there any concern regarding fresh or fresh frozen strawberries now appearing in grocery stores.”

There are other questions and answers, but these, it seemed to me, were relevant and may bring response from witnesses as we proceed with our hearing today.

[The prepared statements of Senator Lugar and Senator Craig follow, respectively.]

STATEMENT OF SENATOR RICHARD G. LUGAR

The committee will hear testimony today regarding the recent outbreak of hepatitis A that caused approximately 250 Michigan school children to become ill. Evidence indicates that the infections were most likely caused by contaminated frozen strawberries served as part of school lunches.

Our attention to this untimely occurrence takes two forms. Broadly speaking, this committee is responsible for leadership on matters of nutrition, including the safety of our food supply. More specifically, we have jurisdiction over the Federal School Lunch and School Breakfast Programs, which make a critical contribution to the nutritional requirements of our Nation’s children.

This morning’s hearing will allow us to establish a record of the facts behind this case. Perhaps more important, I hope that this session will give all of us direction on how to prevent a similar outbreak in the future. It was only recently that enough information on this tragedy in Michigan was unearthed to permit us to have a useful hearing.

Today, we have with us representatives of the Department of Agriculture, the Food and Drug Administration and the Centers for Disease Control and Prevention, as well as the Michigan Department of Community Health. USDA, the Agency for which this committee has direct oversight, has generally done a commendable job in connection with the hepatitis outbreak. However, I am troubled by reports that USDA was aware beforehand that the company suspected of supplying the tainted strawberries may have broken the law regarding domestic origin of school lunch commodities. I hope more light can be shed on this issue by our witnesses today.

I also thank the Senators from Michigan for their leadership on this issue and their assistance in making this hearing possible. My Colleague Senator Abraham is with us this morning and will be testifying shortly, as will Congressman Smith. Also with us from Michigan today are the parents of two students who were stricken with the hepatitis A virus. We welcome them and look forward to their first-hand testimony.

The safety of our food supply, especially the food consumed by our children, is of paramount concern to all of us. We want to ensure continued public confidence in the School Lunch Program, which feeds more than 25-million children every school day.

I look forward to hearing from all our witnesses.

STATEMENT OF SENATOR LARRY E. CRAIG

RE: CONCERNING THE MICHIGAN HEPATITIS A OUTBREAK

Thank you, Mr. Chairman. I would first like to thank the Chair, Senator Lugar, and the Ranking Member, Senator Harkin, for holding this hearing and giving the committee the opportunity to investigate this important topic.

We are here to discuss the recent outbreak of hepatitis A and its many ramifications. I look forward to hearing from our Colleague Senator Abraham, along with Congressman Smith and those who have traveled from Michigan to be with us today. I am sure that they will tell us about the more than 220 people directly affected by this tragedy and how their lives have been changed.

In addition to personal tragedies, this event highlights another national tragedy: a *breakdown* at USDA, and the *entire* School Lunch Program.

The simple fact of the matter is that the strawberries at the root of this hepatitis A outbreak weren't even supposed to be served at school. We have laws, Mr. Chairman, fashioned by this very committee, to prevent the use of foreign commodities in our School Lunch Program. I fear this entire incident, including all the personal pain and suffering we will hear about today, could have been avoided had the USDA only taken the necessary precautions to enforce these laws.

Since the outbreak, the Secretary has announced his 11-point program to avoid future disasters. What of those for whom the 11-point program comes too late? What of those the USDA was supposed to protect and didn't? If the Secretary's new 11-point program is the answer, why wasn't it in place to prevent this episode?

I do, however, support the Secretary's new found focus on food safety. It is surely long over due. I look forward to hearing of the progress being made at USDA and hope the committee can join in supporting this new initiative.

Mr. Chairman, I believe some have a lot of explaining to do. I hope we are all resolved to never let any Federal program be abused like this ever again. Today we will have the opportunity to address these issues as well as the facts surrounding the Michigan event. I look forward to hearing from those before us here today.

The CHAIRMAN. When the Distinguished Ranking Member of the Committee arrives . . . Senator Harkin, I will, of course, recognize him for his statement. For now, it is a pleasure to introduce and to recognize my Colleague, Spence Abraham, of Michigan, for his testimony.

STATEMENT OF HON. SPENCER ABRAHAM, A U.S. SENATOR FROM MICHIGAN

Senator ABRAHAM. Thank you very much, Mr. Chairman, and let me just begin by thanking you and your staff for having worked with us to put this hearing together. We are very grateful, and I know Congressman Smith will be speaking in a few moments and all of us appreciate having the opportunity to have the Agriculture Committee take a look more closely at the issue which we are here today.

The week after Easter, this headline appeared in the Detroit News, one of our large papers. It says specifically, "State Fears More Hepatitis Cases." The accompanying story reports that as of that date, 180 Michigan residents, mostly school children, were infected with the hepatitis A virus after eating contaminated strawberries served in the School Lunch Program. That was April 3. Today, the number is closer to 229 persons in our State, the hard-

est hit, and I think to this extent, the only State which had hepatitis A outbreak linked to the fruit. The outbreak is largely concentrated in Calhoun and Saginaw counties, affecting students, teachers, support staff, and parents.

This much we know about how it began. the strawberries, as you just indicated, were harvested in Mexico, then frozen and processed last spring by Andrew and Williamson, a San Diego company. They were shipped for bulk distribution to USDA-sponsored School Lunch programs in December. In addition, this same company shipped frozen strawberries to about 200 Detroit businesses, primarily bars and restaurants, which the Michigan Health Department was able to track and warn.

Mr. Chairman, this container is an example of the contaminated fruit. This is the type of container which was sent to the schools in question. Michigan schools received this 30-pound container and smaller 6-pound containers were sent to the commercial establishments. This particular container, as I say, came from the company Andrew and Williamson in San Diego.

Before I address the subject of how foreign-grown fruit made it into the School Lunch Program, I would like to take a moment to talk about serious this hepatitis A outbreak was. When this occurred, a number of people indicated, or attempted—I think—to downplay the incident; comparing the symptoms, and its impact to the flu, and describing the virus as an inconvenience which caused some discomfort . . . but, Mr. Chairman, it was much more serious, and I can't emphasize that point enough. Let me just give you some personal examples.

Nine-year-old Amanda Bischoff ate these strawberries at Hughes Elementary School, where she is a student, in Marshall, Michigan. She suffered dehydration and had to be hospitalized. Her father explained that she didn't eat or drink for a week and missed about a month of school.

Michael Rosin, a teacher at Holy Cross Lutheran School in Saginaw, Michigan, and his son Paul, a student at the school, were both seriously infected with the virus over a 6-week period, at substantial personal cost to this working family. I refer the committee to the charts and the data on those charts which I brought to describe the expenses to this family.

As you can see, it includes a doctor's visit . . . \$143, medication, liquids, and nutrient supplements . . . \$100; \$192, which constituted air fare, so that Mr. Rosin's mother could travel to Saginaw to help with the family's 3-year-old, and 9-month-old children who had chicken pox, while he was bed-ridden, and Mrs. Rosin was working. Additional calculations add up to \$75 in lost wages for Mrs. Rosin, who was forced to miss work. Of course—in addition—the parochial school where Mr. Rosin taught had to hire a substitute teacher at a cost of \$240.

The next chart shows a journal outlining this one family's health experience. Let me just provide you with a few excerpts. On March 8, Mr. Rosin had a 103-degree fever, chills, and sweating. On March 13, he became jaundiced, very ill, and left school sick. The week of March 15, he didn't eat for a week, and was bed-ridden all but a few hours. On March 23—15 days into the virus—he still had little appetite and remained very jaundiced. On March 28, the

family had to cancel a vacation, and until April 6, he was feeling very tired, with low energy . . . still jaundiced, and a small appetite. His son, Paul, had similar symptoms from April 6 through the 14.

One of the most serious incidents brought to our attention was the experience of Linda Geyer, a second-grade teacher at Hughes Elementary School in Marshall, Michigan. Her parents, Robert and Patricia Geyer, wrote me to explain their daughter nearly died from eating these strawberries.

I would just read a very brief segment from the letter: "We took her to the emergency room where tests were made. Her condition continued to worsen and she was admitted to the hospital. The next morning, she was in a coma and that afternoon was air-lifted to the hospital at the University of Michigan and to the liver critical care unit where she was made ready for a liver transplant or to go on life support. She was comatose and the doctors told us they did not expect her to live through the night. Fortunately, they were able to treat her so that eventually she became conscious and her liver started to function again. Had she not been sent to that facility, she would have died. She has not returned to work yet. It will take a lot more time for her recovery. We think her problem should be known because hepatitis A can be deadly."

Mr. Chairman, these incidents have provoked outrage in our State. They should not have happened and must not happen again. I requested this hearing, as you know, to make our Colleagues aware of this crisis and to begin a discussion here in the Senate in order to learn how the breakdown occurred and how to prevent its recurrence.

To that end, we must act to ensure that the law be followed and that foreign commodities not be used in the School Lunch Program. The actions of the Andrew and Williamson Company were illegal regardless of where the strawberries were contaminated. Strawberries grown in Mexico are not even supposed to be in the School Lunch Program, but they were.

The integrity of the School Lunch Program, which serves millions of school children every day, has been compromised by these events, and we just need to know how these strawberries made it into the Program. Under the rules which govern the Program, suppliers of foods to the School Lunch Program are expected to certify in writing that their products are of domestic origin. Unfortunately, this honor system approach is inadequate.

In response, last month Secretary Glickman, as probably we will hear a little later, announced an 11-step plan to address these problems. I believe this plan moves us in the right direction. However, I feel we should consider codifying some of these recommendations and instituting tougher punishment provisions to be imposed against those who break the School Lunch Program rules. In this regard, Mr. Chairman, I hope to work with you and the committee and the USDA to explore such a legislative initiative.

In addition, we must determine whether our inspection process is adequate to handle concerns when they are raised. USDA officials have testified before the Early Childhood, Youth, and Family Subcommittee on the House Education and Workforce Committee that there were reports of illegal foreign purchases by this par-

particular company several weeks prior to the distribution of the contaminated lots, but that no action was taken prior to the hepatitis outbreak.

While I understand that many Federal agencies receive rumors of noncompliance from competitors, the facts in this case show that the rumor was correct. So, I believe we need to explore this incident further to just determine how the USDA and the FDA investigate such reports and what, if any, changes in the process might be called for.

In conclusion, Mr. Chairman, again I wish to thank you for moving forward with this hearing. As a father of three young children who are not yet school age, I am especially concerned about these issues. Our kids in school today have a lot to be worried about and concerned about and prepare for when they go to school and they shouldn't have to worry about the food being served in the cafeteria.

It is quite evident that this episode has heightened awareness of food safety across the country, and in my State in particular, and I believe our hearing today can play a very useful role in examining some of the achievements as well as, unfortunately, in this case some of the breakdowns in the Nation's Food Safety Program. Hopefully, we can shed light that will be beneficial and educational for all.

So, Mr. Chairman, again I thank you and the committee for taking the time and focusing the attention that you have today. I appreciate it very much.

The CHAIRMAN. Well, we thank you very much for your testimony, Senator Abraham, and for the careful work you have done in Michigan and the specifics of cases that you have brought to our attention today which have vividly illustrated the seriousness of this problem. We appreciate the thoroughness of your testimony. We look forward to working with you.

Senator ABRAHAM. Thank you very much.

[The prepared statement of Senator Abraham follows:]

STATEMENT OF SENATOR SPENCER ABRAHAM

Mr. Chairman, let me first say thank you and tell you how pleased I am that the Agriculture Committee has agreed to hold this hearing. This is a busy time of the year for the Senate and for the Agriculture Committee in particular. Your assistance in permitting and organizing this hearing is most appreciated.

The week after Easter this front-page headline appeared in the *Detroit News*: "State Fears More Hepatitis Cases." The accompanying story reports that at least 180 Michigan residents, mostly school children, were infected with the hepatitis A virus after eating contaminated strawberries served in the School Lunch Program. That was April 3. Today, that number is closer to 229 persons in my State of Michigan—the hardest hit, and to my knowledge, the only State which had the hepatitis A outbreak linked to the fruit. The outbreak is largely concentrated in Calhoun and Saginaw Counties, affecting students, teachers, support staff and parents.

This much we know about how this began. These strawberries were harvested in Mexico, then frozen and processed last spring by Andrew and Williamson, a San Diego Company. They were shipped for bulk distribution to USDA-sponsored School Lunch Programs in December. In addition, this same company shipped frozen strawberries to about 200 Detroit businesses—bars and restaurants—which the Michigan Health Department was able to track and warn.

Mr. Chairman, this container of frozen strawberries which was supplied to me by the Michigan Department of Agriculture is an example of the contaminated fruit. Michigan schools received a larger 30-pound container and this 6-pound container was sent to commercial establishments. This particular container from the Andrew

and Williamson Company is marked as "lots 7750363 and 7750362" from the Gonzalez farm in Mexico.

Before I address the subject of how foreign-grown fruit made it into the School Lunch Program, I'd like to take a moment to talk about how serious this hepatitis A outbreak was. Many people tried to downplay this incident by comparing it to the flu and describing the virus as an inconvenience which caused some discomfort. It was much more serious, and I cannot emphasize this point enough. Let me give you some personal examples:

Nine-year-old Amanda Bischoff ate these strawberries at Hughes Elementary School where she is a student in Marshall, Michigan. She suffered dehydration and had to be hospitalized. Her father explained that she didn't eat or drink for a week and missed about a month of school.

Michael Rosin, a teacher at Holy Cross Lutheran School in Saginaw Michigan, and his son, Paul, a student at the school were both seriously infected with the virus over a 6-week period at substantial personal cost to this working family. I refer the committee to the data on these charts I've brought which describes the expense to this family. As you can see, it includes:

- a doctor's visit was \$143,
- \$192 in airfare for Mr. Rosin's mother to travel to Saginaw to help with the family's 3-year-old, and 9-month-old children who had chicken pox while he was bedridden, and Mrs. Rosin was working,
- \$100 in miscellaneous expenses to deal with the sickness including medication, liquids and nutrient supplements.
- \$75 in lost wages for Mrs. Rosin as she was forced to miss days of work, which totals \$510 in personal expenses.
- In addition, the parochial school where Mr. Rosin worked had to hire a substitute teacher at a cost of \$240.

The next chart shows a journal outlining this one family's health experience. Let me provide you with a few excerpts. On March 8, Mr. Rosin has a 103-degree fever with chills and sweating. On March 13, he became jaundiced, very ill, and left school . . . sick. The week of March 15, he didn't eat for a week and was bedridden all but a few hours. On March 23—15 days into the virus—he still had little appetite and remained very jaundiced. On March 28, the family had to cancel a vacation; and until April 6, he was feeling very tired with low energy . . . still jaundiced, and a small appetite. His son, Paul, had similar symptoms from April 6 through April 14.

One of the most serious incidents brought to my attention was the experience of Linda Geyer, a second-grade teacher at Hughes Elementary School in Marshall, Michigan. Her parents, Robert and Patricia Geyer wrote me to explain that their daughter nearly died from eating these strawberries. Mr. Chairman, I would ask that the full letter be included into the record. I would like to read the following excerpt from their letter:

"We took her to the emergency room . . . where tests were made. Her condition continued to worsen and she was admitted to the hospital. [The next morning] she was in a coma . . . and that afternoon was airlifted to the hospital at the University of Michigan, and to the Liver Critical Care Unit, where she was made ready for a liver transplant, or to go on life support. She was comatose and [the doctors told us, as her parents] that they did not expect her to live through the night."

"Fortunately, they were able to treat her so that eventually she became conscious and her liver started to function again. Had she not been sent to that facility she would have died. She has not returned to work yet. . . . It will take a lot more time for her recovery. We think her problem should be known. Hepatitis A can be deadly."

Mr. Chairman, these incidents have provoked outrage in our State. They should not have happened and *must* not happen again. I requested this hearing to make my Colleagues aware of this crisis and to begin a discussion here in the Senate in order to learn how the breakdown occurred and how to prevent its reoccurrence.

To that end, we must act to ensure that the law be followed and that foreign commodities not be used in the School Lunch Program. The actions of the Andrew and Williamson Company were illegal regardless of where the strawberries were contaminated. Strawberries grown in Mexico are not even supposed to be in the School Lunch Program, but they were. The integrity of the School Lunch Program, which serves millions of school children every day, has been compromised by these events, and we need to know how these strawberries made it into the Program.

Under previous rules, suppliers of foods to the School Lunch Program must certify in writing that their products are of domestic origin. Unfortunately, this honor system approach is inadequate. In response, last month Secretary Glickman announced an 11-step plan to address these problems. I believe this plan moves us in the right direction. However, I feel we should consider codifying some of these recommendations and instituting tougher punishment provisions to be imposed against those who break the School Lunch Program rules. In this regard, I hope to work with you, Mr. Chairman, the committee and the USDA to explore such a legislative initiative.

In addition, we must determine whether our inspection process is adequate to handle concerns when they are raised. USDA officials have testified before the Early Childhood, Youth and Families Subcommittee of the House Education and Workforce Committee that there were reports of illegal foreign purchases by this particular company several weeks prior to the distribution of the contaminated lots, but that no action was taken prior to the hepatitis outbreak. While I understand many Federal agencies receive rumors of noncompliance from competitors, the facts show that in this case the rumor was correct. I believe we need to explore this incident further, to learn how the USDA and FDA investigate such reports, and what, if any, changes in the process are necessary.

In conclusion Mr. Chairman, I wish to thank you again for moving forward with this hearing. As a father of three young children about to become of schoolage, I am deeply concerned about these issues. Our kids in school today have enough to do without having to worry about what is served in the school cafeteria. It is quite evident this episode has heightened awareness of food safety across this country—and in my State in particular. I believe this hearing can play a very useful role in examining some of the achievements and shortfalls of this Nation's food safety programs, and possibly shed some light on ways to improve the policy and science of protecting the Nation's food supply.

Thank you.

The CHAIRMAN. The Chair would like to recognize now Congressman Nick Smith of Michigan for his testimony.

STATEMENT OF HON. NICK SMITH, A REPRESENTATIVE IN CONGRESS FROM MICHIGAN

Mr. SMITH. Mr. Chairman, thank you very much for holding this meeting. Thanks to the Senators. Thanks to Senator Abraham for his initiation. Employees of government and a lot of the congressional staff, as well as maybe many of us in Congress, too often look at these instances as statistics as we oversee government efforts to improve food safety.

In talking to Pat Devara—she is a nurse in Marshall, Michigan—I think it is important that we put a human face on this kind of catastrophe. She said that people who come down with hepatitis A say it is the worst illness and the worst sickness that they have ever had in their lives. They have high temperatures, as Spence pointed out. They have severe abdominal pain. They have jaundice; their bodies turn yellow due to the liver infections. They have nausea and vomiting, extreme weakness, a very long recovery period that can take 1, 2, 3, 4 . . . and sometimes 5 months.

I think often we become too willing to simply look at the statistics in trying to put off decisions of how to improve food safety because we don't want to hurt or discourage any consumers in this country from buying food products. It is also important that we bring out that our food in the United States probably is the most wholesome; and the best buy of any place in the world. It is safe. But it doesn't mean that we can't be safer.

Over the past few months, many Michigan residents have experienced personal grief because of this outbreak. Two hundred thirty-six people in Marshall, Michigan, and surrounding communities of Calhoun County have now come down with hepatitis A. Maybe the

lesson we should take from this incident is that food safety needs to be emphasized at every point on the production and marketing chain. A part of that is informing consumers in the home how best to handle food to make sure that the food is good to eat, in the way they store it and prepare it.

While it seems likely that the contamination did occur in Mexico, where sanitary standards can be low, it is also possible that the contamination happened during processing in California and elsewhere during the handling and distribution.

I would like to suggest four areas where we need to move ahead to prevent incidents of foodborne diseases. One is enforcing the ban on imported food in the School Lunch Program. The Department of Agriculture has come up with some suggestions. I think they need thorough review to give us assurance that imported food is not coming into the School Lunch Program, in violation of the law.

We need to investigate the sanitary standards of foreign countries that are exporting food into the United States. We need to implement better food labeling in this country, and I think we need to improve food inspection and consumer knowledge. Michigan State University is now just developing a new food safety effort at that school, and I think we need good cooperation between the Federal Government and State governments and local agencies, and overall a better information system on food handling and food distribution in this country.

Mr. Chairman, thank you very much for this opportunity.

The CHAIRMAN. Thank you very much, Congressman Smith, for your personal interest and testimony.

[The prepared statement of Representative Nick Smith follows:]

STATEMENT OF REPRESENTATIVE NICK SMITH

I'm pleased that the Senate Agriculture Committee has agreed to hold hearings on the recent hepatitis A outbreak in Michigan. I'd like to thank Chairman Lugar and Senator Abraham for their efforts to make this hearing possible. It's important that Members of Congress and especially those of us working on agricultural issues in the House and Senate should see the effects of this outbreak on its victims and understand the tremendous importance of food safety.

Over the past few months, however, many Michigan residents have learned the hard way about the potential health hazards associated with food distribution and handling. In all, 236 people in Marshall, Michigan and other areas of Calhoun County contracted hepatitis A from Mexican strawberries that were sold improperly to the School Lunch Program. There were no deaths, but many children and others were profoundly ill as a result of the contamination. I'm sure that Ms. Sue Doneth, a constituent of mine from Marshall who will be testifying on a later panel, will be able to speak from personal experience about the effects of hepatitis A.

The lesson that we should take from this incident is that food safety needs to be emphasized at every point on the production and marketing chain. In the final analysis, we may never know for sure what caused this outbreak. While it seems likely that the contamination occurred in Mexico where sanitary standards can be low, it is also possible that the contamination happened during processing in California or elsewhere. This underscores the need to monitor the handling of food with the utmost vigilance and care.

As a farmer and Member of the House Agriculture Committee, I'm pushing for reforms to improve food safety. In my opinion, the events in Marshall suggest at least four changes that need to be made in food safety regimen:

- (1) *Enforcing the bans on imported food in the School Lunch Program.*—The fact is that the strawberries shouldn't have been in the School Lunch Program in the first place. If the regulations in place are so lax that contracted vendors can illegally use imported food, something is seriously awry. I made this point to Lon Hatamiya, the administrator of

the Agricultural Marketing Service, the department with jurisdiction over the School Lunch Surplus Food Program. He has implemented a new 11-point program designed to prevent further imported food abuses. I think additional protections may also be in order.

- (2) *Investigating sanitary standards in foreign countries exporting food into the United States.*—While this case involved Mexican produce, it would be a mistake to confine our scrutiny to Mexico. We need to consider more aggressive inspection of foreign produce. Although the strawberries should not have come into the School Lunch Program, the fruit could have been sold in a supermarket just as easily.

[With respect to the situation in Mexico, I've spoken with the head of Mexico's Agriculture Ministry, Francisco Labastida Ochoa, and asked him to conduct an analysis of the strawberry contamination. He was very cooperative and I hope that we can work with Mexican health officials as we investigate this incident.]

- (3) *Implementing better food labeling.*—I've asked Treasury Secretary Robert Rubin to implement new regulations to prominently label the origin of foreign food on the front panel of the package. People should be able to find out where their food comes from whether they buy it loose, frozen, canned or in packages.
- (4) *Improving food inspection and consumer knowledge.*—The Federal Government has announced a \$43.2-million food safety initiative to find measures to improve detection and control of foodborne diseases. This is a big step in the right direction. About \$4-million more is being proposed for consumer education programs and a conference that will be held in Washington, DC., later this month. This is especially important because most contamination occurs in the home. In Michigan, a number of the secondary infections may have been avoided with more careful food preparation.

While far from perfect, the U.S. food supply continues to be the safest, most wholesome, and cheapest in the world. That doesn't mean, however, that we can't work together to make it even safer. I look forward to working with this committee and with the Agriculture Committee in the House in the coming months to find out as best we can what happened in Michigan and ensure that it doesn't happen again.

Thank you.

The CHAIRMAN. Let me ask if other Members of the Committee have questions of either Senator Abraham or Congressman Smith before we let them proceed with their congressional duties.

Senator GRASSLEY. I wouldn't have a question, but I would like to put a short statement in the record, and just say that, obviously, we don't have a big commercial strawberry industry in my State. We are more noted for corn, soybeans, pigs, and beef. However, the safety of food that both the Chairman and the two witnesses thus far have testified to is something that is so important that there is no segment of the food industry or agriculture that can't be concerned that when an incident like this happens in strawberries, it somehow impacts all of food production.

As Members of this committee, we have got to assure everybody in the country that we are going to have a safe food supply. If there is anything people take for granted, it is what they put in their mouth in the way of food and water. They just assume, because they are in America, it is going to be safe. When they don't have that assurance, we, obviously, are not only going to have the public health hurt, we are going to have the economy of the country hurt, as well as that of agriculture.

Even more important than just general food supply and what goes through the private sector, when the Federal Government is involved, as we are, in the distribution of surplus commodities and food into our hot lunch programs and through our schools and all

that, it seems to me that there is even a higher standard that we ought to expect of that continuum of supply from producer to consumer because I think even at that level, with the Government's involvement, there is even a higher expectation that it should be safe.

So what appears to be very isolated in Michigan or California, or with one company, one supplier, maybe, can have a very "steam-rolling" impact, "snow-balling" impact, throughout our economy. So that is why I think it is so important you are having this hearing to maintain the confidence that people have had in our food supply.

The CHAIRMAN. Thank you very much, Senator.

Senator Coverdell.

Senator COVERDELL. Mr. Chairman, I want to thank you for holding the hearing. I do have a short statement I will just put in the record.

A question to Congressman Smith. You indicated that the contamination may well have occurred in Mexico, and until that moment I had always thought that the contamination had been found to have occurred in California in processing, and I wondered if you could elaborate on that.

Mr. SMITH. In talking with officials that visited the site where the strawberries were grown and harvested, they indicated that facilities were such, or the lack of sanitary facilities was such that the contamination could have occurred there. But there is no proof that it occurred there in the harvesting process, as opposed to the processing and distribution process.

Senator COVERDELL. I appreciate the answer.

Mr. SMITH. And I think it is somewhat sad that, with our high technology, we are not able to make that kind of investigation that would be so helpful in allowing us to focus on how we can keep this food safe.

The CHAIRMAN. Thank you very much. Earlier, before you came in, Senator Coverdell, I read a response from Donna Shalala, the Secretary of Health and Human Services. She says the source of the contamination is not known and may never be known, but indicates, surprisingly for me, that the strawberries were picked over a year ago, and therefore you are left to speculation about the conditions. The interviews with workers were difficult because of the dispersal and other circumstances of that sort.

[The prepared statement of Senator Coverdell follows:]

STATEMENT OF SENATOR PAUL COVERDELL

I would like to thank Senator Lugar for holding this important hearing today. As the subcommittee Chairman with jurisdiction over food inspections, I believe it is very important to make sure the various products being supplied to our Nation's children, through USDA-sponsored School Lunch Programs, is safe and healthy. For the most part, I think we as a country do an excellent job, and I commend the personnel at USDA for the good work they do in establishing this reputation. Obviously, when we have situations like those which recently occurred with strawberries in Michigan, we must be circumspect in our evaluation of the problem. It is our responsibility on the committee to do everything we can to prevent these types of incidents from occurring in the future.

When this incident first occurred, I contacted the U.S. Department of Agriculture and received assurances that this situation would be remedied. Consequently, it is my hope that the department's testimony will confirm this assurance. The health of school children from my State of Georgia and around the country is of paramount

importance. It is my intent today to verify that all necessary steps are being taken to assure this.

In 1990, a similar outbreak of hepatitis A took place at an elementary school in Georgia. It is very apparent that whatever steps were taken then to prevent contaminated foods from being purchased for the School Lunch Program were not completely effective. More needs to be done in this area, and I look forward to hearing from my Colleague from Michigan, Senator Abraham, who has been greatly affected by this problem. I also welcome the reports of officials from the USDA, FDA, CDC, and others concerning this issue. I am hopeful the information that comes to light from this hearing can be used to prevent this type of health threat from occurring in the future. My staff and I stand ready to assist in these efforts, and I commend the Chairman for his proper focus on this area.

The CHAIRMAN. We thank very much Senator Abraham and Congressman Smith.

Now, the Chair would like to call as a our first panel of witnesses Ms. Mary Ann Keffe, Acting Under Secretary for Food and Nutrition Services, United States Department of Agriculture, Washington, DC.; and Mr. Lon Hatamiya, Administrator of the Agricultural Marketing Service, U.S. Department of Agriculture, in Washington, DC. They will be accompanied by Mr. Craig Beauchamp, Office of the Inspector General; Dr. Harold Margolis, Centers for Disease Control and Prevention; and Dr. Fred Shank of the Food and Drug Administration.

Ms. Keffe, it is good to have you this morning. We appreciate proceeding with your testimony.

STATEMENT OF MARY ANN KEEFFE, ACTING UNDER SECRETARY, FOOD, NUTRITION, AND CONSUMER SERVICES, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, DC.

Ms. KEEFFE. Thank you very much, Mr. Chairman. I appreciate the opportunity to appear before the committee today to discuss the recent hepatitis A outbreak that occurred in Michigan this past March, and to describe the decisive steps the U.S. Department of Agriculture has taken in response. I would like to briefly summarize my written statement that was submitted, Mr. Chairman.

The CHAIRMAN. We would appreciate that, and the full statement will be placed in the record. That will be true of each of the statements submitted today.

Ms. KEEFFE. Thank you. As Acting Under Secretary, I am responsible for the policy and direction of the 15 food assistance programs of the Federal Government. These programs touch the lives of 1 in 5 Americans. One of those programs is the National School Lunch Program, which serves 26-million meals to school children every day in over 93,000 schools, and has been 1 of the most beneficial and successful Federal programs for over 50 years.

I personally have a deep commitment to what I regard as a national health responsibility as it relates to the nutrition assistance programs I supervise. As part of my commitment, I recently traveled to Marshall, Michigan, where I ate school lunch at Hughes Elementary School with children who had contracted hepatitis A, and then I visited with some of their parents.

My hope was to assure them of their Government's caring and concern over this incident and to try and give them an update of the situation, while at the same time renewing their confidence in the integrity of the National School Lunch Program. At the invitation of the Consumer Protection Committee of the Michigan Legis-

lature, I later participated in a public hearing on this issue and tried to convey the same message there as I had earlier with the children and their parents, and which I am confident that this hearing will evoke today.

Mr. Chairman, I believe it is important for you and the Members of the Committee to know that from the onset of this unfortunate situation, the Food and Consumer Service has worked very positively in consultation with all the responsible Federal, State, and local officials. The Food and Drug Administration, which has primary responsibility for the safety of the Nation's supply of fruits and vegetables, and the Centers for Disease Control and Prevention, which worked to prevent outbreaks and to determine their cause, have been invaluable in leading this investigation. Within the USDA, the various agencies involved have worked very closely and cooperatively.

I would like to briefly describe how the incident came to our attention. The USDA's Food and Consumer Service first received reports from the Michigan Department of Education on March 27, 1997, that there might be a link between hepatitis A cases and frozen strawberries provided to schools in Calhoun County, Michigan. Agricultural Marketing Service records showed, and further investigation indicated, that frozen strawberries served in Michigan were sold by a California processor, Andrew and Williamson Company of San Diego, California, to four vendors. Five States received strawberries that were from the same lots as those shipped to Michigan. They were Arizona, California, Georgia, Iowa, and Tennessee.

On March 27, the same day the episode reached our attention, the Food and Consumer Service immediately instructed each of our seven regional offices to notify State agencies of the outbreak in Michigan. As an additional precaution, the Food and Consumer Service placed a hold—that is, a no-use prohibition—on products containing frozen strawberries in 10 additional States and the District of Columbia which received strawberries that originated from Andrew and Williamson, but did not have the lot codes in common with the Michigan strawberries. To date, no additional reports of illness linked to frozen strawberries have been confirmed by the Centers for Disease Control and Prevention.

AMS Administrator Lon Hatamiya will discuss the details of his agency's role in this situation and outline the 11-point plan which is being implemented to increase USDA's surveillance of contracts.

Another area I would like to call to your attention, Mr. Chairman, is that USDA requires the frozen fruit product be originated, indeed requires of all product going to the School Lunch Program, be 100-percent grown, processed, and packed in the United States, and Andrew and Williamson provided such certifications directly to USDA.

However, based on evidence that the strawberries were, in fact, not of U.S. origin, USDA's Office of Inspector General has been working with the office of the U.S. attorney in San Diego to determine if there has been any criminal fraud related to this case. The investigation is being coordinated with the FDA and the U.S. Department of Justice.

On April 24, the Food and Consumer Service suspended Andrew and Williamson Sales Company and its former president, Fred L. Williamson, from doing business with the U.S. Government and most Federal programs, pending the outcome of the investigation.

Mr. Chairman, selling foreign-grown produce under the pretense that it was grown in the United States is a very serious violation and a matter that the Food and Consumer Service believed needed strong, immediate action. I would also like to note that the administration has examined the broader question of food safety and has recently issued a report titled "Food Safety from Farm to Table: A National Food Safety Initiative." It contains several recommendations regarding the hepatitis A virus and the inspection of fruit and vegetable products. My written statement highlights a few of those recommendations.

In closing, I would like to reaffirm the high priority that President Clinton's administration places on the health of all Americans, but especially the health and well-being of children and families. I am here today to assure you that our paramount concern has been and will continue to be the health of America's families, and most especially the children that we serve.

Mr. Chairman, that concludes my testimony and I will be happy to answer any questions at the appropriate time.

The CHAIRMAN. Thank you very much, Ms. Keeffe. We appreciate that testimony.

We will proceed with the testimony of Mr. Hatamiya and then have questions for the panel.

I understand that Senator Abraham and Congressman Smith will want to witness the entire hearing. I would invite them to come to the table, if you would like to. Senator Abraham, if you will sit by Senator Coverdell. Also, Mr. Smith—

Mr. SMITH. Mr. Chairman, thank you, but our Agriculture Committee is meeting at 10, so I have to depart, but thank you.

The CHAIRMAN. I understand. Well, you are welcome. Thank you. Mr. Hatamiya.

STATEMENT OF LON HATAMIYA, ADMINISTRATOR, AGRICULTURAL MARKETING SERVICE, U.S. DEPARTMENT OF AGRICULTURE; ACCOMPANIED BY CRAIG BEAUCHAMP, OFFICE OF THE INSPECTOR GENERAL, U.S. DEPARTMENT OF AGRICULTURE; HAROLD MARGOLIS, CENTERS FOR DISEASE CONTROL AND PREVENTION; AND FRED SHANK, FOOD AND DRUG ADMINISTRATION, WASHINGTON, DC.

Mr. HATAMIYA. Good morning, Mr. Chairman and Members of the Committee. I am Lon Hatamiya, Administrator of the Agricultural Marketing Service at the U.S. Department of Agriculture. AMS has responsibility for the procurement of a significant portion of agricultural commodities that are donated to the National School Lunch Program and we work closely with our sister agency, the Food and Consumer Service, to ensure that such commodities are procured and distributed in accordance with applicable laws, regulations, and policies of the department.

My brief statement today will concentrate on AMS' role relative to the procurement of strawberries from Andrew and Williamson earlier this year that led to the outbreak of hepatitis A in Michi-

gan, and actions that we have taken in recent weeks to increase surveillance of USDA contracts.

Mr. Chairman, I too wish to echo the sentiments of my colleague, Ms. Keffe. Resolution of this issue has been at the top of the department's agenda as we have worked in consultation with the responsible Federal, State, and local officials to pursue and resolve this matter. As you know, the investigations are still ongoing by the Food and Drug Administration and our Office of Inspector General to determine the circumstances underlying the hepatitis A outbreak and the parties responsible for fraudulently providing imported strawberries in connection with USDA purchases for the National School Lunch Program.

The internal review of AMS' procedures for ensuring country of origin documentation and surveillance of USDA contracts has been completed and my comments today will focus on USDA's 11-point plan which is now being implemented. In view of the ongoing investigations, my comments and responses will be limited to those areas which will not impede the investigatory process.

AMS is implementing an 11-step action plan to increase departmental surveillance of contracts to deter packers from illegally distributing imported products in the School Lunch Program. Under these more stringent procedures, increased documentation will include a code so that we can easily do trace-backs on the origin of the product. The additional documentation will also be subjected to a three-level review process, rather than the single-level review process that we previously used.

We will increase the number of unannounced onsite plant reviews to ensure full contract compliance, and hold meetings with vendors to inform them of country of origin and other contract requirements, as well as the potential penalties that may be imposed for noncompliance. We will step up our audit activities so that we actually double the number of postcontract compliance audits.

Mandatory training for graders and supervisors on country of origin requirements will be conducted at regional workshops throughout the country. In addition to the mandatory training for graders and supervisors, we will also issue annual reminders on the requirements for country of origin for USDA purchases.

As part of the upcoming procurement conferences that we hold with potential vendors across the country—we are going to be holding those on the east and west coasts—we will inform vendors of the penalties for making false, fictitious, or fraudulent certification of country of origin. This heightened awareness, coupled with the development of a standardized letter of conformance for product origin in each invitation for offer to sell, will be just part of our continuing efforts to advise vendors of the penalties associated with making false, fictitious, or fraudulent certifications to the U.S. Government.

Mr. Chairman, a copy of the 11-point plan is provided for the record¹ which enumerates in greater detail the procedures for country of origin documentation and surveillance.

Mr. HATAMIYA. This concludes my statement, and I and my colleagues will be glad to respond to your questions.

¹ Retained in Committee files.

The CHAIRMAN. Thank you very much, and the very impressive group that you have assembled with you hopefully may be helpful also and should ask for recognition if you have additional comments on these questions.

In thinking through all of these questions, I have consulted with Senator Abraham, in particular, and others who have been interested and tried to consolidate the questions that we have and our staff has so that we can really get to the heart of what I think are the basic public considerations.

First of all, I would like to ask, Ms. Keffe, for your understanding of how such an outbreak could conceivably have happened. In other words, what is involved at this point in terms of our entire system of inspection, of surveillance, of caution, of care? We have not had, as I understand from the record, an outbreak of hepatitis A of this sort since 1989. That may be an error, but staff in research has come up with that historical fact. So this is an unusual, even extraordinary, event, but I think most Americans ask always, how could it happen?

Can you give us some understanding of where the breakdown occurred or where the vulnerabilities are? Likewise, any of the rest of the panel, as you can give us this background information, this would be helpful.

Ms. KEEFFE. Well, Mr. Chairman, you know, as we heard earlier regarding the safety of America's food supply, we are extremely fortunate in this country and we do enjoy wonderfully safe food. I think that in terms of the School Lunch Program, we can even take that a step further. We do have and have had processes in place that have gone beyond even the commercial marketplace in assuring safe food.

You are correct. This is a very rare occurrence and a very unfortunate one and one that we take very seriously, and did from the outset. I think that having the incident occur made us all step back and really take a hard look and review exactly what was the process, what could have gone wrong.

As we also heard earlier from Secretary Shalala's letter, we may well never know the source of the contamination, and other experts here can speak more to hepatitis A and how it can occur and why that would be the case that we wouldn't necessarily know the source. But, nevertheless, issues that concerned us were certainly the fact that the company certified to something that was not truthful in terms of a source of the product. That concerned us, and I think the steps that the Agricultural Marketing Service has taken to the kind of inspection and really following back the paper trail to better define the source is going to, take care of that kind of situation. So it is unfortunate, it is extremely rare, but I think we have taken very proactive, strong steps to assure that something like this does not happen.

The CHAIRMAN. In my opening statement—and Senator Abraham mentioned this likewise in his statement—there was a rumor or rumors that the origin of the strawberries was outside the country, namely Mexico. Who heard the rumor? Why was it not acted upon? Who might have been relevant to this in the USDA organization?

Ms. KEEFFE. I am going to ask Administrator Hatamiya to address that.

Mr. HATAMIYA. Mr. Chairman, I will attempt to answer that question. In late January this past year and early February, the procurement officials of my agency received unconfirmed reports from strawberry competitors, packers and producers, that potentially what we had purchased was not of domestic origin, or was outside of our country of origin. Again, these were unconfirmed reports. They were nonspecific. They did not name specific packers or producers. It was purely a contract violation complaint, and because it was a contract violation complaint, we had scheduled an audit for those very contracts in the month of April.

Had it been a health concern that was addressed at that time, we would have taken action to put the product on hold. However, I want to emphasize the fact that it was a contract violation, and again they were unconfirmed, unspecific complaints. So we did have knowledge at that point, but we followed the procedure we had in place.

The CHAIRMAN. Senator Coverdell, do you have a followup on this?

Senator COVERDELL. Well, I just wanted to add to the complexity of the question, and somewhat of a clarification. We actually had an outbreak of hepatitis A in Georgia in 1990, and it was contaminated strawberries, and I was curious as to whether or not that had triggered anything in the system which had not developed or—

Mr. HATAMIYA. Mr. Coverdell, there was no connection whatsoever. This is the first time it has been brought to my knowledge that there was an outbreak in 1990. There was no connection, I don't believe, at that time to a School Lunch problem.

The CHAIRMAN. Does anyone else have any further comment?

Dr. Margolis.

Dr. MARGOLIS. I might make a few comments about the fact that hepatitis A is rarely transmitted by strawberries. Yes, in 1990, there was an outbreak in Georgia. It was in a school, but the strawberries were not provided a part of the USDA School Lunch Program. The strawberries were grown in California and picked in California in that outbreak.

Much like we have seen in the present outbreak, strawberries and hepatitis A virus preserve well, so those happened to be in the freezer for 2 years. In the present outbreak, it was almost a year. This virus likes to be frozen and it is not a virus that is easily detected. As I think people are aware, we don't have easy detection methods, so it is not something we can routinely screen for in food products. When these outbreaks have happened, unfortunately, we find out about them way after the fact, which makes it difficult in terms of trying to figure out where it occurred. We have well-educated guesses, but we usually don't have facts or good data to identify precisely where the contamination occurred.

The CHAIRMAN. Well, this is sort of a pessimistic survey of the problem, isn't it? It may be quite accurate, but what you are saying, in essence, is that there is some contamination that may be a yearback, 2 years back. By freezing the strawberries, the virus is kept alive or continues to thrive, and there are not very good screening methods, then, even after you bring it off the shelf or out of the icebox as to what you have there.

Dr. MARGOLIS. But I think there is an important message that we know from hepatitis A. As was pointed out earlier, it is still, unfortunately, a common infection in the United States, with about 150,000 to 250,000 people infected every year. Yes, it does cause very severe disease in some, with almost 150 people who die every year from this disease.

The CHAIRMAN. How many die each year?

Dr. MARGOLIS. About 150.

The CHAIRMAN. In the United States from hepatitis A?

Dr. MARGOLIS. Yes, however that is not all foodborne. In fact, we think less than 2 percent of the cases of hepatitis A are foodborne. But what we do know is that food handlers can contaminate food. I think we have the general view in this case of the strawberry outbreak that the person who is picking a food that is then eaten fresh or raw is very much like a food handler. So, risk assessment issues come into play in trying to prevent these infections or outbreaks.

The CHAIRMAN. Just for the record, there are 250,000-cases-a-year in the United States of hepatitis A?

Dr. MARGOLIS. There are an estimated 150,000 to 250,000 infections.

The CHAIRMAN. Infections.

Dr. MARGOLIS. We have about 23,000 cases of sick individuals, or cases, reported to CDC, and from that number we estimate that there are about 150,000 to 250,000 people who are infected. It is still a common infection in the United States.

The CHAIRMAN. Now, let me ask each of you again just for the record, is Michigan the only site involved in the outbreak that we are talking about presently, and what effects were observed in other States that received the tainted lots of strawberries?

Ms. KEEFFE. Michigan is the only State that had the outbreak of hepatitis A related to the strawberries and the School Lunch Program. We, of course, as I had testified, immediately placed a hold, notifying schools not to use any product from that company either from the lots that came from Michigan or other lots of strawberries that were also processed by the company, so that there was no further use of any of that product. However, a great deal of it had already been consumed in schools by that time, but there were not other incidents of the hepatitis A as a result.

The CHAIRMAN. You have touched upon this, but let me just for the record get your view of what is going to happen to A and W, or the parent of A and W. You have indicated that, apparently, violations of Federal law have occurred and that investigations are occurring, including the Department of Justice, as I recall the testimony. Can you give us any further information as to what is likely to be the outcome of that inquiry and what sort of penalties are available, including Federal prosecution?

Ms. KEEFFE. I am going to ask Mr. Beauchamp from the Office of Inspector General to address that.

Mr. BEAUCHAMP. Well, Mr. Chairman, the investigation is ongoing. We are trying to determine the full extent of what happened in this matter, who knew what, who did what, and based on that then there can be a determination by the Department of Justice on what would be the appropriate charges, if any, on the particular violations or possible violations of Federal law.

We have mentioned here—and this doesn't necessarily relate to this investigation, but we have mentioned that the company or individuals may have submitted false statements to the Government concerning the origin. There is a particular Federal statute addressing false statements to the Government and that has a substantial criminal penalty and criminal fines. So those are the issues we are trying to find out in the investigation—who knew what, who was involved—and then based on that, the Department of Justice will make a determination on what charges would be appropriate.

The CHAIRMAN. Senator Coverdell.

Senator COVERDELL. Is there any type of food product that is uniquely susceptible or could this happen to virtually any product frozen in this manner?

Dr. MARGOLIS. Well, this experience has actually only occurred with strawberries and raspberries, in terms of frozen products—raspberries not in the United States, but in Great Britain. Some fresh foods have been associated with transmission, such as lettuce, but again it is still unusual. It is really an unusual event.

Senator COVERDELL. That is encouraging.

Ms. KEEFFE. Mr. Chairman, if I can elaborate on Mr. Beauchamp's a little bit, or add something there?

The CHAIRMAN. Yes.

Ms. KEEFFE. I had referred in my testimony to the fact that the Food and Consumer Service has moved and suspended the company and its former president from any further business with the U.S. Government. Under our suspension and debarment regulations, we moved to do that while this investigation was proceeding based on the fact that the parent company had come forward early on, saying that, in fact, the berries had come from Mexico, and the certification had been otherwise, saying they were domestic. So on our knowledge of that, we wanted to take action to prevent them from any further business with our programs while the rest of the investigation proceeded.

The CHAIRMAN. So you have made an official administrative finding that underlies that decision?

Ms. KEEFFE. That is correct.

The CHAIRMAN. Is it a permanent suspension? What are the rules of your—

Ms. KEEFFE. No, it is not. In fact, the company and the individual have the right to come forward and request a hearing and proceed along those lines. But I guess you could equate it a little bit like putting the product on hold. Because of the seriousness that we regard the offense, we took that action while the rest of the investigation is proceeding.

The CHAIRMAN. Has the company requested a hearing? Have they protected your action?

Ms. KEEFFE. Yes. It is my understanding that the former president, Mr. Williamson, has requested it.

The CHAIRMAN. And what has been your response, or what is the department going to do about it?

Ms. KEEFFE. Oh, it will be granted.

The CHAIRMAN. The hearing?

Ms. KEEFFE. Yes. The administrator of the Food and Consumer Service is the person that is responsible for conducting that.

The CHAIRMAN. Senator Coverdell.

Senator COVERDELL. Were there any previous violations associated with this company?

Ms. KEEFFE. My understanding is there were not. I don't know whether AMS—

Mr. HATAMIYA. No, not to our knowledge there were not.

The CHAIRMAN. You have outlined the new certification process, the reforms that the department has instituted. To what degree does this make certain that the commodities will, in fact, be domestically produced? Have you closed out the possibility of another occurrence of shipments from Mexico or other nations?

Mr. HATAMIYA. We believe the 11-step process that we have implemented will do that. We have implemented a more stringent process that requires, as I mentioned, a three-level process of review; that if anybody wanted to cheat through this program, they would have a very difficult time of doing that. Again, we are heightened the awareness as to the types of penalties that can be incurred due to a violation of this procedure. So we believe that this 11-step process will ensure 100-percent domestic content in the future.

The CHAIRMAN. From the letter that I have quoted from Ms. Shalala, her idea certainly is that USDA inspectors were in the plant during the processing and shipment of these strawberries. Do you have any reports of their activities; that is, any observations they had? Is there any reason that they would have believed that there was a foreign origin for the strawberries, for example? Anything unusual about that inspection or were they present at all? Is Ms. Shalala correct?

Mr. HATAMIYA. Yes, Secretary Shalala was correct. Graders from my agency were present at two different occasions at Andrew and Williamson. The first occasion at the time the strawberries were processed was back in 1996. We are responsible for grading and certifying quality and condition of processed commodities. We were requested by A and W at that time to come into the plant, and we did that.

Also, prior to that time, any time that we were requested for in-plant inspection, we would do an in-plant survey of sanitation procedures. Our last survey of A&W was done May 23, 1996, and at that time we found that the overall sanitation level was acceptable. If we had found anything wrong with that, through our memorandum of understanding² with FDA, we would have reported that to FDA. But on this occasion we found no problem out of the ordinary.

In further answer to your question, following the procedures we had in place at that time, we found no indication that the strawberries that we were inspecting were other than what was certified to, 100-percent domestically grown.

The CHAIRMAN. For the record, would you explain in more detail what the memorandum of understanding with the FDA includes and how this brings protection for the School Lunch Program, in particular?

Mr. HATAMIYA. Well, I will turn to my colleague, Mr. Shank, to talk about that. We will be glad to provide that MOU for the record

² See page 24.

(Note: copy submitted for the record). What it does, though, is it essentially provides an understanding between our agencies that if, in fact, there is a problem in a processing plant that we share that information. If there is a problem related to sanitation, or any of those other issues, that we share the information jointly.

Mr. SHANK. The MOU, if you would, is a document that clearly articulates the various responsibilities of AMS and FDA. Its primary purpose is to ensure that we do have a consistent system, that their regulations as well as ours are being enforced. Yes, it does call for the referral from AMS to FDA in the event that there are problems that are found.

I would like to point out, however, that this is an area—the coordination among the various agencies, including CDC, is an area that is undergoing a lot of scrutiny at this time, as you know, with the President's national food safety initiative. We believe that we can make additional strides by increased coordination, but that program, as you are aware, is very comprehensive, as was referred to earlier—the changes that are needed in our food supply to improve upon its safety.

We do believe we have a safe food supply, as was mentioned earlier, but we are certainly lacking in certain areas, such as research. We can find hepatitis A in an oyster. We cannot find it strawberries. There is additional research that is needed to be done in those areas. Education was mentioned earlier. Certainly, as we are looking at the practices of harvesting as well the integrity of the entire food distribution system where this type of contamination might occur, education can go a long way in that regard.

I apologize for this lengthy answer, but I did want to address the initiative that is before us as well. Thank you.

The CHAIRMAN. No need to apologize for the length. We really are looking for a comprehensive understanding today.

Let me just ask, Dr. Shank, is the administration, as it proceeds with the President's program, initiating or drafting legislation, and if so, is it legislation that would normally be referred to this committee?

Mr. SHANK. I am unaware of any legislation that is being contemplated at this point in time. As you know, the report was just recently released or presented to the President. There are a number of activities that are underway as to making sure that this report is in the direction that it should go. We are having meetings—both departments are having meetings with various Members of Congress, as well as other stakeholders, and I think that this is the very important next first step prior to seeing whether or not we can achieve this through existing legislation or whether or not legislative changes are necessary.

The CHAIRMAN. It strikes me as you mention the research required that it is timely that you coordinate with the committee. We have before us now the research title to the Farm bill, and clearly the point you have made is an important one. As a country, we are able to find hepatitis A in oysters, as you pointed out, but not in strawberries and perhaps not in other foods.

In other words, one of the great problems, it seems to me, that this hearing uncovers is how difficult it is to find hepatitis A, given the freezing and the long period of time. It is difficult to find where

everything begins and ends in this process. To the extent that you have suggestions, please convey those to our staff soon because we are in the process of trying to think through a comprehensive research program for those things that we normally do through the land grant colleges. Furthermore, the process will include things that we have not normally done, namely a reaching-out to substantial information for the safety of Americans, as well as for extension of our food supply.

Mr. SHANK. Our research component of the food safety initiative is a very important component. We would be glad to share that with you and provide any followup information or assistance that we can.

Ms. KEEFFE. And speaking on behalf of the Department of Agriculture, we certainly will be also, Mr. Chairman, and I know our people in the Agricultural Research Service (ARS) are very much involved in this.

The CHAIRMAN. Yes, Senator Coverdell?

Senator COVERDELL. Mr. Chairman, I will have several written questions to submit later through the committee to the department, and I would hope they would be responsive to those at a later point.

Ms. KEEFFE. Certainly, Senator, we would be happy to.

The CHAIRMAN. We will keep the record open for those questions.

**FOOD AND DRUG ADMINISTRATION
COMPLIANCE POLICY GUIDES**

GUIDE

7155a.01

CHAPTER 55a - MOUs and IAGs - FEDERAL

SUBJECT: MOU with Agricultural Marketing Service Concerning the Inspection and Grading of Food Products* (225-72-2009 mod #1)

MEMORANDUM OF AGREEMENT
BETWEEN THE
AGRICULTURAL MARKETING SERVICE
AND THE
FOOD AND DRUG ADMINISTRATION

The Food and Drug Administration (FDA) of the Department of Health, Education, and Welfare is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act. In fulfilling its responsibilities under the Act, FDA's activities are directed toward the protection of the public health of the nation by insuring that foods are safe and wholesome and that products are honestly and informatively labeled. This is accomplished by inspecting the processing and distribution of foods and examining samples thereof to assure compliance with the Act. FDA also promulgates under the Act mandatory standards of identity, quality, and fill of container for food products after appropriate notices and hearings.

The Agricultural Marketing Service (AMS) of the U.S. Department of Agriculture, under the authority of the Agricultural Marketing Act of 1946, carries out certain voluntary service functions designed to aid in the

¹This Agreement does not apply to egg products, inspection of which is covered by the Egg Products Inspection Act, nor to grains, including rice, dry beans, peas, or lentils, which will be covered by a separate memorandum of agreement between AMS and FDA.

Date: 10/01/80
ISSUING OFFICE: EDRO, Division of Field Regulatory Guidance
AUTHORITY: Associate Commissioner for Regulatory Affairs

PAGE 1

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efficient marketing of agricultural products. These include the development of commercial grade standards and specifications for foods, and furnishing inspection and grading services, including the issuance of certificates of quality and/or condition, to producers, processors, shippers, buyers, or other interested parties. The major purpose is to assist producers in preparing better quality of wholesome products and to provide objective information by means of official certification concerning the grade, quality, or condition of a product which will be of maximum assistance to all interested parties engaged in marketing functions.

The two agencies have certain related objectives in carrying out their respective regulatory and service activities. Therefore, it is believed desirable from the standpoint of public interest to set forth in this Memorandum of Agreement the working arrangements which are being followed or adopted in the interest of each agency discharging as effectively as possible its responsibilities related to inspection and standardization activities for food products.

The Agricultural Marketing Service will:

- (1) Supply to FDA, headquarters, a complete list of all food processing and packing plants which are operating under AMS continuous or other resident-type inspection grading contracts. This list will set forth the type of service provided and the food products involved. AMS will immediately advise the appropriate FDA field office of those plants subject to withdrawal or suspension of service, termination of contract or denial of inspection services because of sanitation or other current good manufacturing practice deficiencies.
- (2) Investigate any report from FDA to the effect that a processor or packer operating under contract with AMS has not corrected objectionable conditions found to exist by FDA, and will take action in accordance with AMS regulations and contracts.
- (3) Decline to inspect or grade samples of products which have been seized by FDA, or which are known to be involved in formal FDA actions. This does not preclude reinspection of legally authorized samples by AMS if the FDA seizure or other actions involved products which had previously been inspected or graded by AMS.

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- (4) Decline to assign a U.S. grade or permit the use of Government official marks or other approved identification on a food product which is considered adulterated under the Federal Food, Drug, and Cosmetic Act, of such type and/or in such amounts so as to result in the food product being subject to regulatory action by FDA or is otherwise found to be not suitable for grade assignment. AMS will make such examinations and tests as are reasonably feasible for those materials and substances that would be likely to contaminate the product.
- (5) Report to the appropriate FDA field office information on any lot of produce which, upon inspection, AMS declines to assign a grade unless such product is so reconditioned as to comply with FDA requirements and/or quality for grade assignment, or is segregated and disposed of for nonfood use or otherwise lawfully shipped or sold.
- (6) Furnish FDA headquarters on request, with any pertinent information concerning the grade or quality determination relative to specific lots of products inspected or graded by AMS that have been proceeded against or are being considered for action by FDA.
- (7) Report on the inspection certificate any pertinent codes or other marks that will serve to identify the specific goods which are inspected or graded.
- (8) Inform FDA headquarters whenever it has information that an employee or USDA-licensed inspector is to be or has been subpoenaed as a witness at judicial proceedings involving FDA action and advise FDA of the nature of his proposed testimony.

The Food and Drug Administration will:

- (1) Recognize that the AMS service provided in connection with the voluntary contract inspection of fruit and vegetable processing establishments contributes to protection of consumers and aids FDA in enforcement of pertinent statutes. The AMS inspection service will not diminish FDA authority to inspect but should minimize FDA inspections in establishments under AMS contract inspection. In this regard AMS inspectors will routinely advise contract establishments of pertinent FDA requirements, advise them on how to comply and provide

Date: 10/01/80

PAGE 3

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advice on compliance. AMS inspectors may not act as FDA inspectors but their inspections and consultations with FDA should reduce the necessity for FDA inspections.

- (2) Invite the AMS inspector stationed at a plant which is operating under AMS inspection to accompany the FDA inspector during his inspection of such plant. The FDA inspector will point out or discuss with the AMS inspector any conditions noted which may result in violations of the Federal Food, Drug, and Cosmetic Act.
- (3) Request AMS headquarters for any pertinent information concerning the grade or quality determinations relative to specific lots of products that have been proceeded against or are being considered for action by FDA and are known or believed to have been inspected by AMS. FDA will take into consideration the results of AMS inspection certificates and other available data unless it has evidence that the product does not meet legal requirements as a food or has deteriorated to such an extent, subsequent to AMS inspection, as to make it unacceptable as food.
- (4) Immediately notify the appropriate AMS field office concerning the details of objectionable conditions whenever such conditions are found to exist in processing or packing plants where AMS is currently conducting inspection of products, or in other food plants, when FDA believes such information would be of value to AMS in its inspection and grading activities.
- (5) Whenever possible mark the claimant's samples of seized products in such a manner that AMS inspectors or graders will recognize such post-seizure samples.
- (6) Discuss with AMS headquarters the criteria used by FDA in order to provide the maximum assurance that AMS does not classify a food as acceptable which FDA would consider actionable under the Federal Food, Drug, and Cosmetic Act.
- (7) On request of AMS review labels, legends, stamps, and other official marks for products packed under the various inspection services of AMS from the standpoint of possible conflict with the misbranding provisions of the Federal Food, Drug, and Cosmetic Act.

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It is mutually agreed that:

- (1) Both agencies will maintain close working relations with each other, both in headquarters as well as in the field.
- (2) Proposed regulations by either agency establishing or amending any food products standard will be referred to the other agency for review and comment prior to issuance.
- (3) Both agencies will cooperate jointly and with industry in the improvement of sanitation and food handling practices in processing plants. Both agencies will mutually exchange data and cooperate in the development of sampling plans, methodology and guidelines for determining natural and unavoidable defects common to products inspected and graded by AMS.
- (4) Both agencies will work with industry toward greater efficiency in connection with improvement in coding methods.
- (5) Both agencies will cooperate in the handling of those cases of misbranding which also come under the provisions of the Perishable Agricultural Commodities Act of 1930, as amended.
- (6) Each agency will designate to the other a central contact point to which communications dealing with this agreement or matters affected thereby may be first referred for attention.
- (7) Nothing in this Agreement modifies other existing agreements, nor does it preclude entering into separate agreements setting forth procedures for special programs which can be handled more efficiently and expeditiously by such special agreement.
- (8) The provisions of this memorandum may be modified at any time by mutual agreement.

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FOR THE AGRICULTURAL MARKETING SERVICE

Date

June 25, 1975

Approved

E. L. Peters
 Administrator
 Agricultural Marketing Service

FOR THE FOOD AND DRUG ADMINISTRATION

Date

JUN 9 1975

Approved

A. W. Schmidt
 Commissioner
 Food and Drug Administration

Effective Date.

This agreement becomes effective _____ (date of
 publication in the FEDERAL REGISTER) and supersedes
 Memorandum of Understanding dated August 28, 1973.

Date: 10/01/80

PAGE 6

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The CHAIRMAN. Let me ask, while I have this distinguished panel, about a topical issue in the State of Indiana. There have been recent press reports regarding a possible outbreak of bacterial infection caused by *e. coli* 0157:87. Tests have confirmed at least two of the sick individuals—and these were infants—have been infected by *e. coli*, a virulent strain of *e. coli*, and there was a possible link to a fast-food restaurant that has now been confirmed.

Are you aware, Dr. Margolis, at CDC, whether these cases of *e. coli* in Indiana are under investigation or whether you have taken any action?

Dr. MARGOLIS. I am personally not aware of that, but we will find out about this and get back for the record and to you with the information.

The CHAIRMAN. I would appreciate that; unrelated to school lunches and the strawberries today, but, obviously, of concern to the parents of these infants who have had contaminated food.

Senator Leahy, do you have a comment or a question of our witnesses?

Senator LEAHY. I am just glad you are doing this, Mr. Chairman. I think it is an important hearing. If I had any question, it would be of Ms. Keffe, and I have been following the hearing earlier this morning. Senator Lugar asked about whether this company, A and W, which sold the strawberries may have filed false statements to conceal the fact that the strawberries were bought in Mexico, in violation of the Buy American Act.

Is this a matter that has been looked at by the Justice Department, or has it been referred to the Justice Department?

Ms. KEEFFE. It is currently still under investigation, Senator.

Senator LEAHY. By whom?

Ms. KEEFFE. Well, our Office of Inspector General, the U.S. attorney in San Diego, the Justice Department, and the Food and Drug Administration have all been part of the investigation really since the day we all—

Senator LEAHY. The U.S. attorney, though, is involved in that?

Ms. KEEFFE. Yes.

Senator LEAHY. OK.

Ms. KEEFFE. And, you know, it has not been concluded.

Senator LEAHY. Thank you very much. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Leahy.

Well, we thank you very much for your testimony today; likewise, for your assurance of cooperation with the committee and the follow-through on the research aspects, as well as potential legislation that might be of benefit to the American people. Thank you very much.

Ms. KEEFFE. Thank you, Mr. Chairman.

The CHAIRMAN. The second panel of witnesses are Dr. David Johnson, Chief Medical Officer of the Michigan Department of Community Health, in Lansing, Michigan; Mr. Thomas Schimm, of Bay City, Michigan; and Ms. Susan Doneth, of Marshall, Michigan. If these witnesses would come to the table, we would appreciate it.

Thank you very much for coming to this hearing. The Chair will recognize the three witnesses in the order in which you have been

introduced; first of all, Dr. Johnson, then Mr. Schimm, and then Ms. Doneth.

Will you please proceed with your testimony, Dr. Johnson?

STATEMENT OF DAVID R. JOHNSON, CHIEF EXECUTIVE AND MEDICAL OFFICER, COMMUNITY PUBLIC HEALTH AGENCY, MICHIGAN DEPARTMENT OF COMMUNITY HEALTH, LANSING, MI

Dr. JOHNSON. Good morning. I am Dr. David Johnson, Chief Executive and Medical Officer for the Public Health Agency at the Michigan Department of Community Health. Thank you for the invitation to testify on the recent hepatitis A outbreak in our State.

I would also like to thank Senator Spencer Abraham for his involvement following the outbreak. The Senator has worked closely with us and with the families who were affected in Michigan in order to prevent something like this from happening in other communities.

My intent this morning is to share with you an overview of the outbreak from our perspective, including some estimates of resources brought to bear in its investigation and control.

Hepatitis A, as you have heard, is one of several kinds of viral liver disease. Signs and symptoms include loss of appetite, nausea, abdominal discomfort, and classically jaundice, a yellowing of the skin and eyes. Disease onset is usually 4 weeks after a susceptible person ingests food or water contaminated with hepatitis A virus. The disease lasts 1 to 2 weeks, sometimes longer.

Convalescence often is prolonged. Hospitalization is rather uncommon, and hepatitis A-related death is fortunately rare. There are no specific treatments for hepatitis A disease. It can be prevented by receiving one or two shots of hepatitis A vaccine well in advance of exposure or by receiving a single shot of immune globulin after exposure.

In early March of this year, local health authorities in Calhoun County recognized a cluster of hepatitis A cases in their jurisdiction. Over the ensuing days, the number of cases grew rapidly. About the same time, 120 miles away, in Saginaw County, a smaller cluster of hepatitis cases was developing. Investigators from our State health department were asked to assist in Calhoun County. They, along with staff from the Michigan Department of Agriculture, began to organize the early outbreak data. As the outbreak grew, we invited the Centers for Disease Control and Prevention to send up investigators as well, which they promptly did.

The overwhelming majority of those with hepatitis A in both counties had a link to schools. Many cases reported having consumed strawberries at school lunches or other events about a month before illness onset. Two different epidemiological studies confirmed the link between consumption of sliced frozen strawberries and hepatitis A in this outbreak.

At this point, the U.S. Department of Agriculture and the Food and Drug Administration traced the implicated strawberries, as you have heard, back to a distributor in southern California. Unfortunately, potentially contaminated strawberries from no less than 13 large lots were distributed in early 1997 in our State. More specifically, over 1,300-thirty-pound containers were distributed to 289

schools in 28 Michigan counties in the west and central portions of our lower peninsula.

Those 28 counties are served by 20 of the finest local health departments in the Nation. Over the Easter weekend, we contacted those local health departments and they began to track down the potentially contaminated strawberries in their jurisdictions, in spite of the fact that many schools were closed for spring break. The message from local health departments to schools was, "If you have these strawberries in your freezer, do not serve them; if you have served them in the last 2 weeks, we will administer immune globulin to those who ate them."

Other local health departments in our State became involved when it was learned that these strawberries had been served near the end of March at a Grand Rapids area Special Olympics, which drew participants from across Michigan. How large was the control effort? Quite large. The Michigan Departments of Agriculture and Community Health invested nearly \$50,000 in personnel and laboratory costs. More than 17,000 people received Michigan-manufactured immune globulin, at a value of \$110,895. Local health departments in Michigan bore much of the burden of the control efforts. These front-line public health agents invested 7,324 person-hours, at a value of \$314,134. Altogether, then, State and local agencies devoted nearly \$475,000 in person power and other resources for this outbreak.

Let me hasten to add that this impressive figure does not include either the cost to schools or—and this is most important—the cost to those who contracted the disease—direct medical care cost, pain and suffering, time away from school and work, as you have heard. Nor does the figure include any accounting of the anxiety and discomfort of thousands who had to undergo immune globulin injections.

We know that in Calhoun County there were 245 cases of hepatitis A. Saginaw County recorded 22 cases. In the 2 locations, approximately 10 percent of these persons were hospitalized. Fortunately, no one died, although that would not have been extraordinary for an outbreak this large. What we don't know is how many cases were prevented through the control efforts in Michigan and in other States.

In summary, then, this was one of the largest hepatitis A outbreaks in Michigan, and one of the largest in the country in recent memory. The investigation and control efforts represent a high level of collaboration between Federal, State, and local agencies. Many hours and great expense went into that collaborative process.

I hope I have succeeded in giving you an overview of the strawberry-related hepatitis A outbreak from our perspective. I think I am speaking for all involved when I thank you for your interest in this matter. I would be happy to answer questions from you at the appropriate time.

The CHAIRMAN. Thank you very much, Dr. Johnson. Mr. Schimm, would you give your testimony?

STATEMENT OF THOMAS W. SCHIMM, TEACHER, MINISTER OF MUSIC, HOLY CROSS LUTHERAN CHURCH AND SCHOOL, SAGINAW, MI

Mr. SCHIMM. I also want to thank Senator Abraham for the invitation to come to this meeting.

My name is Thomas Schimm. I am a teacher and minister of music at Holy Cross Lutheran Church and School in Saginaw, Michigan. My family and I live in Bay City, Michigan.

On Wednesday, March 5, my son Ben started feeling sick while he was at school. From that day through March 27, Ben was absent from school because of hepatitis A. Because Ben was an eighth-grader this year, these 3 weeks at home sick made things especially difficult for him. On Thursday, March 6, I began showing the same symptoms as Ben, and except for March 9-12, when I felt somewhat better, I was also sick at home until Thursday, March 27, with hepatitis A.

My wife, Naomi, and I were very pleased with the concern and care given to us by our PA, James Knight. At Ben's first appointment on Wednesday, March 12, he felt that it was more than just a flu virus and wanted to obtain a blood count and take an abdominal x-ray to test for possible appendicitis or other problems. On the morning of March 13, he called and wanted us to get Ben to a pediatrician that day because the blood tests seemed to indicate that Ben had hepatitis. On Friday, March 14, he had Naomi and me come in for a blood test, and strongly suspected that I also had hepatitis. On March 17, Knight had Naomi and I and our three children go in for inoculation.

Around March 20, the Bay County Health Department sent a representative to our house to interview Ben and me in an effort to help find the source of the hepatitis A virus. Both Ben and I suffered anorexia, and so we ate and drank very little for a period of about 2 weeks. We also were basically bed-ridden or inactive for about 3 weeks. A more normal diet and activity level were slowly regained after many more weeks, and other health problems have been experienced since then. It has been shared with us that full recovery could take up to a year's time.

During the month of March, Holy Cross Congregation had to cover costs for substitute teachers and substitute organists for worship services. Our family has been hurt financially because of the added medical expenses caused by this hepatitis A virus. Apparently, some of the people from Holy Cross church and school that live in the Saginaw were more critical of how the hepatitis A virus was handled. After several students and some of the staff at the church and school became ill in the early part of March, it was generally thought that a flu virus was going around.

Even after the first hepatitis cases were confirmed, some parents were distressed that their doctor wouldn't even consider a blood test. There was quite a bit of confusion about what the virus was or how it could be transmitted, and since the source of the illness was not yet known, much suspicion was put on the food service program at our school and the personnel preparing the food. The local health department was initially unable to provide our school staff with information that could be included in a letter

sent out on Monday, March 17, to our school families. The staff needed to collect some information for this letter from some medical books of their own.

Upon the request of one of our Board of Day School members, St. Luke's Hospital sent two health representatives that conducted a meeting on Tuesday, March 18, for parents and any concerned persons. As more cases were confirmed, the local news people reported on it almost every day. The health department was now able to provide us with information and agreed to provide inoculations for all of our students, staff, siblings, and parents who wished to participate. Over 400 people were inoculated within the next 2 days.

The source of the virus was found to be the frozen strawberries served on Monday, February 10, at our school. Our hot lunch program at Holy Cross Lutheran School has been endangered by this experience. Some parents have lost their trust in it and are no longer having their children eat hot lunch, and so our school has lost much revenue in the hot lunch program.

In general, our community experienced some panic and confusion due to lack of information. Our school and certain staff people have been hurt financially. One of our older members came close to losing his life, all due to the irresponsibility of this company that supplied food for school lunch programs.

The CHAIRMAN. Thank you very much, Mr. Schimm.

Ms. Doneth, will you give your testimony?

**STATEMENT OF SUSAN J. DONETH, MOTHER AND MEMBER,
SAFE TABLES OUR PRIORITY (S.T.O.P.), MARSHALL, MI**

Ms. DONETH. Thank you, Mr. Chairman. Before I begin my testimony, I would like to thank you for giving me the opportunity to participate in this hearing. I would also like to personally thank Senator Abraham and Congressman Smith for their continued support and efforts on behalf of the people in Michigan.

My name is Susan Doneth and I am the mother of a 10-year-old child who became extremely ill with hepatitis A. On February 12, 1997, my daughter, Lindsay, a fourth-grade student at Madison Elementary School in Marshall, Michigan, enjoyed a serving of strawberry shortcake, her favorite dessert, as a part of her school lunch. Exactly 28 days later, Lindsay became ill.

I am a member of S.T.O.P. Safe Tables Our Priority, and I am submitting this testimony to record the experience of my daughter and speak on behalf of the other 244-hepatitis A victims in my community and the 10,800 other people in my county who received IG shots in an attempt to protect them from the virus.

On March 11, 1997, Lindsay began complaining of severe body aches, headache, and abdominal pain. She had a very high fever and she started to vomit. I assumed that Lindsay had the flu and kept her home from school for 4 days, until it became apparent that Lindsay had something much more serious than the flu. I did not know that Lindsay was suffering from hepatitis A.

On March 14, 1997, we took Lindsay to the emergency room and the doctor decided that Lindsay needed to be hospitalized. Lindsay became hysterical. She said to me, "Mommy, I am not afraid of what they are going to do to me. I just don't want to move. Please don't make me move because it hurts."

Lindsay needed immediate I.V. fluids, as she was severely dehydrated. I had to leave the room as my husband and 3 hospital personnel held my 10-year-old daughter down to try to start the I.V. Lindsay was screaming in pain and she was terrified. I couldn't bear to help hold her down and hurt her, so I went to the hallway and sobbed, leaving my husband to do what I was incapable of doing.

On day 2 of her hospital stay, Lindsay stopped talking and she would barely open her eyes. We knew she was in pain because her eyebrows would furrow and tears would silently roll down her face. I remember my child whispering to me through dry, dehydrated, cracked lips, "Mommy, I hurt everywhere." This is the point where my husband broke down. He sat in the hospital chair and cried as he watched his little girl suffering in a hospital bed and feeling helpless to do anything to help or protect her.

Together, we held our child's head and wiped her brow with a cold wash cloth as she violently tried to vomit. She endured endless dry heaves in trying to get rid of the poison that had overtaken her body, and with each convulsion she would only cry harder because she couldn't breathe and her liver was so enlarged and inflamed that the movement was excruciating for her.

I couldn't imagine how my child had contracted this virus, and I can't describe to you the horror I felt when I learned she became sick from something she ate in her school lunch. After 6 days, we brought our little girl home, but for weeks Lindsay continued to battle fatigue, stomach pain, headaches, and nausea after eating. I talked to other mothers who had children hospitalized and it appeared that all of our children were experiencing the same type of recovery, slow and tedious.

We all had children whose liver enzymes were elevated off the charts. How can an infection of that magnitude not have a damaging effect on the liver of a child? We were scared to death and we did the best we could to support each other. As I was dictating this testimony, I received a phone call from a mother in my county who has a 17-year-old boy who is on his way to the University of Michigan Hospital in Ann Arbor. He has been on morphine for several weeks because he is still experiencing intense pain, and he has developed complications as a result of this virus.

The hepatitis A epidemic that hit my county is merely symptomatic of a much larger problem, and that problem is the overall safety of our food supply, whether from domestic or imported food, school lunches, or any other form of food distribution. There is a gaping hole in our Government's processes for ensuring safe food that is incredibly huge that the School Lunch Program is being affected.

Quite frankly, it is not surprising that we have a problem, given the fact that the U.S. plants are inspected once every 10 years and only 1 to 2 percent of imported food is inspected at all. As a parent, I absolutely expect and demand that the food served through my child's school lunch program is safe for her to eat. When I learned that 9,000-people-a-year die from food poisoning and over 30 million become ill, I was outraged.

The city I live in has a population of less than 9,000 people, which essentially means that the equivalent of 1.5 times my entire

town is wiped out every year from foodborne illness. Like the people in my community, those people have names, faces, and they matter. Thank God, nobody died in my community, but the important message is many could have. This virus is not a nonfatal virus, as described. People can die from it, people have died from it, and at least one individual in my community came very close to death as a result of it. I am well aware that I could have lost my child. If these strawberries were contaminated with a pathogen like *e. coli* 0157, we would have dead children instead of sick children.

You need to examine your system very carefully and make necessary changes, even if it doesn't fit in with the current desire to downsize everything in government. The fact that contaminated food is slipping through the system and being served to children in their school lunches is indicative of the magnitude of this problem.

I am very confident that this committee will address the obvious questions regarding this epidemic. However, I am not confident that our Government won't just look for an easy fix by finding a scapegoat—in this case the distribution company—and completely ignore the larger problem of unsafe food. We can't simply trust for-profit industry to always play by the rules. They are in the business of making money, and you should be in the business of protecting those of us who trust you to do that.

We weren't protected and we need to know why. You also need to tell us what you are going to do to prevent it from happening again. The bottom line is the food should be safe, regardless of where it comes from. I urge you to implement changes in your system that focus on prevention rather than on implementing better methods to monitor the problem and track the paperwork.

I don't want to leave this hearing simply learning that this system failed. I already know that. I feel that I have done my job as a parent and as a citizen by raising questions and demanding answers and accountability, and I sincerely hope that you will all do your job in providing us with those answers, taking responsibility and, quite frankly, fixing the problem. If you don't change things, this problem will not go away. It will continue to grow, and what happened in Calhoun County will happen again. Answers, accountability, and action are the only things that will restore my faith and my daughter's faith in your system, and restore our trust in all of you. Please don't disappoint us.

Thank you.

The CHAIRMAN. Thank you very much, Ms. Doneth.

Ms. DONETH. Mr. Chairman, if I may—I am not sure what the protocol is. I received a letter late yesterday afternoon from a high school senior in Battle Creek. I did give copies to Senator Abraham's office and we would like that submitted for the record.³

The CHAIRMAN. It will be placed in the record and recorded in full.

Ms. DONETH. Thank you, Mr. Chairman.

The CHAIRMAN. Let me just comment apropos of Ms. Doneth's testimony, which is very compelling both from the personal circumstance as well public policy, that at the outset of the hearing

³ See Appendix, page 56.

I mentioned the responsibility this committee has, and we take that very seriously. We are one branch of government. We have had relationships today and dialog with the administration of our Government and that is an important aspect. Even after policy is determined and laws are determined, the administration of such policy needs to be competent.

For this reason, these oversight hearings, of which this is a dramatic instance, are especially important because they bring citizens such as yourself and Mr. Schimm, and likewise Dr. Johnson, who is a public official working to mitigate the disaster in Michigan, into contact with legislators, with the press and with the public, through the forum these hearings provide.

I believe that we have seen some headway, and this is why I recognize the changes in regulation that USDA has made and the thoughts with regard to research that were mentioned today. These are going to require a good bit more follow-through, and likewise prosecution, not in finding a scapegoat, but in actually prosecuting a violation of law that has had injury for citizens.

The scope of the problem has surprised me. The revelation of CDC—that 250,000 cases occur and 23,000 people get sick every year, and over 100 die from hepatitis A—is a very serious predicament, as you have illustrated from your own personal experience. So this has to be a source of concern, not only for this committee, but for every one of us involved in public health in the country. I take seriously that charge and this is one reason we have proceeded.

We appreciate very much your personal testimony, all three of you. Senator Abraham's diligence in making certain that persons who are competent to testify can do so in an articulate way really has been presented to the committee. We are grateful for that.

Let me simply say that at this stage, we will proceed as we have been with the USDA people, the CDC, and others to pursue each of the leads that have been suggested today. This will not be the end of the story, but it is important interval. The initial shock is completed and we are now trying to assess what occurred. I commend the public health officials in Michigan for the containment of what could have been a much worse disaster, and likewise, those who alerted other States and other schools.

As has been suggested, these shipments went a lot of places, and fortunately the circumstances were not as dire as those that were involved in Michigan. But we can't take that for granted. The cooperation of citizens who submitted their children for inoculation and worked cooperatively is very important, too, because in each of these situations lack of cooperation can lead to some weak links in terms of human beings and their conduct.

Senator Abraham, do you have a comment or a question or a valedictory statement at this point?

Senator ABRAHAM. Well, I don't have a valedictory statement. I just welcome these witnesses from our State, and I have had the chance during the last month or so to work with all three of them and to meet with them and hear about this. I think that as I indicated in my opening statement, at least initially there was a certain mood or atmosphere that suggested that somehow, because this wasn't hepatitis B, people in Michigan ought to be somehow

either grateful or less worried. I think the testimony today hopefully has helped to put this in perspective. Hepatitis A not only is a much farther-reaching problem than we thought, but it is also a much more serious illness than some were at least willing to concede when this outbreak began. I think that was an important point made by the witnesses, as well, I hope, by me.

I also want to compliment Dr. Johnson. I think our community health department did an extraordinarily good job of not only containing this, but really of pulling together a number of different clues. This was sort of Columbo-type mystery when it began because you had outbreaks in two different places which finally got traced back to the same source. Thanks to their efforts in coordinating the Agencies at the county level, we were able to succeed.

But I guess I would share the sentiments, I think, of this panel that we need to look at ways, and there are a number that I am interested in. The research component, in particular, is one I look forward to working with the committee on. I mentioned in my testimony some of the specific steps that USDA has taken with regard to the School Lunch Program in terms of their plan, I think, maybe being more appropriately codified legislatively, which again I am looking forward to working with the committee, as well as the Department of Agriculture, on.

But I think everybody here has done a very nice job of presenting this, and presenting it in a very thoughtful way, but I don't think we should allow that to in any sense allow anyone to think that there aren't a lot of hard feelings and a lot of outrage. The parent groups I met with in both Marshall as well as in Saginaw, a large group of Saginaw families—you know, it is interesting, the point that was made up there was more than anything they want an apology from someone, too.

I mean, this shouldn't have happened, and it is yet to be quite clear as to who, but someone owes us an apology and a fuller explanation. So, hopefully, today, Mr. Chairman, we have moved in that direction, and I thank you for having given us that first step in the right direction. We appreciate it very much.

The CHAIRMAN. Thank you, Senator Abraham, for your leadership.

This concludes our hearing. We thank you for coming to testify and for all who participated in listening carefully to you.

This hearing is adjourned.

[Whereupon, at 10:34 a.m., the committee was adjourned.]

A P P E N D I X

PREPARED STATEMENTS

Acting Under Secretary Mary Anne Keeffe

I want to thank the Chairman for the opportunity to appear before the committee today to discuss the recent hepatitis A outbreak in Michigan and to describe the decisive steps the U.S. Department of Agriculture (USDA) has taken in response. I am Mary Ann Keeffe, Acting Under Secretary for Food, Nutrition, and Consumer Services at USDA. Accompanying me today from USDA is Lon Hatamiya, Administrator of the Agricultural Marketing Service (AMS), and Craig Beauchamp, of the Office of Inspector General, as well as Dr. Harold Margolis, representing the Centers for Disease Control and Prevention (CDC), and Dr. Fred Shank, representing the Food and Drug Administration (FDA).

As Acting Under Secretary, I am responsible for administering 14 food assistance programs plus the Food Stamp Program. The Programs for which I am responsible touch the lives of one in five Americans. To give you a couple of examples Mr. Chairman, 1 out of every 10 persons receives food stamp benefits, over 50 percent are children; and 1 in 4 babies born in the United States receives WIC benefits. Over 93,000 schools participate in the National School Lunch Program. Every school day, USDA serves 26-million meals to school children—4-billion-meals-a-year.

Behind these dry statistics, Mr. Chairman, is the reality of infants who thrive because of USDA commodities, of children who are alert in school because of breakfast and lunch programs, of adults who are better parents and more productive citizens because of food stamps. I am here today to assure you that our paramount concern has been and will continue to be the health of America's families and most especially the children that we serve.

Mr. Chairman, I believe it is important for you and the Members of the Committee to know that from the onset of this unfortunate situation, the Food and Consumer Service has worked very positively in consultation with all the responsible Federal, State, and local officials. The Food and Drug Administration, which has primary responsibility for the safety of the Nation's supply of fruits and vegetables and the Centers for Disease Control and Prevention, which work to prevent outbreaks and to determine their cause, have been invaluable in leading this investigation, and within the USDA, the various agencies involved have worked very closely and cooperatively.

I would like to briefly describe how this incident came to our attention.

The USDA's Food and Consumer Service (FCS) first received reports from the Michigan Department of Education on March 27, 1997, that there might be a link between hepatitis A cases and frozen strawberries provided to schools in Calhoun County (Battle Creek), Michigan.

As FCS does in such situations, we located the potential problem products, immediately informed affected States to prevent further use of the product in question, and worked with other Federal agencies having responsibility for the safety of the Nation's food supply.

Agricultural Marketing Service records showed, and further investigation indicated, that frozen strawberries served in Michigan were sold by a California processor/packer, Andrew and Williamson Sales Company, Inc., of San Diego, California, to four vendors: Kendall Frozen Fruits, Inc., of Encino, California; Pacwest Foods, Inc., of Newbury Park, California; JSO Associates, Inc., of Great Neck, New York, and New West Foods of Watsonville, California. Five States received strawberries that were from the same lots as those shipped to Michigan—Arizona, California, Georgia, Iowa, and Tennessee.

On March 27, 1997, the same day the episode reached our attention, FCS immediately instructed each of its seven regional offices to notify State agencies of the outbreak in Michigan. FCS' regional offices alerted each State distributing agency in the affected States who in turn were responsible for notifying each school district in their respective States.

In this case, this is a standard USDA/FCS procedure for notification whenever a product is suspected to have a problem. As an additional precaution, FCS placed a hold, that is, a no-use prohibition, on products containing frozen strawberries in 10 additional States and the District of Columbia, which received frozen strawberries that originated from Andrew and Williamson, but did not have lot codes in common with the Michigan strawberries. These additional States were: Florida, Illinois, Indiana, Maine, New Jersey, New York, North Carolina, North Dakota, Utah, Wisconsin, and Washington, DC. To date, no additional reports of illness linked to frozen strawberries have been confirmed by the Centers for Disease Control and Prevention.

AMS Administrator Lon Hatamiya will discuss the details of his Agency's role in this situation and outline an 11-point plan which is being implemented to increase USDA's surveillance of contracts. However, I would like to give the committee some background on some additional items involving both FCS and AMS.

In the applicable contracts for the purchase of these strawberries, USDA required the processed frozen fruit to originate from crops 100-percent grown, processed, and packed in the United States. In addition, the contracts required each of the 4 contractors to supply a written statement certifying that the products delivered to USDA have been 100-percent grown and packed in the United States.

Andrew and Williamson provided certifications directly to USDA that strawberries used to fill 3 of the contracts were 100-percent grown and packed in the United States. However, based on evidence that the strawberries were in fact not of United States origin, USDA's Office of Inspector General (OIG) has been working with the Office of the U.S. Attorney in San Diego, California, to determine if there has been any criminal fraud related in this case. The investigation is being coordinated with the FDA and the U.S. Department of Justice.

On April 24, 1997, FCS suspended Andrew and Williamson Sales Company, Inc., and its former president, Fred L. Williamson, from doing business with the U.S. Government and most Federal programs pending the outcome of the investigation. Mr. Chairman, selling foreign-grown produce to the National School Lunch Program under the pretense that it was grown in the United States is a very serious violation, and a matter that the FCS believed needed strong, immediate action.

I would also like to note that the administration has examined the broader question of food safety and has issued a report: *Food Safety from Farm to Table: A National Food-Safety Initiative* with several recommendations regarding the hepatitis A virus and the inspection of fruit and vegetable products.

I would like to highlight a few recommendations from that report. USDA and FDA will immediately begin a comprehensive review of current production and food-safety programs to identify preventive measures for pathogens in fruits and vegetables including inspection, sampling, and analytical methods.

Another recommendation of the report that will occur in fiscal year 1997 is the designation of one position within each department or agency as the food borne outbreak coordinator. This will be established as a formal institutional position with appropriate backup designees. For outbreaks that fall within USDA, for example, the under secretary for food safety will coordinate for USDA.

Based on the best available science, FDA will produce regulatory and nonregulatory options for the manufacture of fruit and vegetable juice products. A fiscal year 1998 activity, will be for the CDC to begin a case-control study of hepatitis A to determine the proportion of cases due to contamination of food so that optimal control strategies can be determined.

Finally, FDA and USDA are cooperating in evaluating the feasibility of Hazard Analysis Critical Control Points (HACCP) for commodities such as fruits and vegetables.

I know that we can work together on these initiatives and others that have the goal of providing the safest food supply possible.

The Clinton administration places a high priority on the health of all Americans, but especially the health and well-being of children and families. There has been no greater sign of the administration's commitment to this than its support for USDA's School Meals Initiative for Healthy Children which is aimed at improving the health of 50 million of our Nation's children.

I personally have a deep commitment to what I regard as a national health responsibility as it relates to the nutrition assistance programs I supervise. As part of my commitment, I recently traveled to Marshall, Michigan, where I ate school lunch with children who had contracted hepatitis A, and, then, I visited with some of their parents. My hope was to assure them of their Government's caring and concern over this incident and to try and give them an update of the situation while at the same time renewing their confidence in the integrity of the National School Lunch Program. At the invitation of the Consumer Protection Committee of the Michigan Legislature, I later participated in a public hearing on this issue and tried to convey the same message there as I had done earlier with the children and their parents, and which I am confident that this hearing will evoke today.

Mr. Chairman, that concludes my testimony, my associates and I would be pleased to answer any questions the committee may have.

[ATTACHMENTS FOLLOW ON PAGES 42 THROUGH 45.]

Fact Sheet
Hepatitis A Outbreak Associated with Consumption of Frozen Strawberries
Centers for Diseases Control and Prevention
Tuesday, June 03, 1997

General

Cases of hepatitis A determined to be associated with consumption of frozen strawberries have been reported in Calhoun (N=242) and Saginaw (N=22) counties, Michigan.

State, local and CDC officials continue to investigate hepatitis A cases occurring in Maine (N=36), Louisiana (N=2), Wisconsin (N= 5) and Tennessee (N=1). However, association between these reported cases and the implicated product has not been established.

Timeline

March 23: EIS officers traveled to Michigan at the request of the state health department to investigate an increased number of hepatitis A cases in Calhoun County

March 24: CDC investigation initiated in cities of Marshall and Battle Creek, Calhoun County, MI

March 27: The Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) informed about the possible relationship of illness and consumption of frozen strawberries in school lunch programs. USDA initiates a hold on frozen strawberries distributed by the involved processor. Thirteen lots processed on three different days were shipped to Michigan, but no records on which lots were consumed in the schools with illness.

March 28: CDC concludes from preliminary results of epidemiologic investigation that there is a strong relationship between consumption of frozen strawberries and hepatitis A. FDA makes the decision to recall product. CDC makes the decision to telephone state epidemiologists that received frozen strawberries from the involved processor, with lot numbers in common with Michigan lot numbers, for their school lunch programs. CDC also recommends that immune globulin be given to children who consumed frozen strawberries, if within 14 days.

March 29: CDC sends letter (via fax) to state epidemiologists in 5 affected states (additional state identified several days later and notified)

April 2: EIS officers travel to Maine to investigate an increase in hepatitis A associated with school children and school teachers in several school

CDC update - Hepatitis A outbreak associated with frozen strawberries - 06/03/97 - Page - 1/2

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districts in different parts of the state

April 3: CDC sends letter to all State and Territorial Epidemiologists to inform them of the outbreak and to recommend that no intervention be taken unless the 13 suspect lots were served in their school lunch programs.

April 3 to present: State and local officials and CDC continue to investigate hepatitis A cases occurring in Michigan and elsewhere.

Epidemiology

Calhoun County, Michigan

As of May 28, 1997, 242 cases of laboratory confirmed hepatitis A have been reported in Calhoun County, with dates of onset since March 3, 1997. Forty-one (16.9%) of these cases are secondary (contacts of primary cases). All primary cases have had direct or indirect association with the school system.

A case-control study conducted in Marshall school district and a cohort study conducted in one school in Battle Creek have shown a strong association between consumption of frozen strawberries and hepatitis A. No other food item was associated with hepatitis A.

Trace back investigation of lots consumed in Calhoun County have not allowed identification of a lot number(s) specifically associated with illness among the 13 lots shipped to Michigan that were recalled nationwide on March 28, 1997.

Saginaw County, Michigan

As of May 28, 22 cases have been reported in Saginaw County.

All cases were reported within one school, except for a secondary case in a mother of a schoolchild.

A cohort study conducted among children and staff members of this school showed a strong association between consumption of frozen strawberries and hepatitis A. No other food item was associated with hepatitis A.

Maine

As of May 29, 1997, 36 cases have been reported with dates of onset between February 20, 1997 and May 14 1997. Twenty-nine (80.5%)

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cases were school associated, and 7 (19.4%) were secondary.

Cases occurred in 20 schools in 10 of the 16 Maine counties. A majority of these schools served frozen strawberries from the same processor, but from lots that are different from the 13 lots implicated in Michigan.

Two case-control studies have been conducted to identify a potential source of infection but they have not implicated any food item.

Investigations of these patients are ongoing to determine whether they have any risk factors in common. These studies are limited because of a small sample size.

Louisiana

Two cases of hepatitis A were reported from New Orleans metro area among children aged 11 (onset March 14) and 16 years (onset March 26).

Both patients ate strawberry smoothies from two different retail establishments. The two establishments had received frozen strawberries from the Californian processor that was implicated from the outbreak in Michigan.

Investigation to date has not revealed other risk factors for these patients. No other cases in Louisiana have been identified that might be potentially associated with consumption of frozen strawberries.

Wisconsin

Five serologically confirmed cases of hepatitis A were reported among school children of 4 classrooms in a school in Shawano County. Onset dates ranged from March 21 to April 4. The ages of the children ranged from 8 to 11 years old.

Frozen strawberries from the same processor, but with different lot numbers than involved in Michigan, had been served in the school a month before illness. The 3 children for whom the information is available reported eating strawberries (served as strawberry shortcake) at the school approximately one month before onset of symptoms.

The school is located close to an Indian reservation that had a hepatitis A outbreak in the past. As part of general preventive measures, the State Health Department is administering hepatitis A vaccine to children at the school, according to Advisory Committee for Immunization Practices recommendations for the use of hepatitis A vaccine.

HEPATITIS A OUTBREAK ASSOCIATED WITH FROZEN STRAWBERRIES

Tennessee

A 6 year old school child with hepatitis A has been reported in McMinn, Tennessee. The date of onset of illness is March 12. The child does not have apparent risk factors for hepatitis A. Frozen strawberries from the lot implicated in Michigan were served at the school in the month preceding illness. No other case has been reported in the county since 1996.

Laboratory Investigations

Serum and/or stool samples from the majority of the reported cases have been sent to the Hepatitis Branch at CDC for testing. Hepatitis A virus nucleic acid is being amplified from these specimens using the polymerase chain reaction (PCR) and nucleotide sequencing studies are under way to attempt to determine if the viral isolates obtained from the different clusters of cases are related.

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David R. Johnson

Good morning. I am Dr. David Johnson, chief executive and medical officer for the Community Public Health Agency at the Michigan Department of Community Health. Thank you for the invitation to testify on the recent hepatitis A outbreak in our State.

I'd also like to thank Michigan Senator Spencer Abraham for his involvement following the outbreak. The Senator has worked closely with us and the families who were affected in Michigan in order to prevent something like this from happening in other communities.

My intent this morning is to share with you an overview of the outbreak, including some estimates of resources brought to bear in its investigation and control.

Hepatitis A is one of several kinds of viral liver disease, and is generally thought to be one of the more mild forms of hepatitis. Signs and symptoms include loss of appetite, nausea, abdominal discomfort, and—classically—jaundice, a yellow discoloration of the skin and eyes. Disease onset is usually close to 4 weeks after a susceptible person ingests food or water contaminated with human waste containing hepatitis A virus. Generally the disease lasts days to weeks. Hospitalization for supportive care is rather uncommon, and hepatitis A related death is rare. There are no specific treatments for hepatitis A related disease. It can be prevented by receiving one or two shots of hepatitis A vaccine well in advance of exposure, or by receiving a single shot of immune globulin (IG) shortly after exposure.

In early March of this year, local health authorities in Calhoun County recognized a cluster of hepatitis A cases in their jurisdiction. Over the ensuing days, the number of cases grew rapidly. Most of the cases were students or teachers at Calhoun County schools. About the same time, about 120 miles away in Saginaw County, a smaller cluster of hepatitis cases, again associated with primary and secondary schools, was developing.

Investigators from our State health department were asked to assist in Calhoun county. They, along with staff from the Michigan Department of Agriculture, began to organize the early outbreak data and to develop hypotheses about causation. As the outbreak grew in numbers, we invited the Centers for Disease Control and Prevention to send up investigators as well, which they promptly did.

Since the overwhelming majority of those with hepatitis A had a link to schools, plausible hypotheses included those of exposure to some common source of food or drink at the schools. Many cases reported having consumed strawberries at school lunches or other events about a month before illness onset. Two different epidemiological studies—retrospective cohort and case-control studies—confirmed the link between consumption of sliced, frozen strawberries and hepatitis A in this outbreak.

At this point, the U.S. Department of Agriculture and the Food and Drug Administration traced the implicated strawberries, as you have heard, back to a distributor in southern California. The Michigan based distributor for this product, a firm in Kalamazoo, was contacted. Unfortunately, potentially contaminated strawberries from no less than 13 large lots were distributed in early 1997 in our State, not to mention the other States that received portions of these same lots. More specifically, over 1,300-thirty-pound containers were distributed to 289 schools in 28 Michigan counties in the west and central portions of our lower peninsula. Those 28 counties are serviced by 20 of the finest local health departments in the Nation. Over the Easter weekend, we contacted those local health departments and they began to track down the potentially contaminated strawberries in their jurisdictions, in spite of the fact that many schools were closed for spring break.

The message from local health departments to schools was: *If you have strawberries from any of the implicated lots in your freezer, do not serve them. If you have served them in the last 2 weeks, we will administer immune globulin to all those who ate them.* Other local health departments in our State became involved when it was learned that these strawberries had been served near the end of March at a Grand Rapids-area Special Olympics, which drew participants from across Michigan.

How large was this effort? Quite large. Allow me to share some figures concerning the investment of time and resources made by some of the State and local agencies involved in the investigation and control of this outbreak. The Michigan Department of Agriculture estimates they used 1,003-person-hours, which translates into \$29,219. Costs at our State laboratory totaled \$2,496, including technician time and reagents used. Our epidemiologists put in 286-person-hours, or approximately \$16,478 worth of time. More than 17,000 people received Michigan-manufactured immune globulin, at a value of \$110,895.

Local health departments in Michigan, I think it is fair to say . . . bore much of the burden of the control efforts. Across the State, frontline public health agencies invested 7,324 person-hours, at a value of \$314,134. Altogether then, State and local

agencies devoted nearly \$475,000 in person power and other resources to the investigation and control efforts for this outbreak.

Let me hasten to add that this impressive figure does not include either the costs to schools or—and this is most important—the costs to those who contracted the disease: direct medical care, pain and suffering, time away from school and work. Nor does the figure include any accounting of the anxiety and discomfort of thousands who had to undergo immune globulin injections.

We know that in Calhoun County there were 201-primary and 44-secondary cases of hepatitis A. Saginaw County recorded 22 cases. In the 2 locations, approximately 10 percent of these 267 cases were hospitalized. Fortunately, no one died, although that would not have been extraordinary for an outbreak this large. What we don't know is how many cases were prevented through the control efforts in Michigan and in other States.

In summary, then, this was one of the largest outbreaks of hepatitis A in Michigan, and one of the largest in the country in recent memory. The investigation and control efforts represent a high level of collaboration between Federal, State, and local agencies. Many hours and great expense went into that collaborative process.

I hope I have succeeded in giving you an overview of the strawberry-related hepatitis A outbreak from our perspective at the Michigan Department of Community Health. I think I am speaking for all involved when I thank you for your interest in this matter. I would be happy to answer questions you may have for me, or attempt to clarify any issues I may not have presented fully.

Thomas W. Schimm

RE: TESTIMONY ON THE "HEPATITIS A" OUTBREAK AT HOLY CROSS LUTHERAN SCHOOL

My name is Thomas Schimm, and I am a teacher and the minister of music at Holy Cross Lutheran Church and School in Saginaw, Michigan. My family and I live in Bay City, Michigan.

On Wednesday, March 5, my son, Ben, started feeling sick while he was at school. From that day through March 27, Ben was absent from school because of hepatitis A. Because Ben was an eighth-grader this year these 3 weeks at home, sick, made things especially difficult for him.

On Thursday, March 6, I began showing the same symptoms as Ben and except for March 9-12, when I felt somewhat better, I was also sick at home until Thursday, March 27 with hepatitis A.

My wife, Naomi, and I were very pleased with the concern and care given to us by our P.A., James Knight. At Ben's first appointment on Wednesday, March 12, he felt that it was more than just a flu virus and wanted to obtain a blood count and take an abdominal X-ray to test for possible appendicitis or other problems. On the morning of March 13, he called and wanted us to get Ben to a pediatrician that day because the blood test seemed to indicate that Ben had hepatitis. On Friday, March 14, he had Naomi and me come in for a blood test and strongly suspected that I also had hepatitis. On March 17, Knight had Naomi and our other three children go in for an inoculation (immu-globulin).

Around March 20, the Bay County Health Department sent a representative to our house to interview Ben and me in an effort to help find the source of the hepatitis A virus.

Both Ben and I suffered anorexia (a symptom of hepatitis A) and so we ate and drank very little for a period of about 2 weeks; we also were basically bedridden or inactive for about 3 weeks.

A more normal diet and activity level were slowly regained after many more weeks, and other health problems have been experienced since then. It has been shared with us that full recovery could take up to a year's time.

During the month of March, Holy Cross congregation had to cover costs for substitute teachers and substitute organists for worship services. Our family has been hurt financially because of the added medical expenses caused by this hepatitis A virus.

Apparently, some of the people from Holy Cross Church and School that live in the Saginaw area were more critical of how the hepatitis A virus was handled. After several students and some of the staff at the church and school became ill in the early part of March, it was generally thought that a flu virus was going around. Even after the first hepatitis cases were confirmed some parents were distressed

that their doctor wouldn't even consider a blood test. There was quite a bit of confusion about what the virus was or how it could be transmitted, and since the source of the illness was not yet known, much suspicion was put on the food service program at our school and the personnel preparing the food. The local health department was initially unable to provide our school staff with information that could be included in a letter sent out on Monday, March 17 to our school families. The staff needed to collect some information for this letter from some medical books of their own.

Upon the request of one of our board of day school members, St. Luke's Hospital sent two health representatives that conducted a meeting on Tuesday, March 18, for parents and any concerned persons.

As more cases were confirmed the local news people reported on it almost every day. The health department was now able to provide us with information and agreed to provide inoculations for all of our students, staff, siblings and parents who wished to participate. Over 400 people were inoculated within the next 2 days.

The source of the virus was found to be the frozen strawberries served on Monday, February 10.

Our hot lunch program at Holy Cross Lutheran School has been endangered by this experience. Some parents have lost their trust in it and are no longer having their children eat hot lunch, and so our school has lost much revenue in the hot lunch program.

In general, our community experienced some panic and confusion due to lack of information, our school and certain staff people have been hurt financially, one of our older members came close to losing his life, all due to the irresponsibility of this company that supplied food for school lunch programs.

Thank you for having me hear today. I am happy to answer any questions you may have.

Susan J. Doneth

My name is Susan Doneth, and I am the mother of a 10-year-old child who became extremely ill with hepatitis A after eating contaminated strawberries served in her school lunch. I am a member of S.T.O.P.—Safe Tables Our Priority, and I am submitting this testimony to record the experience of my daughter, my family, and my community.

On February 12, 1997, my daughter, Lindsay, a 4th grade student at Madison Elementary School in Marshall, Michigan, consumed strawberry shortcake, her favorite dessert, as a part of her school lunch. Exactly 28 days later, Lindsay became extremely ill exhibiting symptoms of severe body aches, headache, fever, abdominal pain, and vomiting. I assumed that Lindsay had the flu and kept her home from school. After 3 days of these symptoms, which continued to increase, I became alarmed. Lindsay would not eat, she would not drink, and she was deteriorating. By the fourth day at home, I knew something was seriously wrong. Lindsay spent most of the day on the couch with tears streaming down her face because she was in so much pain. On this day, a huge ice storm had hit Marshall and along with most of the city, we had no electricity, I had two other children at home at the time and my husband was out of town. I spent the day trying to comfort my child and frantically trying to reach my husband. I was sure that Lindsay needed immediate medical attention, but I could not leave my other two children at home with no heat, lights, or running water. After my husband arrived home late in the evening, we again called our physician and decided to take Lindsay to the emergency room. Lindsay became hysterical about the idea of going to the hospital. I assumed she was afraid of being prodded and poked by doctors and I tried to reassure her. She said to me, "Mommy, I'm not afraid of what they are going to do, I just don't want to move. Please don't make me move. I can't move, because it hurts."

When we arrived at the emergency room, Lindsay was asked to provide a urine specimen. When my daughter walked out of the bathroom with the urine cup in her hand, the specimen looked like weak coffee. When I saw the cup with brown liquid in it, I panicked and asked the doctor, "My God, what is wrong with her?" The doctor immediately admitted Lindsay to the hospital and told my husband and I that she suspected that Lindsay had hepatitis, but we would need to wait several days for laboratory tests to confirm the diagnosis. The doctor explained to us the different forms of hepatitis and tried to alleviate our fears by telling us she was "quite certain" our daughter had hepatitis A, because there were confirmed cases in Calhoun County in the previous few days. Needless to say, we were scared to death. I had so many questions and no answers. We would know little until the laboratory tests were returned.

Lindsay needed immediate IV fluid as she was severely dehydrated. I had to leave the room as my husband and three hospital personnel held my daughter down to try to start the IV. Lindsay was screaming in pain and she was terrified. I was crying as hard as she was and I didn't want to frighten her further. I couldn't bear to help pin her down while a nurse tried several times to get a needle in Lindsay's small vein. I know that Lindsay needed the IV, but as her mother, someone she trusts to protect her, it was unnatural and cruel to expect me to help them hold her down so they could hurt her. I went into the hallway and sobbed and left my husband to do what I was incapable of doing.

The day after Lindsay's admission to the hospital, a small article appeared in the local paper confirming that there were three cases of hepatitis A in Calhoun County. We didn't know what was happening but had a sinking feeling that our community was on the verge of something awful. We knew that there were more than three cases by talking to others in the community who had sick children with the same symptoms.

The next 6 days were worse for Lindsay than the previous 4. She continued to vomit and her stomach pain increased. She was on continuous IV fluid, pain medication, and anti-nausea drugs. We helped Lindsay to the bathroom dragging an IV pole behind us and held her up because she felt on the verge of fainting when she stood up and her pain dramatically increased. I have never seen a child so sick and I cannot describe to you what it is like to witness a child so ill, especially when that child is your own.

On day 2 of her hospital stay, Lindsay stopped talking. She would barely open her eyes and would barely respond to us when we spoke to her. We could tell she was in pain when her small eyebrows would furrow and tears would silently roll down her face. I remember my child whispering to me through dehydrated, cracked lips, "Mommy, it hurts everywhere." [*This is the point where my husband broke down.*] I was such an emotional mess that he had been holding himself together for me, and for Lindsay, but he just couldn't take it anymore. He sat in the hospital chair and cried, as he watched his little girl lying miserable in a hospital bed, and feeling helpless to do anything to help her. As we cried, we held our daughters head, and wiped her brow with a cold washcloth as she violently tried to vomit. Lindsay had not eaten or had anything to drink in over a week; and there was nothing in her stomach to get rid of. She would endlessly heave trying to get rid of the poison that had overtaken her body. With each convulsion, she would continue to cry, because she couldn't breathe; and her liver was so enlarged—and inflamed—that the movement was excruciating for her.

By day 3, the number of confirmed cases of hepatitis A was increasing drastically and the hospital personnel was showing signs of concern. Hospital beds were filling up quickly and I overheard nurses in the hallway commenting about the record number of admissions; they didn't know where they would put all the patients and they were working with nearby hospitals if they needed to refer patients elsewhere. They were pulling nurses from every floor to assist, because the hospital was becoming overwhelmed. We were forced to double up in rooms and now we were sharing a room with another little girl, Hallie Dopp, who was just as sick and miserable as Lindsay. Children were dropping with this virus in record numbers and nobody seemed to know why. Where was this virus coming from? What did these children all have in common and how big would this epidemic get? Hallie's mother and I speculated and tried to think about what our children had in common. As the epidemic increased it appeared obvious that the likely source of contamination was in the school system. Thankfully, our local physicians and local health department moved into action and worked around the clock to find the answer. I cannot describe to you the horror I felt when I learned that my child had become sick from something she ate in her school lunch. I have never felt so angry in my life and never felt so determined to demand explanation and answers. How could this have happened? What system or person didn't do their job to prevent it? Who was going to be accountable to my child, to me, and to my community for this horrific system failure? Didn't food in the School Lunch Program receive *extra* attention to ensure safety?

By day 4 in the hospital, I had to go home because I was recovering from a back injury and couldn't take the make-shift cot the hospital had provided for parental sleeping. My husband stayed with Lindsay and I went home to experience the worse panic attack I have ever had in my life. I shook and cried uncontrollably for over an hour. I remember calling my brother, who is with me here today, and crying on the phone. All I could manage to say is, "She is so sick, something is terribly wrong, she is so sick." My family rallied around me and somehow we got through it.

After 6 days, we brought our little girl back home, but believe me, it was not over. It was not over for her and it was not over for us. Lindsay continued to battle fa-

tigue, stomach pain, headaches, and nausea after eating. She had lost 10 percent of her body weight during the acute phase of this illness and we were trying to encourage her to eat to get her strength back. After 2 weeks at home, she would feel better for a few days and then go right back down with the same complaints. I began keeping a diary because I was still not convinced that my child would get better and if complications arose, I wanted a detailed account of her symptoms. I was assured by my physician that Lindsay would continue to improve, but we would have to be patient as it could take up to 6 months for her to fully recover. I talked to other mothers who had children hospitalized and it appeared that all of our children were experiencing the same type of recovery—slow and tedious. We all worried about what the long-term effects would be on our children. None of us were convinced that our children were out of danger. Could anyone guarantee us that our children would not suffer any long-term effects from this virus? My daughter's liver enzymes were 100 times normal; how can an infection of that magnitude not have a damaging effect on the liver of a 10-year-old?

During my daughter's recovery, I became actively involved in searching for information and demanding answers—no easy task. I had so many conversations with agencies and government officials that I felt like I was drowning in the black hole we refer to as government. I became a prisoner of my telephone, my laptop computer, and a fax machine. I was confident that if I persisted, somebody would listen to me. I felt I owed that to my daughter and I felt a responsibility to do that for the 244 other people in my community who had the hepatitis A virus, and the 10,800 people in my community who received IG shots to protect them from the virus.

I am not an expert, but from what I've gathered, there doesn't appear to be a "gap" in the system to ensure safe food in the School Lunch Program or safe food in general. There is a "gaping hole" and the processes for ensuring safe food are so incredibly poor that we can't even depend on school lunches to be safe for consumption. It is absolutely unacceptable to me that U. S. plants are inspected once every 10 years and only 1–2 percent of imported food is inspected at all. This is a system that I should feel safe with? I think not. As a tax payer, I can't think of a better place to spend my tax dollars than on ensuring a safe food supply. As a consumer, I would willingly pay a few pennies more for a product that I am confident is safe. We can't get much more basic than the food supply. If 9,000-people-a-year continue to die and over 30 million become ill from foodborne illness, clearly, we are not doing the job. The community that I live in has a population of less than 9,000 people, which essentially means that the equivalent of my entire town is wiped out every year from foodborne illness. Now I am quite certain that if my entire community was wiped out from a foodborne illness or any other cause, we would be doing something somewhere to change things. If a bomb went off or a person or persons systematically killed everyone in my city, we would move heaven and earth to find, try, and punish whoever was responsible. Why is it that we don't have the same commitment to this issue? Does the fact that the 9,000 people who die each year don't all die at once make the issue or the problem less important? I don't think we need a higher body count to signal a problem and 9,000 people is 9,000 people no matter how you look at it.

The hepatitis A epidemic that bit my county is not an isolated incident of a *problem*, it is symptomatic of *the problem*. Thank god, these strawberries were not contaminated with a deadly pathogen, at least as far as we know. Thank god, these strawberries didn't contain *e coli 0157* or something just as deadly. Richard L. Seiglar, a pediatric nephrologist at the University of Utah School of Medicine in Salt Lake City, describes *e coli 0157* by saying, "the poison produced by the bacteria may be the most potent toxin ever described. An ounce of it would kill everybody in the upper Midwest." If a few microbes, let alone an ounce, were in these strawberries, what would the results be? What would that have done to my daughter and to the other 244-hepatitis A victims in my community? What action would be taken, if Calboun County had 245 deaths from a foodborne illness from eating food served in a school lunch?

Thankfully, nobody died in my community, but the important message is, many could have and because of what happened, it is truly a miracle that we didn't lose anyone. The description of the hepatitis A virus as a "mild, nonfatal flu-like illness" is completely misleading. The virus that my daughter and the other 244 people in my community experienced was not flu-like and the symptoms were anything but mild. Furthermore, this virus is not a "nonfatal" virus; people can die from it, people have died from it, and at least one individual in my community came close to death as a result of this virus.

I have come to know parents who have lost their children to foodborne illness. I cannot begin to comprehend how a parent survives such a thing. No one deserves

to die from eating and the fact that these deaths are preventable and we aren't preventing them is inexcusable. How many deaths will it take before somebody does something? If 9,000-deaths-a-year isn't enough, what is the magic number to promote change?

I no longer operate under the assumption or blissful ignorance that the food served in my child's lunch is safe, or the food that is in my local grocery store is safe. I used to operate under such assumptions and I have learned first-hand that we are all at risk. I am all too aware that I could have lost my child. Many parents before me sat next to a hospital bed with a sick child, a child sick from food, and they didn't take their children home with them, because those children were visited by the face of death and they never went home. I can't give those parents their children back, but what I can do is continue to have a voice, I will continue to demand change, and I will not be satisfied until something is done to prevent foodborne illness and death. It is preventable and we need to examine our current system carefully and make the necessary changes, even it doesn't fit in with the current desire to "downsize" everything in . . . government. We are talking about the food supply and the safety and health of all of us. I can't imagine that we wouldn't spend the money or find the resources to prevent foodborne illness and death. As a parent, I did nothing wrong, the school system did nothing wrong; we could not prevent this, but somebody certainly should have.

I want to know how a for-profit industry "certifies" to the USDA that 1.7-million pounds of strawberries are U.S. grown and passes them off for distribution through our school lunch program. Why do we trust the current self-policing system of certification? If the USDA received "tips," anonymous or not, that something was illegally being done and the potential danger was there, why didn't somebody follow up on that information? What are we doing right now to assure that this doesn't happen again? How am I going to regain my confidence in the School Lunch Program?

I am aware that the activities of the distribution company involved in this epidemic have been suspended. I am also aware that criminal prosecution is being investigated. What does that mean? What will happen to this company? What will happen in terms of government if we discover that the USDA did not do their job? What will the repercussions of that be? I am also aware that the CDC is still testing these strawberries. Why? Is there a possibility that something else is in these strawberries? Is there a possibility that the hepatitis A virus experienced by my community is somehow different than a typical strain of hepatitis A? Did the virus mutate or change form and is it something different than what has historically been experienced? I have learned that less than 1 percent of hepatitis-A victims require hospitalization and my community experienced an 8-percent hospitalization rate. My community did not have the flu and there are many who are still fighting to recover. It does not appear to me that my child, or many of the other victims in my community, experienced the "mild, flu-like illness" historically seen with hepatitis A. We don't appear to fit with any of the "typical" characteristics of hepatitis A. Therefore, I am not comforted by the limited information I get from research and medical professionals that my daughter will fall into the "typical" category and not suffer any long-term effects. I don't think anyone can guarantee me that and I am not convinced that she won't suffer any lingering effects from this illness.

I am familiar with the 11-step plan proposed which outlines procedures for Country of Origin Documentation And Surveillance, dated April 18, 1997. I have serious concerns about the 11-step plan, because it still doesn't appear to address prevention. It will give us a better system to track statistics and a better "trace-back" procedure once an outbreak occurs. Although this is important, it will not solve the problem. Although the "country of origin" is a big issue in this particular outbreak, I am concerned about specifically focusing on that issue. My understanding is that there is still some question as to where the contamination of these strawberries occurred. Therefore, regardless of the country of origin of the product, it is obvious that there are many existing problems in THIS country with food distribution. The bottom line is that *the food must be safe*, regardless of where it comes from. That is the issue, that is the problem, and *prevention* should be the focus. Whether we are talking about school lunches or any other form of food distribution.

Thank you for offering me the opportunity to submit this testimony and share my views on this important issue. I would also like to personally thank Senator Abraham for supporting the victims in Michigan and requesting that we have the opportunity for input and participation in this hearing. Senator Abraham has done a commendable job in giving us an opportunity to have a voice and I hope you are listening.

I don't want to walk away from this hearing learning that "the system" failed—we already know that. I want to know what all of you are going to do to make sure

that this doesn't happen again, and I want you to tell me who is to blame, and what you are going to do about it. If you don't do something about it, it *will* happen again. People will continue to get sick, people will continue to die, and we will all live with the consequences of a system that continues to fail.

There are so many things in this world that I have to protect my children from and this is something that is beyond my control. The only control I have is to try to implement change and I assure you that I will continue to fight to do that. I will show my children, through my example, that we all have the power and the responsibility to fight for what we believe in and if we fight hard enough and long enough, we will succeed. Now it is up to you—please don't disappoint us. Thank you.

SENATORS' QUESTIONS SUBMITTED TO THE WITNESSES AND RESPONSES THERETO

Senator Landrieu's Questions submitted to the Centers for Disease Control and Prevention

Question 1. As I understand, there were hepatitis A cases in Louisiana associated with the contaminated strawberries. Could you please comment on these cases?

Response. During March 1997, four cases of hepatitis A were reported among adolescents in the New Orleans metropolitan area. Two of the patients were siblings, and the other two were unrelated. All patients ate strawberry smoothies from several retail establishments that received frozen strawberries from the same California processor that distributed frozen strawberries to Michigan. The investigation to date has not revealed other risk factors for these patients. No other cases in Louisiana have been identified that might be potentially associated with consumption of frozen strawberries.

Since the relatively small number of cases precludes conducting an epidemiologic study such as a case-control study, it is difficult to conclude that these cases are definitively linked to consuming frozen strawberries. Eventually, laboratory analysis of serum samples from these cases may help to determine whether the viruses causing illness in Louisiana are related to each other and/or to the viruses causing illness in Michigan. These analyses are underway at the Hepatitis Branch, CDC.

Senator Coverdell's Questions for the Centers for Disease Control and Prevention

Question 1. In 1990, there was an outbreak of hepatitis A at an elementary school in my home State of Georgia due to contaminated strawberries, similar to what occurred recently in Michigan. What safety precautions were implemented by USDA and other Federal agencies back then to prevent this from happening in the future?

Response. The outbreak in 1990 was linked to strawberries grown and processed in northern California. Immediately following the investigation of the outbreak, recommendations were made regarding maintaining high levels of sanitation during picking, processing, and packing strawberries and other fruit and produce. In addition, recommendations were made that workers who harvest fruit and produce, and workers who process and package these items, should have ready access to handwashing and bathroom facilities.

Question 2. Obviously, since another outbreak of hepatitis A occurred in 1997 the safety measures implemented in 1990 were not completely effective. What additional safety precautions do you now suggest be implemented or have been implemented to prevent any further outbreaks? How do you know these new measures will work?

Response. The outbreak in 1997 was linked to strawberries grown in Mexico and processed in southern California; the investigation has not been able to establish whether hepatitis A virus contamination of the strawberries occurred during growing/harvesting or during processing/packing. To prevent further outbreaks, CDC is working with other agencies to reinforce messages among the industry about main-

taining high levels of sanitation and hygiene at all stages of fruit and produce production and preparation. In addition, CDC and other agencies have had ongoing communication with Mexican health and agriculture authorities with the objectives of sharing scientific information to prevent foodborne illness. Information regarding this outbreak has been disseminated to public health authorities in the United States and Mexico. Through increased awareness and disease surveillance systems, we can determine the effectiveness of these measures. Hepatitis A outbreaks related to frozen strawberries appear to be relatively uncommon. The outbreak in 1990 and the outbreak in 1997 are the only strawberry-related outbreaks that have been detected during the past several decades.

Question 3. Is it currently possible to detect hepatitis A on fruits and vegetables? If so, what testing procedures are in place to detect hepatitis A on fruits and vegetables?

Response. A method has not yet been developed to find hepatitis A virus in fruits and vegetables. In contrast, there is a method to find hepatitis A virus in clinical specimens such as blood or feces, and in raw shellfish. The method, which is based on the polymerase chain reaction, has been used in research settings and in outbreak investigations. CDC and FDA are collaborating on laboratory investigations to determine the best methods to identify hepatitis A virus in fruits such as frozen strawberries.

Senator Landrieu's Questions submitted to the Food and Drug Administration (FDA)

Question 1. Since the recent hepatitis-A scare, what actions have been taken by the administration to prevent similar occurrences in the future, especially with over-sight and certification measures?

Response. It is important to point out that the source of the contamination of the strawberries is not known and may never be identified. We are continuing to investigate. The berries were picked and processed a year ago. They were sampled 6 months ago. Thus, it is not possible to know the conditions that existed at those times in the plant or in the fields.

Although the source of the contamination has not been identified, the Food and Drug Administration (FDA) is taking actions to ensure that growers, processors, and other entities involved in the handling of the products exercise appropriate controls to reduce the possibility of a recurrence of the problem. As examples, FDA has advised the processor/packer, Andrew and Williamson (A&W), of good manufacturing practices. A&W has indicated they do not intend to reopen this year and that they intend to build a new plant before resuming operations next year. The Department of Agriculture's Agricultural Marketing Service (AMS) has asked FDA, and we have agreed, to conduct a comprehensive review of AMS' voluntary inspection program to include sampling and inspectional procedures. On May 20, 1997, Federal officials from FDA and the Centers for Disease Control and Prevention (CDC), State officials from California, and Mexican health and agriculture officials met in Mexico City. The participants discussed sanitary conditions for the growing fields and shared information from this outbreak. At the conclusion of this meeting, representatives from the United States and Mexico signed a joint declaration agreeing to improve information exchange mechanisms and to enhance scientific cooperation in the area of foodborne illness.

As produce items are grown in the soil and naturally contain microorganisms, it is not possible to guarantee that produce will be free from contamination. We only can work to minimize the risk. FDA routinely examines fresh produce for signs of filth and pesticides. FDA is working with the National Advisory Committee on Microbiological Criteria for Foods to address prevention strategies for microbiological contamination with pathogens on fresh produce. At present, there is no test available for detecting the hepatitis A virus in fruit. FDA and CDC are working together to develop a test method; however, these research efforts take extensive time and resources. There also is no treatment process available that would eliminate the virus without destroying the fresh character of the fruit. The President's National Food Safety Initiative proposes additional funding for research to address these needs. The hepatitis A virus is one of the pathogens included in the Initiative.

USDA has implemented an 11-point plan to improve compliance with the requirement that food in the School Lunch Program be of domestic origin.

Question 2. Could you please comment on any efforts the administration has taken in the following areas:

1. Investigating sanitary standards in foreign countries exporting food into the United States.

Response. As mentioned above, FDA, CDC, and others have provided technical assistance to officials from the Mexican Government to ensure proper sanitation in the growing fields. FDA also has mutual recognition agreements (MRAs) with trading partners to ensure that food is produced and manufactured under systems that provide comparable levels of safety.

The Food Safety Initiative proposes several new methods to improve the reliability of imported foods. It requests funding in the fiscal year 1998 budget to increase the number of MRAs. It also suggests a Federal-State communication system for States to use to notify Federal agencies of problems found with imported products. This enhanced communication system will enable us to better target problem products at the border. The proposed funding also would improve our ability to provide technical assistance to foreign countries.

Question 2.—Continued

2. Improving food inspection and consumer knowledge.

Response. As you are aware, President Clinton has made food safety a priority of his administration. The goal of the Food Safety Initiative is to reduce the incidence of foodborne illness. The President's budget includes funding to implement a new early warning system for foodborne illnesses, to enhance seafood safety inspections, and to expand food safety research, risk assessment, training, and education.

Secretary Shalala has been working with Secretary Glickman of the Department of Agriculture and Administrator Browner of the Environmental Protection Agency to identify opportunities for public/private partnerships to improve food safety. We have already held public meetings to solicit recommendations from all stakeholders in food safety, including consumers industry, members of the scientific community, State, tribal, and local public health officials.

Secretary Shalala, Secretary Glickman, and Secretary Riley of the Department of Education have signed a Memorandum of Understanding to join the Partnership for Food Safety Education. This public/private partnership consists of government health officials, food industry groups, consumer organizations, State associations, and others interested in promoting safe food handling behavior to prevent foodborne illness. This partnership seeks to develop accurate, science-based, and consumer-oriented messages to educate consumers and food industry workers of safe behaviors. A public conference on food safety education was held June 12–13, 1997.

Senator Coverdell's Questions submitted to the Food and Drug Administration (FDA)

Question 1. Obviously, since another outbreak of hepatitis A has occurred in 1997, the safety measures implemented in 1990 were not completely effective. What additional safety precautions do you now suggest be implemented or have been implemented to prevent any further outbreaks? How do you know these measures will work?

Response. The most frequently reported source of infection for hepatitis A is either household contact or sexual contact with an infected person. Hepatitis A transmittal through a foodborne route occurs infrequently. It is important to more that the source of the contamination of the strawberries is not known and may never be identified. The berries were picked and processed a year ago. They were sampled 6 months ago. Thus, it is not possible to know the conditions that existed at those times in the plant or in the fields.

Although the source of the contamination has not been identified, the Food and Drug Administration (FDA) is taking actions to ensure that growers, processors, and other entities involved in the handling of the products exercise appropriate controls to reduce the possibility of a recurrence of the problem. As examples, FDA has advised the processor/packer, Andrew and Williamson (A&W), of good manufacturing practices. A&W has indicated they do not intend to reopen this year and that they intend to build a new plant before resuming operations next year. The Department of Agriculture's Agricultural Marketing Service (AMS) has asked FDA, and we have agreed, to conduct a comprehensive review of AMS' voluntary inspection program to include sampling and inspectional procedures. On May 20, 1997, Federal officials from FDA and the Centers for Disease Control and Prevention (CDC), State officials from California, and Mexican health and agriculture officials met in Mexico City. The participants discussed sanitary conditions for the growing fields and shared information from this outbreak. At the conclusion of this meeting, representatives

from the United States and Mexico signed a joint declaration agreeing to improve information exchange mechanisms and to enhance scientific cooperation in the area of foodborne illness.

As produce items, are grown in the soil and naturally contain microorganisms, it is not possible to guarantee that produce will be free from contamination. We only can work to minimize the risk. FDA routinely examines fresh produce for signs of filth and pesticides. As discussed in our response to your question No. 6, there is no test available at present to detect the hepatitis A virus in fruit.

As you are aware, President Clinton has made food safety a priority of his administration. The goal of the President's National Food Safety Initiative is to reduce the incidence of foodborne illness. The President's budget includes funding to implement a new early warning system for foodborne illnesses, to enhance seafood safety inspections, and to expand food safety research, risk assessment, training, and education. Hepatitis A is one of the pathogens included in the initiative.

Question 2. Is it currently possible to detect hepatitis A on fruits and vegetables? If so, what testing procedures are in place to detect hepatitis A on fruits and vegetables?

Response. At present, there is no test available for detecting the hepatitis A virus in fruit. FDA and CDC are working together to develop a test method; however, these research efforts take extensive time and resources. There also is no treatment process available that would eliminate the virus without destroying fresh character of the fruit. Cooking the fruit to at least 185°F for 1 minute, as is done in making jams and jellies, inactivates the virus. Irradiation can inactivate the virus; however, the levels necessary for inactivation would destroy the fruit.

FDA is working with the National Advisory Committee on Microbiological Criteria for Foods to address prevention strategies for microbiological contamination of pathogens on fresh produce. One of the most critical needs in food safety research is for rapid methodologies to accurately identify and characterize foodborne hazards. The President's National Food Safety Initiative proposes additional funding for research to address these needs.

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L E T T E R

Kevin R. Thompson
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Battle Creek, MI. 49017

6-4-97

Testimony submitted to Senate Agriculture Committee
June 5, 1997.

I graduated from Pennfield High School this week. I was the first case reported at my school. I was 165 lbs, and lost 20 lbs the first week of my illness. My total weight loss is 25 lbs. I plan on playing football and basketball for Albion College this fall. As of now, I don't have a lot of my strength back. I was in top physical condition for the upcoming season. I planned on running track but I was unable to due to my illness. I run a 4.6 in 40 yards. I had a excellent chance at getting a scholarship in track.

My illness started March 21 and still continued in full strength until May 7, 1997. My recent lab work is still off and I don't have my strength back yet. I had symptoms of horrible headaches, body aches, fevers and night sweats, stomach cramping with pain, loss of appetite, extreme and fast weight loss, nose bleeding due to low plaletes. My back pain was so intense that I would cry out in pain, hit my mattress and headboard and plead with my mom to help me. I wasn't able to take any pain med, as my liver wasn't able to metabolize anything. My lab results were off, my SGOP was 8,310, normal range was 0-40. My Sgpt was 7,613, normal range is 5-40. I was in the hospital for three days and went home with a IV for two days. I had to use an urinal for several weeks as I had no strength to get up. My nights were long as I couldn't sleep with all the constant pain. I wouldn't wish this on anyone. I still have some problems now, my strength hasn't returned yet, and I'm very tired most of the time. My lab work still hasn't returned to normal.

During this period, I missed Golf Shores, Alabama for Spring break, Grandma and Mother's and my birthdays. Most of all I was in top physical condition for my upcoming freshman year playing football and basketball for Albion College. I lost the possibility of getting a scholarship from track and getting the student athletic award for best athlete in my 97 class. I have excelled in sports throughout school and have won many awards like All City in Football and Basketball, All Conference in both and All State Honorable Mention in Football. My family lost income because of this. My brother Scott also had strawberries and developed Hep A. Scott had the immunization shot given along with the rest of my family. My father later developed Hep A.

I thought that we had a better system than we did inspecting our food. I didn't realize that several different parts of the government were involved but really didn't work well together. I believe that you will create a safer way of inspecting our food products.. and I thank you. This is the good that will come out of this.

Thank you,
Kevin Thompson

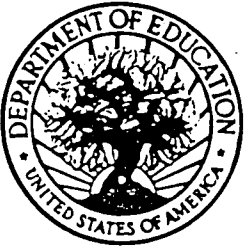
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