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EXAMINE THE CURRENT PET FOOD RECALL

HEARING

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

SPECIAL HEARING

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EXAMINE THE CURRENT PET FOOD RECALL

THURSDAY, APRIL 12, 2007

U.S. SENATE, SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES, COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 2 p.m., in room SD–192, Dirksen Senate Office Building, Hon. Herb Kohl (chairman) presiding.

Present: Senators Kohl, Byrd, Durbin, and Bennett.

OPENING STATEMENT OF SENATOR HERB KOHL

Senator KOHL. At this time, we'll proceed with this hearing.

We appreciate everyone coming on such short notice to discuss an issue that is of great concern to pet owners all across our country.

On March 16, Menu Foods began recalling dog and cat foods produced at their facilities in Kansas and New Jersey. Their recall covered products made between December 3, 2006, and March 6, 2007. It has since been expanded to nearly 100 brands. Though this comprises only a portion of all the pet food in commercial channels, it is, indeed, a very serious issue to the owners of the 60 million dogs and 70 million cats all across the United States. Just about every American household with a pet is cognizant of this problem, and many are extremely concerned.

While the FDA maintains that there have been approximately 16 animal deaths attributable to this problem, other reports are more troubling. Banfield, the largest pet hospital network in the country suggests that up to 39,000 animals have gotten sick, and others estimate as many as 3,500 pets have likely died. Since the outbreak began, FDA has received over 13,000 complaints from consumers, more than double the number they receive usually on all topics during an entire year. And that number keeps growing. People are confused. They don't know what is safe and what is not safe, and they have seen the recall expand several times now.

Unfortunately, the FDA web site has inadvertently exacerbated that bewilderment. As of Monday, a page titled FDA Update and Synopsis stated that, quote, "all the contaminated wheat gluten has been traced." But, a few clicks away, in a "Frequently Asked Questions" section, the FDA states, quote, "We are still tracing the contaminated wheat gluten." So, obviously, pet owners can get two very different ideas, depending upon where they click.

FDA's public assurances have failed to provide adequate confidence to pet owners. Each time the recall is expanded, they wonder, "What's next? Is the FDA confident that this recall will not

grow? When we will get the all-clear signal? And what assurances can the FDA give us with 100 percent confidence?"

So, those are my key questions to our first panel. We need to insist that pet owners have the right information, from this point on. That is our central task today. Let us present exactly what we know in a way that I could understand if I were a dog owner in Appleton, Wisconsin, trying to navigate this huge recall.

For many in America, pets are more than just companions, they are members of the family. They go out of their way to ensure their pet's health and happiness, often buying the most expensive dog or cat food on the shelf. So, when they do all of these things and their pet gets sick or dies for no apparent reason, not only is there guilt and sadness, people rightfully feel angry and fearful. They trust that the products on the store shelves will be safe for their pets, and feel betrayed when they are not. So, we need to make some progress in addressing these concerns today.

We've gathered a good group of witnesses. Our first panel will include Dr. Stephen Sundlof, the director of the FDA Center for Veterinary Medicine, and Dr. Steve Solomon, the head of the FDA's field operations. They are very busy with this recall, and so we appreciate their taking time to join us.

On the second panel, we will have Dr. Elizabeth Hodgkins, a veterinarian and director of the All About Cats, Wellness Center in California, and Dr. Claudia A. Kirk, Associate Professor of Medicine and Nutrition at the University of Tennessee College of Veterinary Medicine. Both of these witnesses have worked for the pet food industry, as well as their current positions. Also on the second panel we will have Dr. Duane Ekedahl, Executive Director of the Pet Food Institute, and Mr. Eric Nelson, a feed specialist with the Wisconsin Department of Agriculture, Trade, and Consumer Protection. Mr. Nelson is also the president of the American Association of Feed Control Officers, the group who help set the standards for animal feed.

We'd like to thank all of the witnesses in advance, and we look forward to their testimony and their questions.

And now I would like to turn this microphone over to the ranking member on this Committee, Senator Bennett.

STATEMENT OF SENATOR ROBERT F. BENNETT

Senator BENNETT. Thank you very much, Mr. Chairman. And thank you for your prompt action in calling the hearing. I think it's very important, as you say, that people get an assurance of where we are.

The products that have been recalled comprise a very small percentage of the total amount of pet food, roughly 1 percent, but that statistic is of no comfort to those who feel their pets are at risk, and we need to know, and hope to find out at this hearing, whether there is any chance that that 1 percent will grow. And I'd like to know how lethal that 1 percent really is, because 1 percent still is an awful lot of animals and an awful lot of companions, as you say. For many people, a pet is an important part of the family.

The FDA has reacted swiftly to this incident, and we're glad of that. But I welcome Dr. Sundlof here, and look forward to what he has to tell us.

Thank you.

Senator KOHL. Thank you very much, Senator Bennett.

Senator Durbin.

STATEMENT OF SENATOR RICHARD J. DURBIN

Senator DURBIN. I want to thank Chairman Kohl and Senator Bennett. I called Chairman Kohl, over the Easter break and asked him if he would consider this hearing and he said yes, and we moved very quickly.

We want to thank the witnesses, who came here on short notice, because I think they feel, as we do, that this is a matter of great urgency.

There are two reasons why I've asked for this hearing. The first is because I know what pets mean to the lives of so many people. More than 60 percent of U.S. households own pets. That's more than 68 million households. Someone once said, "Old age means realizing you'll never own all the dogs you wanted to." Well, we love our cats and dogs and other pets. They give us uncompromising love and loyalty. But we owe them loving care in return.

Unfortunately, with this recall we've been tracking over the last several weeks, many Americans are losing their cats and dogs to contaminated pet food. Many more are worried about what to feed their animals. The numbers are in dispute. The Food and Drug Administration suggests only 16 reported animal deaths due to poisoning, but other sources are in the hundreds, sometimes thousands. State Veterinary Medical Association reports significantly higher totals. Michigan reports 38 animal deaths; Oregon, 35. If these numbers are consistent with veterinarians around the country, we're looking at the possibility of hundreds of dead pets, maybe more.

Most recently, Banfield Pet Hospital, the largest pet veterinary practice in the United States, with more than 615 veterinary hospitals, shared data with the FDA that showed a 30-percent increase in kidney failure among cats during the 3 months that the contaminated food was sold. The Vet Information Network, linking 30,000 vets, recently did a survey of 1,400 members, found a third reported at least one incident, and estimated that between 5 and 10,000 pets may have fallen ill from eating contaminated food, and 1 to 2,000 may have died.

There are still many unknowns in this situation. The FDA investigation is ongoing. And, due to the nature of the contamination, we'll probably never have a definitive tally. The FDA also has not confirmed the source of the contamination. There is an association between the substance melamine and the pet deaths, according to FDA. That chemical is used in fertilizer in China, and in plastics and industrial products in the United States. We also don't know why a batch of Chinese wheat gluten was contaminated with this chemical, and, perhaps most importantly, we don't know why the recall unfolded so slowly while contaminated pet food sat on the shelves or made its way into the dishes of dogs and cats in homes across America. I think it's important we have this public hearing to clarify what we know, what we need to know, why this happened, and the steps we should take to make sure it never happens again.

And that takes me to the second reason why I have asked for this hearing. What is the connection between E. coli on spinach and contaminated pet food? Unfortunately, it's the same broken food safety system: too many agencies—12 to 15 different Federal agencies—with the responsibility for food safety. Too many laws—up to 30 different laws with different standards—some calling for daily inspections, others, annual inspections, some, much different. Too many committees on Capitol Hill that have jurisdiction because of all these different agencies. Too many special interest groups.

What we clearly need, and Congresswoman Rosa DeLauro and I have been pushing for it, and will continue to, is one single food safety issue—agency for human food, for pet food, driven by science, not by politics or tradition. I think that's the only way we're going to get to the bottom of this, ultimately.

What disturbs me about this incident is that it confirms, yet again, that pet food, as well as human food, is at risk, because of the gaps in the system of regulation and inspections that govern our food industry in America today. There are significant health implications to this broken system: illness, death, lost economic activity, and healthcare costs.

Dr. Sundlof, who will testify today from the FDA, implied so much when he was quoted, more than a week ago, and here's what he said, after looking at the pet food contamination, "In this case, we're going to have to look at this after the dust settles and determine if there's something from a regulatory standpoint that we could have done differently to prevent this incident from occurring."

There are three areas, in particular, I am concerned about. I hope we get into them today. First, timing. Menu Foods, the pet food manufacturer involved, first noticed a potential problem on February 20, 2007. The company has reported that, on this date, it first started noticing test animals were getting sick and refusing to eat their product. How long did the company wait to notify the Food and Drug Administration? Almost 3½ weeks. They notified the Food and Drug Administration on March 15, 2007, after the contaminated food products for pets obviously were spread across this country. Why did it take so long? In the meantime, other companies were selling tainted products. And the supplier wasn't aware that it had provided wheat gluten contaminated with melamine. I think that companies that unnecessarily delay reporting and endanger human and animal health should face penalties, severe penalties.

Second, I'm concerned by media reports that have stated the Emporia Kansas facility, where many of these products were made, had never been inspected. It appears that there is a limited Federal presence in this area. We rely on a patchwork of State inspection systems and voluntary compliance.

I want to know what this patchwork looks like. I want to know if the FDA needs to standardize a set of processes, practices, and inspection systems to make sure our pets are protected.

I also think we need more data and better reporting. Blogs and nonprofit web sites have sprouted up as the best way to share information on this contamination. It's a voluntary effort of pet own-

ers that is spreading more information quickly than our Government. The Federal Government ought to be harnessing this power by ensuring that State veterinarians, or even pet owners, could comment and alert the FDA of contaminations in a more timely manner. If sites like Veterinary Information Network and PetConnection.com can do this, so can our Federal Government.

There are a lot of questions asked, and we need answers. That's why we're here today, to learn who's inspecting pet food manufacturing plants, what goes into that food, and whether we need to update a food safety system to protect pets and human health.

I thank the witnesses for being here, and I thank you, again, Mr. Chairman.

Senator KOHL. We thank you, Senator Durbin.

And now, we'd like to call our first two witnesses, Dr. Sundlof and Dr. Solomon, to step forward and give us their testimony.

Dr. Sundlof, thank you so much. We'll start with you.

STATEMENT OF STEPHEN F. SUNDLOF, D.V.M., Ph.D., DIRECTOR, CENTER FOR VETERINARY MEDICINE, FOOD AND DRUG ADMINISTRATION

ACCOMPANIED BY DR. STEVEN SOLOMAN, OFFICE OF REGULATORY AFFAIRS

Dr. SUNDLOF. Thank you, Mr. Chairman, for the opportunity to appear today at this hearing.

With me is Dr. Steve Solomon, from FDA's Office of Regulatory Affairs, who has been the lead in the field part of the investigation. And he will be helping me answer some of the questions on the mechanics of the investigation.

As a pet owner and a veterinarian, I recognize how important pets are to many Americans, and I offer my sympathies to the pet owners whose pets have become ill or died due to this pet food contamination.

The recall hit very close to home for me, as I have two dogs. And when we learned of the recall, I was feeding one of the products on the recall list. FDA's investigation has been very aggressive and comprehensive. We've been working on this, day and night, since we learned of this. At this time, we have no evidence whatsoever that any of the affected wheat gluten has gotten into the human food supply. And that's been consistent throughout the investigation. However, we are continuing to investigate and confirm the safety of human and pet food. We are leaving no stone unturned.

Our first priority was to limit the risk of animal injury and death related to pet food contamination. We worked to quickly identify the scope of the problem, to ensure that manufacturer removed potentially contaminated products from the market, and to inform consumers not to feed their pets the recalled product. FDA's Office of Crisis Management activated FDA's Emergency Operations Center, which works seamlessly with a number of offices, including the Center for Veterinary Medicine, the district offices, FDA headquarters, the laboratories that were instrumental in identifying the melamine, the public affairs Office and the Office of International Programs, to alert our trading partners.

Within 24 hours of learning, from Menu Foods, of the problem, FDA investigators were on site at the Emporia Kansas plant, searching for the source of contamination. FDA sent samples of

wheat gluten to our Forensics Chemistry Center in Cincinnati, and, using advanced analytical techniques, the FDA scientists identified the presence of melamine within 24 hours of receiving a pet food sample from FDA's field staff.

We then identified the importer and the initial distributor of the contaminated wheat gluten. Our investigation also identified the Chinese supplier. FDA has asked the Chinese Government to participate in this investigation. FDA issued an import alert on wheat gluten by the Chinese supplier to assure that contaminated product does not enter U.S. commerce. At this time, we are also sampling 100 percent of import shipments of wheat gluten from China and from the Netherlands. China and the Netherlands are the source of most of the wheat gluten imported into the United States.

Ten FDA district offices have inspected manufacturing and distribution facilities, and five field laboratories have analyzed wheat gluten in pet food samples. More than 400 FDA employees across the country have been involved in the investigation, sample analysis, communication, management, and have taken numerous calls from consumers and veterinarians who reported potential illness involving their pets.

These events give you an understanding of the thoroughness of the FDA's investigation, and we promptly identified the source, the importer, its supplier, and the parties directly receiving the suspect material, wheat gluten, which was contaminated with melamine.

To ensure the success of the pet food recall, FDA is working with the recalling firms and with our many public health partners. We are communicating with the 50 State Departments of Agriculture, health authorities, veterinarians, and the Association of American Feed Control Officials.

FDA is also conducting recall-effectiveness audits. These audits will ensure that the manufacturers and other recalling firms remove all recalled products from the pet food supply chain, and that retailers remove all recalled products from store shelves. This is one of the largest pet food recalls in history, if not the largest. However, according to the Pet Food Institute, the product recall currently represents less than 1 percent of all dog and cat food on the market. This indicates that consumers have access to an ample supply of pet food. We appreciate the extraordinary cooperation of our Federal and State partners, health authorities, veterinarians, the news media, the American public, and others who have supported this investigation. We also appreciate the prompt action and cooperation of the firms who voluntarily initiated recalls and continued support of other distributors and retailers affected by the recall.

PREPARED STATEMENT

The cooperation and coordination of all the professionals who worked with the FDA to respond to this contamination incident enhanced the FDA's ability to respond in the moment, to focus on the public health issue at hand, and to help ensure the safety of America's pet food.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF STEPHEN F. SUNDLOF, D.V.M., PH.D.

Introduction

Mr. Chairman, I am Stephen F. Sundlof, Director of the FDA Center for Veterinary Medicine. Joining me today is Dr. Steven Solomon, Deputy Director for the Office of Regional Operations, for FDA's Office of Regulatory Affairs. Thank you for the opportunity to appear at today's hearing to discuss the recent contamination of pet food. As a pet owner, and as a veterinarian, I recognize how important pets are to many Americans. I offer my sympathy to pet owners whose pets have become ill or died due to contaminated pet food.

The recall hit very close to home for me, as I have two dogs of my own. At the time that FDA first learned of the contamination, I was feeding my dogs one of the "cuts and gravy" dog foods on the recall list.

FDA is conducting a thorough investigation of the pet food contamination. During the past four weeks we have aggressively worked to identify the source and scope of the contamination, to assure the removal of all contaminated products from the supply chain and store shelves, and to keep the public informed. At this point, we believe we have identified the source, the importer, its supplier, and all of the parties directly receiving the suspect material—wheat gluten contaminated with melamine.

In addition to responding to the pet-related dynamic of this situation, we actively investigated any potential risk to the human food supply. At this time, we have no evidence to suggest that any of the imported wheat gluten contaminated with melamine entered the human food supply. As an added precaution, however, we have asked the Centers for Disease Control and Prevention to use its surveillance network to monitor for signs of human illness, such as increased renal failure, that could indicate contamination of the human food supply.

Background on FDA Regulation of Pet Food

The pet food industry is responsible for adherence to good manufacturing practices. FDA conducts risk-based inspections targeted toward products that pose the greatest risks to public health. However, inspections cannot identify every potential contaminant and are only one aspect of our work to detect and contain problem such as this. In addition, it is important for all participants in the production and distribution process to maintain the highest standards for safety to protect the American consumer, whether that consumer is human or animal. As with human food safety, FDA recognizes that we need to use strong science capable of identifying both the sources of risk and effective control measure. To that end, FDA is working to develop a risk-based Animal Feed Safety System that describes how animal feed should made, distributed, and used. The Animal Feed Safety System is designed to minimize risks to humans and animals from unsafe animal feed.

Scope of the Pet Food Recall

To date, manufacturers have voluntarily recalled more than 100 brands of dog and cat food across the nation. Manufacturers participating in the recall of pet food products include: Menu Foods, Hill's Pet Nutrition, P&G Pet Care, Nestle Purina PetCare Company, Del Monte Pet Products, and Sunshine Mills. The importer, ChemNutra, has also recalled the raw ingredient, wheat gluten. Although this is one of the largest pet food recalls in history, according to the Pet Food Institute, a trade association representing pet food manufacturers, the product recalled currently represents less than one percent of all dog and cat food on the market. This indicates that consumers have access to an ample supply of pet food to meet the needs of their pets. Nonetheless, we recognize the serious risks that the contaminated pet food represents to pets that consume this food, which is why we are devoting the resources needed to assure the success of the investigation and the pet food recall.

To ensure the success of the pet food recall, FDA is working with the recalling firms and with our many public health partners. We are cooperating with the 50 state departments of agriculture, health authorities, veterinarians, the Association of American Feed Control Officials. FDA is also conducting recall effectiveness audits to ensure manufacturers and other recalling firms remove the recalled product from the pet food supply chain.

Investigation of Pet Food Contamination

FDA's investigation has been aggressive and comprehensive. As soon as FDA received word of a problem with pet foods, our first priority was to limit the risk of animal injury and death related to contamination. We worked to quickly identify the scope of the problem, to ensure that the manufacturer removed potentially-contami-

nated products from the market, and to inform consumers not to feed their animals the recalled products.

FDA began a large-scale investigation. Within 24 hours of learning from Menu Foods of the problem, our investigators were on-site at the Menu Foods Emporia, Kansas plant searching for the source of contamination. FDA sent samples of wheat gluten to our Forensic Chemistry Center (FCC) in Cincinnati, and within 24 hours the FCC scientists confirmed the presence of melamine in samples taken from the pet food and wheat gluten. In addition, FDA's Office of Crisis Management activated FDA's Emergency Operations Center, which has worked seamlessly with FDA's Center for Veterinary Medicine, district offices, headquarters, labs, public affairs and office of international programs.

More than 400 FDA employees in all 20 district offices have taken calls from consumers and veterinarians who reported illnesses potentially associated with the contaminated pet food. FDA received more than 12,000 reports during the past four weeks, which is more than twice the number of complaints that our consumer compliant coordinators typically receive in a year. Additionally, ten FDA district offices have inspected manufacturing and distribution facilities and five field laboratories have analyzed samples.

To ensure consumers awareness of the contamination, FDA participated in six on-camera broadcast interviews, answered hundreds of inquiries from media outlets across the world and conducted five media briefings with 75 to 100 reporters. To keep consumers up to date on the recalled pet foods, FDA continues to give background phone interviews and updates to broadcast media.

A review of records allowed FDA to identify the importer and initial distributor of the contaminated wheat gluten. Through our investigation, FDA determined the Chinese supplier, Xuzhou Anying Biologic Technology Development Company. FDA has asked the Chinese government to participate in the investigation. To prevent manufacturers from using contaminated wheat gluten in pet food and to assess how widespread the melamine contamination of wheat gluten is, FDA issued an import alert regarding the supplier from China. Under FDA's import alert, we are detaining all wheat gluten imported from Xuzhou Anying Biologic Technology Development Company to assure that contaminated product does not enter U.S. commerce. We also initiated an import sampling assignment. This assignment requires 100 percent sampling of import shipments of wheat gluten from China and from the Netherlands, which is known to source some of its wheat gluten from China.

To understand how the contamination affected dogs and cats, FDA scientists, in conjunction with academia and industry, are reviewing blood and tissue samples of affected animals to understand how wheat gluten contaminated with melamine contributed to the pet illnesses. We are also working with data from Banfield Pet Hospital, (a nationwide network of veterinary hospitals), the Veterinary Information Network, Poison Control Centers, universities, and other organizations to assess the number of cats and dogs affected by the contaminated wheat gluten. This is a collaborative partnership providing FDA access to information and helping FDA deliver essential health communications about the safety of pets.

Closing

This investigation has been a massive effort drawing from many parts of the FDA and will continue until we are completely satisfied that the cause has been determined, the scope identified, and full and complete corrective action is initiated and effective. Thousands of dedicated professionals across the country are working to respond to this contamination. We will continue to monitor the ongoing recalls to ensure that they are effective and to support the safety of all food and animal feed in the United States. We will also promptly inform the public of any additional findings from the investigation on the recent outbreak of cat and dog illness.

We appreciate the extraordinary cooperation of our Federal and State partners, health authorities, veterinarians, the news media, the American public, and others who have supported this investigation. We also appreciate the prompt action and cooperation of the firms who voluntarily initiated recalls and the continued support of other distributors and retailers affected by the recall. The cooperation and coordination of all of the professionals in this contamination incident enhanced FDA's ability to respond in the moment, to focus on the public health issue at hand, and help ensure the safety of America's pet food.

Senator KOHL. Do you have a statement, at this time, Dr. Solomon.

Dr. SOLOMON. No sir, thank you.

Senator KOHL. Thank you.

PRODUCT ON RETAIL SHELVES

Dr. Sundlof and Dr. Solomon, a few hours ago FDA put out a press release saying that there may still be some contaminated product on store shelves, and reminding retailers to remove it. And so, consumers cannot just trust that their retailer has removed all the bad product. What should consumers do, Dr. Sundlof?

Dr. SUNDLOF. Thank you, Mr. Chairman.

Well, we recognize that all of the recall audits have not been completed at this date. We have inspectors, both at the State level and the Federal level, out in the actual retail stores, checking to make sure that, in fact, the product is recalled. And we know that there's not 100 percent of the product off the shelf. So, we advise consumers to go back to our web site and make sure that, if they bought a product, that appears on that recall list, that they do not feed their pet with this recalled product.

GROWING RECALL

Senator KOHL. Is the FDA confident, Dr. Sundlof, that the recall, at this point, will not grow to yet more products?

Dr. SUNDLOF. Mr. Chairman, we are still deep into the investigation. We continue to identify small shipments of wheat gluten that may have gotten into the pet food. We continue to follow every lead that we have. We know where all the shipments went, at this point. But we're trying to account for it on a pound-by-pound basis, and sometimes they don't always—reconcile. So, we're trying to reconcile all of the products so that we can make that final determination, that we have effectively covered all products.

Senator KOHL. You're not at that point yet?

Dr. SUNDLOF. We are not at that point yet.

Senator KOHL. So, it's possible that there may be yet additional recall products?

Dr. SUNDLOF. That's a possibility.

Senator KOHL. All right. And you don't know when we will get the all-clear.

Dr. SUNDLOF. No. I can't say that. I'll ask Dr. Solomon if he has better information.

Dr. SOLOMON. No, as we've described before, this is a very active and ongoing investigation. We're following a lot of leads. We're doing a lot of testing of products. There's been hundreds of samples that have been tested. When we find additional positive samples, we immediately go out, find out where those samples were from, contact the firm, and work to get those products off the market.

RECALL LIST

Senator KOHL. If consumers want to know which products are on the recall list, they can check your web site? Every last product on the recall list at any moment is on the web site. Is that correct?

Dr. SUNDLOF. That's correct.

Senator KOHL. And if consumers go into the store and have any concerns about whether or not all banned products have been removed, then, what, they should check very carefully with the proprietors in the store to be sure that they've removed all banned product?

Dr. SUNDLOF. Well, that would be one step. But the final assurance is to actually check the product against the list on the web site.

Senator KOHL. On the web site.

Dr. SUNDLOF. Yes.

Senator KOHL. Thank you so much.

Dr. SOLOMON. If I could just add to Dr. Sundlof's comment, in that we did a blitz activity of 400 audit checks, and we found a high rate of compliance. But as Dr. Sundlof said, some of the products were still on the market. When we brought that to the retailers attention, they immediately removed it. We then have asked our State regulatory counterparts to assist us in making sure they can go out there, using the same audit forms and the same procedures, to continue to try and make sure this——

Senator KOHL. Okay.

Dr. SOLOMON [continuing]. Get the product is off the market.

IDENTIFYING RECALLED PRODUCT

Senator KOHL. Before I turn this over to Senator Bennett, I just want to go back to your efforts on the recall work that you're doing. You've said that you're not able to state, at this point, with certainty, that all the recall has occurred. Are you totally confident, or very, very confident, that you're way, way over, and close to 90 to 100 percent through that process of identifying all recalled product?

Dr. SUNDLOF. Yes, I think that's a fair statement. We've been able to track all the shipments, basically from China, throughout the distribution chain. Where we are still finding some issues is on individual portions of shipments getting diverted to other places. But based on the information that we have, including the Banfield data, and they've indicated that the number of animals that seem to be affected has peaked and is now going down. So, we believe that the recall has been very effective in preventing further illness and death in pets. And we believe that we've gotten the vast, vast majority off of the market, but we are not going to leave any of those stones unturned. We're really going to follow every lead that we have.

Senator KOHL. Thank you.

Senator Bennett.

Senator BENNETT. Thank you, Mr. Chairman.

FEED INSPECTIONS

Dr. Sundlof, I understand that there are inspections of animal feed manufacturers, including firms that manufacture pet food, done by States, as well as by the FDA. Is that correct?

Dr. SUNDLOF. That is correct.

Senator BENNETT. Okay. Are you satisfied that the division of responsibility between the FDA and the States will assure the safety of the animal feed supply?

Dr. SUNDLOF. Yes. It's a very good partnership. We've had this partnership for many, many years with the States. Dr. Solomon has worked directly with the States, and I'd like to have him speak to the relationship between FDA and our State partners.

Dr. SOLOMON. Thank you, Dr. Sundlof.

We do work very closely with our State counterparts. We do work with the American Association of Feed Control Officials, and directly with the State departments of agriculture, State departments of health. We work with them through several different mechanisms, we have 34 States that work with us directly under contract and some States prefer other mechanisms to work with us, so we have partnerships and cooperative agreements with other States to try and enhance our activities. The important component here is that when they're working under contract or in partnership with us, they're following the same sets of guidance; they're following the same procedures for inspections; they're getting training at the same place that the FDA investigators are getting training; their work products, their inspections, are reviewed by the FDA, they're put into the FDA database. So, we see this as a good leveraging opportunity.

Senator BENNETT. Well, yeah, but what prompts you to conduct inspections through contracts with a State agency, or to conduct your own inspection? What is the tipping point that says, "This one we use with contracts, and this we say, Let's use an FDA inspector" ?

Dr. SOLOMON. Thank you for that question.

We solicit to the States and offer them the opportunity to work under contract. For some States, that's a good opportunity to increase their revenues and to be able to support the infrastructure in their program. Many of the States conduct programs under their own activities, so it's a good opportunity to avoid redundancy, by having one person going there. We're trying to avoid that the State may go in there under their own authorities, FDA go under their separate authorities. And this ensures, by working with a contract arrangement, they're working under the same standards, they're following the Food, Drug, and Cosmetic Act, and those reports are all reported into a central database and evaluation.

MONITORING ANIMAL POPULATION

Senator BENNETT. Okay. Now, Dr. Sundlof, you've heard the suggestion that there needs to be an organization like the CDC to monitor the health of the animal population. You're familiar, obviously, with what's done at USDA and FDA, and now the States. Do you have an opinion on the CDC proposal?

Dr. SUNDLOF. Thank you, Senator.

Certainly, an organization like the CDC brings a lot of good expertise. We've been having very good success for——

Senator BENNETT. Have you used them in this investigation?

Dr. SUNDLOF. We've been in touch with them, and I've been assured by the CDC that whatever help we need, they would be willing to provide. So, those contacts have already been made.

There is a society out there in the veterinary community that deals with a lot of the same kinds of issues. There's professional societies. One of them is called the American Association of Veterinary Laboratory Diagnosticians. They represent the scientific experts in the diagnostic labs that deal with animal diseases in all of the States. We are working with them to develop criteria by which we determine whether or not the illness in the animal is actually related to the pet food.

And one of the questions we continuously get is, How many animals have been impacted? Before we can really answer that question definitively, we need to define, What are the criteria that would cause us to make that definitive connection?

Senator BENNETT. But let me get back to my question, though. Is the CDC proposal a good idea? I'm glad to hear the details of how you're working with——

Dr. SUNDLOF. Yes.

Senator BENNETT [continuing]. Them, and how helpful they are.

Dr. SUNDLOF. It's——

Senator BENNETT. And I'm glad to know that they were helpful here.

Dr. SUNDLOF. Yes. It's——

Senator BENNETT. But we're talking in terms of policy. Do you think that's a good idea?

Dr. SUNDLOF. It's certainly something that we should consider. I certainly don't see any downside to that. I would say that this is the first time we've really needed the firepower to deal with an investigation this big. In the past, we have not really had the need for that. This is an exceptional case. And I don't know if one exceptional case would justify that. But it's certainly something that we will be looking into as we continue with this.

PUBLIC RELATIONS

Senator BENNETT. One of the CDC responsibilities—or activities, I guess, better way to put it—with respect to any kind of finding is the fairly widespread public relations program. Now, the Chairman and Senator Durbin have both referred to some difficulties, in terms of the public relations aspect of the pet food outbreak. How do you feel the FDA has managed that issue, of making information available to pet owners?

Dr. SUNDLOF. Well, we made the decision, early on, that we were going to get information out as quickly as possible, recognizing that we were in the midst of an early investigation, that the facts were going to change over time, that we were going to discover things that we hadn't anticipated before. But we felt that it was important to let the public know what we were doing, so that they could have as much confidence as possible, recognizing that they had to understand, also, that we did not know the full extent of the recall at the time. And we recognize that there was a lot of confusion. We didn't have all the answers, ourselves. So, it was, for us, a matter of either waiting until we had all of the information that we thought was necessary, or going out, when we learned new information. And we decided to take the latter approach.

Senator BENNETT. Yeah, I think that's probably right, that you tell the truth at the time, even if it's not as complete as you might like.

One last quick question. Are the pet food companies required to notify you when they come across safety problems?

Dr. SUNDLOF. Yes, they are.

Senator BENNETT. I see.

Thank you.

Senator KOHL. Thank you very much, Senator Bennett.

Senator Durbin.

Senator DURBIN. Thank you very much.

HUMAN FOOD

Dr. Sundlof, you said, "No evidence that contaminated wheat gluten is in the human food supply."

Dr. SUNDLOF. That's correct.

Senator DURBIN. I'd like to ask you, because there was a report of concern that a batch of wheat gluten with the same lot number as the contaminated wheat gluten was introduced into the food-human-food manufacturing process, and then pulled after it had been processed into retail items. Are you aware of this?

Dr. SUNDLOF. I'm going to defer to Dr. Solomon.

Dr. SOLOMON. Thank you, Senator, for that question.

The agency is committing a lot of resources to this, and there's 400 very dedicated people doing analysis, tracing back, tracing forward, doing inspections, investigations. In the thoroughness to look at that, we identified wheat gluten shipments from different manufacturers.

The wheat gluten that's contaminated all came in from the Xuzhou Anying company. We've looked at some other large wheat gluten importers, and, by happenstance, found that there was a similar lot number to some of the contaminated. There's nothing unique about the lot number. The lot number was simply the date that the product was manufactured.

In our concern about tracing that forward, only because a different manufacturer in China, or a different source in China, but the same lot number, we took additional steps to go out and test that wheat gluten with—the same lot number, and to test the product that that was made from, and advised the company to hold that product until those tests were completed. We did those tests very rapidly. All those tests were negative. All the wheat gluten from other suppliers has all tested negative, to date.

Senator DURBIN. Good.

REPORTING REQUIREMENTS

Dr. Sundlof, you said that there is a requirement, for companies that discover contaminated pet food, to report to the FDA. And what is the timeline of that requirement?

Dr. SUNDLOF. Well, anytime that they believe that they have a problem, they are supposed to notify us, and especially if they are—determined that they need to recall product. They need to notify us immediately. But it is up to the pet food company to determine when they believe they have a problem that is sufficient enough to notify the FDA.

Senator DURBIN. What is the penalty for failure to report on a timely basis?

Dr. SUNDLOF. I will have to get back to you on that. I don't know the answer.

[The information follows:]

When injuries or illnesses are associated with FDA regulated products, the reporting process and requirements differ by the commodity area. Patients or consumers are never required to report to the FDA, but often do through formal (e.g. Consumer Complaint Report) or informal/indirect means (e.g. through a pharmacist or health care provider). In some circumstances, when health care providers receive informa-

tion about illness or injury attributed to an FDA regulated product, reports may be filed with the FDA through the MedWatch system. In some cases such a report is mandatory. For example, hospitals, nursing homes, and certain other user facilities are required to report to FDA deaths that may be associated with medical devices.

Manufacturers of FDA regulated products have a greater responsibility to alert FDA of problems associated or potentially associated with their products. For example, in the area of prescription human drugs and prescription and over the counter animal drugs, drug sponsors are required to submit information about adverse drug experiences. These reporting requirements apply to sponsors of new animal drugs that are used in animal feeds. Licensed medicated feed mills are also required to report certain adverse event information to FDA. Manufacturers of medical devices are required to file "Medical Device Reports" when they have reason to believe that a medical device may have caused or contributed to serious injury or death or has malfunctioned in a way that, if it recurred, would be likely to cause or contribute to serious injury or death. Medical device manufacturers are also generally required to notify FDA when they initiate a correction or removal of a medical device to reduce a risk to health posed by the device or to remedy a violation that may present a risk to health. Biological product manufacturers, in addition to reporting adverse experience information, are also required to file "Biological Product Deviation Reports" with FDA when they become aware that a deviation from current good manufacturing practice or from other requirements, or an unexpected or unforeseeable event, may affect a distributed, licensed product s safety, purity, or potency. Recent legislation will mandate, effective December 2007, that manufacturers of non-prescription drugs and dietary supplements report serious adverse events to the FDA relating to those types of products.

Reporting of injuries or illnesses is generally not mandatory for food, although responsible manufacturers typically report such information to FDA in the interest of public health. One exception, as noted above, is the recently-enacted requirements for dietary supplements. When manufacturers fail to submit reports that are required by statute, a prohibited act charge may be appropriate (e.g. 21 USC 331(e)). The acts and the causing of the acts subjects persons to the penalty provisions of 21 USC 333 and the injunction provisions of 21 USC 332. There are also fines of up to $250,000 provided for by 18 USC 3571.

Senator DURBIN. I wish you would. And would you consider reporting 3 weeks after the discovery of contamination of pet food, or suspicion of contamination of pet food, to be timely?

Dr. SUNDLOF. Well, it depends—I can't answer for what the company knew and when the company knew it and if they put that together and said, "We have a problem with our pet food"—I just don't know. But certainly we would hope that as soon as they felt that they had a problem, that they would report to us immediately.

Senator DURBIN. Would you agree that their failure to report contaminated pet food increased the likelihood that pets across America, and maybe Canada, as well, would be in danger?

Dr. SUNDLOF. Well, I think any delay would result in increased illness and death, yes.

LEGAL AUTHORITIES

Senator DURBIN. And could you tell me, does the Food and Drug Administration have the legal authority for mandatory recall of contaminated product?

Dr. SUNDLOF. We don't have that mandatory authority. We have other measures that we can use to make sure that contaminated product doesn't get into the market, such as the seizure of product, if we need to go that far. But, in this case, all of the manufacturers that we've dealt with have voluntarily recalled product.

Senator DURBIN. After you announced the danger in their product?

Dr. SUNDLOF. After Menu Foods announced their recall, all of the other companies that knew that they had products that came through Menu Foods recalled their product.

INSPECTIONS

Senator DURBIN. Has the Food and Drug Administration established basic standards for the State inspection of pet food processing facilities?

Dr. SUNDLOF. Again, I'm going to defer to Dr. Solomon.

Dr. SOLOMON. As I said before, when they're done under contract agreement, partnership agreement, cooperative agreement, then they're following the same exact processes and procedures. Most States are actually working to—or, have adopted the Food, Drug, and Cosmetic Act, so they're working off the same standards. And the Association for Feed Control Officials can talk some more about their standards that they've put into place.

Senator DURBIN. In my callow youth, I was working, summers, earning enough money to go to college, in a meatpacking facility in East St. Louis, Illinois. It was a pork-producing facility, and it had a section known as "Dog Food." I don't need to tell you what ended up in the dog food section. But at that plant, we had USDA, Department of Agriculture, inspectors on the scene every minute of every day that the plant was in operation to make certain that the products that left that plant were wholesome. I don't know what happened to the raw materials of dog food after it left the plant, but at least until that point, it was subject to daily inspection.

I've taken a look at your report of FDA, of the frequency of your inspection of pet food facilities, and it leaves something to be desired. Would you tell me, on average, how often the Food and Drug Administration inspects pet food processing facilities in the United States?

Dr. SUNDLOF. I can't give you a statistic. I can tell you how many pet food establishments we've inspected since beginning of fiscal year 2004. I think it's on the order of 661 pet food establishments that we have inspected. I will say that most of those were for BSE, mad cow, inspections, because the pet food manufacturers, as well as other feed manufacturers, are responsible for complying with those regulations. But there have been many that were for other reasons. Some of them were just routine, routine inspections, others were for cause, where we found a problem; for instance, last year we had a problem with aflatoxin in the dog food. But, over the past 3½ years, we have inspected approximately 30 percent of all of the pet food manufacturers in the United States.

Senator DURBIN. Less than one-third of the pet food processing facilities have been inspected once—some as many as three times—but once in the last 3½ years.

Dr. SUNDLOF. That's correct.

Senator DURBIN. Do you think that's an adequate inspection to protect the quality and wholesomeness and safety of pet food products?

Dr. SUNDLOF. Well, the way that we try and adjust our inspections, we look at it, at a risk basis, so we try and get to the most risky products first, including human food and pet food. We're obviously very concerned about mad cow disease, so we spend a lot of

our activities inspecting those facilities that potentially manufacture feed that could result in BSE.

Petfood is in fact, traditionally, has been a very safe product, and we find few problems with pet food. This is quite disturbing, in this case, because this is so unusual, and we're dealing with a substance that we had never encountered before. So, given the limited resources that the FDA does have for inspections, we really try and make sure that we hit those plants that pose the greatest risk. And so, in this case, we probably didn't inspect, because we felt that these companies were in compliance. And when we did go in and inspect the Menu Foods, in Emporia, Kansas, after we learned of the recall, we did an inspection, and they passed the FDA inspection.

FDA RESOURCES

Senator DURBIN. I am sorry that Commissioner von Eschenbach could not come today—we invited him, and his schedule did not allow his participation in this hearing because I would like to ask questions about the resources of the FDA. I will concede it's an important agency with limited resources and a lot of very important responsibilities, but I think what's happened with pet food contamination is an indication that we are not dedicating the most basic resources to this endeavor. And we've seen the outcome.

RECALL LIST

The last point I'll make to you—or I'll ask you, Have you gone to your web site to try to find out which pet food is contaminated?

Dr. SUNDLOF. Yes.

Senator DURBIN. And did you have any difficulty?

Dr. SUNDLOF. I admit I did.

Senator DURBIN. I did, too. This is hard to follow. We've got to do a lot better than this, because what we have here, click-ons go to press releases for different companies. And so, if you are someone who's buying pet foods and want to go to the store, you have to work your way through every single press release to figure out all of the dangerous products. And, as has been mentioned, you're adding contaminated products to the list even today.

Dr. SUNDLOF. Right.

Senator DURBIN. Can I suggest to the Food and Drug Administration that someone ought to spend a few minutes, go through your web site and put it in a user-friendly, petowner-friendly format, so that people can be warned if there's a product out there that they've left on their shelves that might be dangerous?

Dr. SUNDLOF. Point well taken, Senator.

Senator DURBIN. Thank you.

Senator KOHL. Thank you, Senator Durbin, and Senator Byrd.

Senator BYRD. Thank you. Thank you, Mr. Chairman.

I thank you, Mr. Chairman and Senator Bennett and my Senator here from Illinois, where Mayor Daley used to be the mayor. And I was a good, close friend of Mayor Daley.

With reference to the ongoing confusion and heartache caused by the recent recall of several brands of pet food, I am reminded of a poem that has always meant so much to me. It begins with this stanza, "All things bright and beautiful, All creatures great and

small, All things wise and wonderful, The Lord God made them all." I didn't write that poem. That poem was written by Cecil F. Alexander, and it comes from "Hymns for Little Children," dated 1848. Now, I don't go back quite that far.

There is a special relationship between pets and people. My little dog is a Shih Tzu. They were lapdogs. They were trained to be lapdogs in the palace in Tibet, China. And my wife, who is no longer right here where you can see her, saw this dog coming one day, and Erma said, "Here comes trouble." And that has been my little dog's name ever since.

For many Americans, their pets are not just dogs or cats, but are, instead, viewed as members of the family. I'm talking, because I know. I'm one of those people. I can tell you a lot about great dogs in history. Harry Truman, the former President, said, "If you want a friend in Washington, get a dog"—or "buy a dog."

Dogs, in particular, have, over time, earned the title "man's best friend." The relationship between a dog and his master represents unselfish, unselfish love, trust, and loyalty. As a pet owner and a dog lover, I have joined with millions of my fellow Americans in anxiously hoping that I had not poisoned my pet, my dog, with a special snack or a serving of food.

Our pets are our companions, our soul mates, and our hedge against emotional turmoil. It is well known that pets assist emotional stability, mental health and well-being for millions of Americans.

When the FDA protects our pets, they, the FDA protects the health of millions of Americans. Vigilance for our best friends is vigilance for the health of human owners.

I hope that this hearing will bring to light, Mr. Chairman, the cause of the recent pet deaths and what actions the Food and Drug Administration will take to ensure that we never have to face a similar problem in the future.

May I ask a question, Mr. Chairman?

Senator KOHL. Yes, you may ask questions. Go right ahead.

INFORMATION TO PUBLIC

Senator BYRD. Dr. Sundlof, thank you for appearing before the subcommittee today. We appreciate the work being done by the FDA to get to the bottom of this situation. One of the most troubling aspects of this recall has been the lack of clear information for the public on what products were being recalled.

This problem was compounded by the expanding number of items on the recall list. What are the criteria that are used by FDA to determine which items should be recalled? You don't have to answer that at the moment. Can we now be certain that all of the tainted products are on the recall list? Now, that—my question—and are you under oath? Would you put this—would you mind putting him under oath?

Senator KOHL. Would you stand and take the oath?

Do you solemnly swear that the testimony you provide today shall be the truth, the whole truth, and nothing but?

Dr. SUNDLOF. I do.

Senator KOHL. We thank you.

Senator BYRD. Thank you.

Sir, I have asked the question. Would you please proceed to answer?

Dr. SUNDLOF. Thank you, Senator.

The way that we have added products to the recall list is that, when we trace the contaminated wheat gluten to different plants that are manufacturing pet food, if we find out that that pet food is manufactured with the contaminated wheat gluten, those products go on the recall list.

Now, in addition to that we have found products when we traced out the contaminated wheat gluten, didn't find that they went into certain products. Where we have gotten information from veterinarians that pet food has made an animal sick, we have analyzed the pet food. If we find melamine in that pet food, then that pet food immediately goes on the recall list. And that's why it's coming in pieces. As we learn more, as we identify new products, we put them on the recall list, and we try and get the information out to the public immediately. We think that we've accounted for just about all of it, but we cannot make that statement, as an absolute, at this point. And we will continue to look, as we get information from veterinarians and from universities, where they believe that they've identified sick pets associated with the recall, we'll be analyzing product and making sure that it's safe. And if it isn't, we will recall it.

Senator BYRD. Thank you.

Now, Mr. Chairman, may I say to you and Senator Bennett, I—and this is not a preparation for political—what is—I'm not running until 2012.

I haven't said I'm running again. The good Lord will determine that.

Question number 2—may I?

Senator KOHL. Go ahead.

Senator BYRD. There seems to be a discrepancy in information coming from the FDA and media outlets regarding how many pets have suffered injury or death due to the contaminated food. Can you explain the difference in the reported incidents? And do you have confidence in the number of fatalities and injuries that you are reporting to this Committee today?

Dr. SUNDLOF. Thank you, Senator.

Senator, we don't have a good number for how many animals may have been sick—made ill or have died as a result of this. We are now up to almost 15,000 phone calls that have been received by the FDA. We now that other organizations are also receiving thousands of phone calls. At this point in the investigation, we're just trying to make sure that no other pets are affected by this. And once we are sure that all of the contaminated pet food is off the market, then we will go back and start looking through all these records, with the help of a lot of other people, and try and come up with what we assess as the true prevalence of disease that has been caused by this pet food.

Senator BYRD. Thank you.

CONTAMINATED FOOD ON THE MARKET

Question, if I may, Mr. Chairman and Senator Bennett. Do we know for certain how long tainted food products have been sold to the public?

Dr. SUNDLOF. Well, we know when the wheat gluten came into the United States. And that's the product that's causing the disease. We traced that back to the beginning of November 19, 2006.

Senator BYRD. Third question, if I may, Mr. Chairman. I'm not going to impose on you or the committee or the people or the witnesses. But I am a pet owner.

IMPORT SCREENING SYSTEM

Question three: Can you explain to the subcommittee what screening systems are deployed by the FDA to ensure that harmful substances, like contaminated wheat gluten, do not poison pet food products?

Dr. SUNDLOF. Senator, the pet food manufacturers are required to produce food that is safe, that is wholesome, that does not contain contaminants, and that is properly labeled. That's what they're required, under the Food, Drug, and Cosmetic Act, to do. The pet food manufacturers are responsible for ensuring that the ingredients that they're purchasing to produce their pet food are free of contaminants. We inspect the pet food companies, on occasion, to determine whether or not they are complying.

They are supposed to maintain records of the ingredients that they received. And those records contain information about the analysis of the products. In this case, we do know that the Xuzhou Anying company from China did supply records of analysis to the United States importer. They did test for a number of contaminants, including pesticides, or at least the certificate indicated that. They did not test for melamine, and melamine would not normally have been a substance that we would consider to be a contaminant. And we're still trying to understand why that is. But that's how the system worked. They system is supposed to work, that the manufacturers are responsible for producing a safe product, and they are supposed to have records that, when we go in and inspect, show us that they have exercised their due diligence in making sure that those ingredients are safe.

Senator BYRD. Mr. Chairman and Mr.—Senator Bennett, I have imposed on the time here of all. I have some further questions, which I will leave with the chairman, and he will either ask the questions or have them answered for the record. But I would ask that that be taken care of.

And I'm going to take about 1 more minute.

Senator DURBIN. We'll take care of it.

Senator KOHL. Thank you, Senator Byrd.

Senator BYRD. Can you hear him? He's telling me to leave.

Senator KOHL. Most politely.

Senator BYRD. In a nice way.

Thank you, Mr. Chairman.

Senator KOHL. You're a good man.

Senator BYRD. Thank you.

Senator KOHL. Thank you so much.

CDC INTERACTION

Senator DURBIN. Mr. Chairman, could I ask a question?

Senator KOHL. Yes, go right ahead, Senator Durbin.

Senator DURBIN. Can I ask you what the involvement with the CDC was in this investigation of contaminated pet food? Have you asked for any surveillance by the Centers for Disease Control about renal failure or kidney failure in humans?

Dr. SUNDLOF. In humans, yes. Yes, we have. And when we learned that the wheat gluten was the cause, and we didn't know, at the time, whether or not wheat gluten had made it into the human food supply, we asked CDC to put a special emphasis on looking at increased incidence of renal failure in people. We've determined that batch material did not go into human food.

Senator DURBIN. Is there any evidence or statistics to indicate an increased incidence of renal failure?

Dr. SUNDLOF. Not that I'm aware of, but we'll have to get back with CDC and make sure that that's correct.

REGULATION FOR PET FOOD INDUSTRY

Senator DURBIN. If I could make one last point, Mr. Chairman.

In a letter which your agency sent in reply to Congresswoman DeLauro and myself, you said, at one point, when I asked about FDA's overall regulatory posture with respect to the pet food industry, "There is no requirement pet food products have premarket approval by the FDA; however, FDA ensures that the ingredients used in pet food are safe and have an appropriate function in pet food."

Now, it's clear to me that you didn't inspect this wheat gluten shipment that was included in Menu pet food sold in the United States. Is that correct?

Dr. SUNDLOF. That's correct.

Senator DURBIN. So, when you make that statement, can I assume that it means, in generic terms, wheat gluten, as an ingredient, is a safe ingredient?

Dr. SUNDLOF. Yes. Its just like in human food, if there is something added to the food, it has to be determined to be safe, or generally recognized as safe, yes.

Senator DURBIN. Thank you very much.

Dr. SUNDLOF. Thank you.

Senator BENNETT. I have no further questions.

Senator KOHL. We thank you so much for coming today. You've put a lot of light on the problem that we face, and we have confidence that you're going to get to the bottom—and the very bottom—in the very near future.

And, with that, we are willing to let you go.

Dr. SUNDLOF. Thank you very much, Mr. Chairman.

Senator KOHL. We will now ask the second panel to step forward.

We will hear from Dr. Kirk, Mr. Nelson, Dr. Hodgkins, and Mr. Ekedahl.

Dr. Kirk.

STATEMENT OF CLAUDIA A. KIRK, ASSOCIATE PROFESSOR OF MEDICINE AND NUTRITION, UNIVERSITY OF TENNESSEE COLLEGE OF VETERINARY MEDICINE

Dr. KIRK. Good afternoon. Thank you, Chairman Kohl and Committee members, for inviting me to participate this afternoon.

Today, I'd like to address three key areas in my testimony. My concerns cover the safety and testing of U.S. food ingredients, pet food manufacturing oversight, tracking adverse health events in companion animals.

First, safety and testing of ingredients. It's apparent that the U.S. food supply for pets and people is at risk for accidental toxin contamination and agroterrorism. The Menu Food contamination was caused by undetected toxins in an ingredient widely used in pet food manufacturing. Contributing to the scope of the problem is poor tracking of the contaminated ingredient within the marketplace.

This begs the question, Can we prevent future ingredient contaminations? I doubt that we can prevent all contaminations. There are hundreds of thousands of toxins, many toxins yet to be identified, others difficult to detect, even with sophisticated testing methodology. Our ability to completely test all samples of every imported or transported ingredient seems infeasible. While regulatory oversight helps to protect foods produced within the U.S., global suppliers are not under the same level of regulatory scrutiny. In the Menu Food example, I do not believe melamine would have been detected by our standard screening processes. We screen for the expected, and that did not include melamine.

Increased USDA and AFIS oversight, along with the ongoing Homeland Security measures, can improve food safety. However, research into more effective screening tools and access to specialized laboratories are warranted. Can we limit the exposure to contaminated ingredients? The Menu example highlights the lack of adequate tracking of our ingredient supply. Nearly a month after the suspected ingredient was identified, manufacturers continue to discover products with the banned ingredient. This represents an additional month of pet exposure to potentially toxic feeds. Tracking of ingredients from the point of origin to final disposition will facilitate rapid implementation of the total recall, and thereby limit further exposure.

Second, pet food manufacturing oversight. I believe the pet food industry is under far greater regulatory oversight than has been portrayed by the media. While certain aspects of these regulations require self-monitoring, the regulations for product claims, nutritional adequacy, ingredient use, and animal testing as stringent, well defined, and, from my experience with the FDA, closely monitored. Most visitors to pet food manufacturing facilities are impressed by the degree of ingredient evaluation, product testing, research, and quality control provided voluntarily by these companies.

While this level of self-monitoring is not uniform across all companies, in my experience most manufacturers are extremely diligent in their efforts directed toward product quality and animal health.

Would more oversight prevent pet food contaminations? In some cases, yes. The FDA reports on Diamond and Go!Natural Pet Food recalls suggested inspections may have improved adherence to quality control and good manufacturing practices, thereby preventing those contaminations. It is unlikely, however, that additional oversight would have fully prevented the Menu Food contamination.

Could more vigilant regulatory intervention help limit exposure? If it were mandatory for manufacturers to immediately report significant adverse events to its centralized regulatory agents, earlier investigative action and product withdrawals could occur. However, establishing reasonable criteria for when to alert regulators is difficult.

Finally, I'd like to discuss tracking adverse events. Surveillance and centralized reporting by the CDC has helped to identify and contain food-borne diseases in people. There are no such surveillance and reporting services available for companion animals. Complaints of adverse events, whether for drugs or pet foods, are directed primarily to the manufacturers. Because Menu Food produced products for several companies, multiple brands were affected. No doubt, part of the delay in recognizing the problem stemmed from scattered reports to individual companies, and no clear pattern of cases could be identified to indicate there was a serious problem afoot.

Additionally, the inability to capture data and identify the true scope of the problem has resulted in pet-owner distrust of government agencies and pet food manufacturers, alike. While some estimates of the magnitude of pet deaths are clearly exaggerated, the official reports of confirmed cases are unrealistically low. Those attempting to report cases have been frustrated by the inability to contact the FDA, due to the overwhelming volume of calls.

What can we do to prevent—or to improve the safety and limit exposure to tainted pet foods? One solution is to establish a centralized site for veterinarians and consumers to report adverse events and catalog affected cases. Earlier detection, notification, and withdrawal of tainted products will help prevent ongoing exposure. Earlier consumer notification will alert veterinarians to evaluate pets for toxic exposure and preserve needed information to document that exposure. Tracking pet health provides the additional benefit of acting as a sentinel to our human food supply.

PREPARED STATEMENT

Sadly, we will never know the true scope of the Menu problem. It is unlikely that owners of pets that were affected prior to the March 16 recall can prove their pet was a victim of the toxicity. The pet food labels are gone, and the pets have been laid to rest.

Thank you for your attention.

[The statement follows:]

PREPARED STATEMENT OF CLAUDIA A. KIRK

Good afternoon, I would like to thank the Chairman Kohl and the committee members for inviting me to this hearing.

Today I would like to address 3 key areas in my testimony. My concerns cover (1) the safety and testing of the U.S. food ingredients, (2) pet food manufacturing oversight, (3) and tracking of adverse health events in companion animals.

Safety and Testing of Ingredients

It is apparent that the U.S. food supply for pets and people is at risk for accidental toxin contamination and agriterrorism. The Menu Foods contamination was caused by undetected toxins in an ingredient widely used in pet food manufacturing. Contributing to the scope of the problem was poor tracking of the contaminated ingredients within the market place.

Can we Prevent Future Ingredient Contaminations?

I doubt that we can prevent all contaminations. There are hundreds-of-thousands of toxins. Many toxins are yet unknown and others are difficult to detect, even with sophisticated testing protocols. Our ability to completely test all samples of imported or transported ingredients is would seem infeasible. While regulatory oversight helps to protect foods produced within the United States, global suppliers are not under the same level of regulatory scrutiny. In the Menu Foods example, I do not believe melamine would have been detected by our standard screening processes. We screen for the expected—and that does not include melamine. Increased USDA and APHIS oversight along with ongoing homeland security measures can improve food safety. However, research into more effective screening tools and access to specialized laboratories are warranted.

Can we Limit the Exposure to Contaminated Ingredients?

The Menu example highlights the lack of adequate tracking of our ingredient supply. Nearly a month after the suspected ingredient was identified; manufacturers continue to discover products with the banned ingredient. This represents an additional month of pet exposure to potentially toxic foods. Tracking of ingredients from the point of origin to final disposition will facilitate the rapid implementation of a total recall and thereby limit further exposure.

Pet Food Manufacturing Oversight

I believe the pet food industry is under far greater regulatory oversight than has been portrayed. While certain aspects of the these regulations require self-monitoring, the regulations for product claims, nutritional adequacy, ingredients use, and animal testing are stringent, well defined, and from my experience with the FDA, closely monitored. Most visitors to pet food manufacturing facilities are impressed by the degree of ingredient evaluation, product testing, research, and quality control provided voluntarily by the companies. While this level of self-monitoring is not uniform across all companies, in my experience most manufacturers are extremely diligent in their efforts directed toward product quality and animal health.

Would More Oversight Prevent Pet Food Contaminations?

In some cases, Yes. The FDA reports on Diamond and Go Natural pet food recalls suggest inspections may have improved adherence to quality control and good manufacturing practices, thereby preventing these contaminations. It is unlikely that additional oversight would have fully prevented the Menu Foods contamination.

Could More Vigilant Regulatory Intervention Help to Limit Exposure?

If it were mandatory for manufacturers to immediately report significant adverse events to a centralized regulatory agency, earlier investigative action and product withdraw could occur. However, establishing reasonable criteria for when to alert regulators could still be a challenge.

Tracking Adverse Events

Surveillance and centralized reporting provided by the CDC has helped to identify and contain food born disease in people. There are no such surveillance and reporting services available for companion animals. Complaints of adverse events, whether from drugs or pet foods, are directed primarily to manufacturers. Because Menu Foods produced products for several companies, multiple brands were affected. No doubt, part of the delay in recognizing the problem stemmed from scattered reports to individual companies and no clear pattern of cases to indicate a serious problem.

Additionally, the inability to capture data and identify the true scope of the problem has resulted in pet owner distrust of government agencies and pet food manufacturers alike. While some estimates of the magnitude of pet deaths are clearly exaggerated, the official reports of confirmed cases are unrealistically low. Those attempting to report cases have been frustrated by the inability to contact the FDA due to the overwhelming volume of calls.

What can we do to Improve the Safety of Pet Foods and Limit Exposure to Tainted Pet Foods?

One solution is to establish a centralized site for veterinarians and consumers to report adverse events and catalog affected cases. Earlier detection, notification, and withdrawal of tainted products will help prevent ongoing exposure. Earlier consumer notification will alert veterinarians to evaluate pets for toxic exposure and preserve needed information to document such exposure. Tracking pet health provides the additional benefit of acting as a sentinel for the human food supply.

Sadly, we will never know the true scope of the Menu problem. It is unlikely that owners of pets affected prior to the March 16th recall can prove their pet was a victim of toxicity. The pet food labels are long gone and their pets have been laid to rest.

Thank you for your attention.

Senator KOHL. Thank you very much, Dr. Kirk.

Dr. Hodgkins.

STATEMENT OF DR. ELIZABETH HODGKINS, VETERINARIAN

Dr. HODGKINS. Chairman Kohl, Senator Bennett, Senator Durbin, thank you all for asking me to speak this afternoon.

I speak today not as a previous pet food company employee, but as a veterinarian with a deep concern for the health of my own pets, my many patients, and, indeed, dogs and cats everywhere. Notwithstanding the pet food industry's insistence that it is already stringently and adequately regulated, experience tells us otherwise. In the past 18 months alone, there have been no fewer than three national-level pet food recalls, including the most recent Menu Foods recall. Although the Federal Food, Drug, and Cosmetic Act requires that pet foods not be adulterated, the definition of which includes not containing any poisonous or deleterious substance, it is clear that breaches of this requirement are occurring at an alarming rate.

The present pet food safety crisis is not an unfortunate aberration, but part of mounting evidence of a systemic breakdown in the commercial pet food safety assurances demanded by the pet-owning public.

Pet foods carry both an implicit and an explicit guarantee of safety in the label statement that they carry, conferred by the American Association of Feed Control Officials, AAFCO. It is important to note that the sweeping safety and adequacy guarantees that are ubiquitous on pet food labels today cannot be found on any human food. No human food, whether it is fresh produce, meats, or commercially processed and packaged human consumables, is allowed to bear such broad guarantees of wholesomeness and nutritional completeness.

The widely allowed, but inadequately substantiated, pet food AAFCO label guarantees are the fundamental flaw in the present system that has allowed adulterated ingredients repeatedly to enter the pet food supply chain. This flaw is also responsible for the proliferation of AAFCO statement labeled foods that are far from adequate for long-term feeding of pets as an exclusive diet.

AAFCO label statement guarantees are not based on routine testing of individual ingredients by either the companies under whose brands those foods will be marketed or by the co-packers who may produce the foods for those companies at distant manufacturing plants. There is no systematic inspection of supplies—suppliers of these ingredients. Similarly, the nutritional adequacy

guarantee explicit in this claim is not based on long-term feeding of guaranteed foods. The most rigorous testing protocol for a lifetime adequacy claim is based upon the feeding of a representative food, not each food, to a very small number of animals for a short period of time, only several months, at best. As long as no disastrous effects of the representative food are seen in these few test subjects over a very short period of time, the representative food will gain the right to carry this long-term adequacy claim, as will all of that company's related, but untested, foods.

Unfortunately, because these label statements are ubiquitous and allow the pet food purchaser no way to differentiate between available commercial products, no company has any incentive to test and prove the quality of its foods beyond the bare minimums required for the AAFCO statement.

Although the Federal Food, Drug, and Cosmetic Act requires that meaningful inspections of production facilities must occur, the increasing size of the industry has prevented this inspection process from keeping up with that growth. Governmental inspection of plants cannot solve the problem of adulterated ingredients, because of the sheer volume, variety, and sources of those ingredients. Increased facility inspections cannot prevent the marketing of foods with misleading claims, that they are nutritionally adequate for the long-term exclusive feeding of pets, since such scientific authentication must be proven in long-term clinical studies.

The Federal Food, Drug, and Cosmetic Act already provides the framework for meaningful regulation of the pet food industry, without new laws and without a significant increase in the size of government. What we need now is stronger adherence to the simple, clear meaning of the act.

To begin meaningful reform, I propose that the FDA adhere to the letter of the Federal Food, Drug, and Cosmetic Act that pet food labeling may not be false and misleading, by adopting a presumption that all safety and nutritional adequacy claims for pet food are disallowed. Petfoods could be marketed without claims, as is the case with almost all human foods, with consumers and veterinarians aware that the product carries no label claims for safety or nutritional adequacy.

Thereafter, the pet food industry and FDA/AAFCO might well work out a system of honestly informative label statements that notify pet owners and veterinarians of the actual safety and adequacy testing to which each labeled food is subject. No implicit or explicit safety claims could be made without rigorous ingredient testing by the manufacturer and/or the ingredient supplier. No long-term nutritional adequacy claims could be made without long-term, well-controlled clinical studies proving that adequacy to genuine scientific standards.

Conscientious manufacturers would undoubtedly rise to the occasion and properly test their ingredients and their finished foods themselves in order to gain the competitive advantage that honest, carefully allowed label claims would provide. The consumer would have a more informed choice of pet food quality, as indicated by truthful labels. Veterinarians would have far more meaningful guidance about what foods to recommend to their clients.

PREPARED STATEMENT

There is no doubt that the present system of pet food regulation needs meaningful reform. This can be achieved as a first step by a "truth in pet food labeling" initiative that would stimulate America's best pet food-makers to provide and prove the quality and safety of their foods. This is no less than what pet owners desire and deserve, and what will be required to regain faltering public confidence in the industry.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF DR. ELIZABETH HODGKINS

Chairman Kohl, Senator Bennett, Members of the Subcomittee, I speak today not as a previous pet food company employee, but as a veterinarian with a deep concern for the health of my own pets, my many patients, and indeed, dogs and cats everywhere. Notwithstanding the pet food industry's insistence that it is already stringently and adequately regulated, experience tells us otherwise. In the past 16 months alone, there have been no fewer than three national level pet food recalls, including the most recent Menu Foods recall. Although the Federal Food, Drug, and Cosmetic Act requires that pet foods not be "adulterated," the definition of which includes "not containing any poisonous or deleterious substance," it is clear that breaches of this requirement are occurring at an alarming rate. The present pet food safety crisis is not an unfortunate aberration, but part of mounting evidence of a systematic breakdown in the commercial pet food safety assurances demanded by the pet owning public.

Pet foods carry both an implicit and explicit guarantee of safety in the label statement that they carry conferred by the American Association of Feed Control Officials (AAFCO). It is important to note that the government guarantees that are ubiquitous on pet food labels today cannot be found on any human food. No human food, whether it is fresh produce, meats, or commercially processed and packaged human consumables is allowed to bear such sweeping, broad guarantees of wholesomeness and nutritional adequacy.

These widely allowed, but poorly substantiated AAFCO label guarantees are the fundamental flaw in the present system that has allowed adulterated ingredients repeatedly to enter the pet food supply chain. This flaw is also responsible for the proliferation of AAFCO-statement-labeled foods that are far from adequate for long-term feeding of pets, as an exclusive diet.

AAFCO label statement guarantees are not based on routine testing of individual ingredients by either the companies under whose brands those foods will be marketed, or by the co-packers who oftentimes produce the foods for those companies at distant manufacturing plants. There is no inspection of suppliers of these ingredients. Similarly, the nutritional adequacy guarantee explicit in this claim is not based on long-term feeding of guaranteed foods. The most rigorous testing protocol for a lifetime adequacy claim is based upon the feeding of a representative food, not each food, to a very small number of animals for a short period of time, only several months at best. As long as no disastrous effects of the representative food are seen in these few test subjects, over a very short period of time, the representative food will gain the right to carry this long-term adequacy claim, as will all of that company's related, but untested foods. Because these label statements are ubiquitous and allow the pet food purchaser no way to differentiate between available commercial products, no company has any incentive to test and prove the quality of its foods beyond the bare minimums required for the AAFCO statement.

Although the FFDCA requires that meaningful inspections of production facilities must occur, the rapidly increasing size of this industry has prevented this inspection process from keeping up with that growth. It is doubtful that governmental inspection of plants can solve the problem of adulterated ingredients because of the sheer volume, variety and sources of those ingredients. It is even more doubtful that increased facility inspections can prevent the marketing of foods with misleading claims that they are nutritionally adequate for the long-term feeding of pets, since such scientific authentication must be proven in long-term clinical studies.

The Federal Food Drug and Cosmetic Act already provides the framework for meaningful regulation of the pet food industry without new laws and without a significant increase in the size of administrative government. What we need now is stronger adherence to the simple, clear meaning of the act. To begin meaningful re-

form of pet food regulation, I propose that AAFCO and FDA adhere to the letter of the FFDCA that food labeling may not be "false or misleading" by adopting a presumption that all safety and nutritional adequacy claims for pet food are disallowed. Under this presumption, pet foods could be marketed without claims, as is the case with almost all human foods, with pet food purchasers and veterinarians aware that the product carries no label claims for safety or nutritional adequacy.

Thereafter, the pet food industry and FDA/AAFCO might well work out a system to allow honestly informative label statements that adequately notify pet owners and veterinarians of the actual safety testing and adequacy testing to which each labeled food is subject. No implicit or explicit safety claims could be made without rigorous ingredient testing by the manufacturer and/or the ingredient supplier. No long-term nutritional adequacy claims could be made without long-term, well-controlled clinical studies proving that adequacy, to genuine scientific standards.

In such an environment, conscientious manufacturers would undoubtedly rise to the occasion and properly test their ingredients and their finished foods themselves in order to gain the competitive advantage that honest, carefully-allowed label claims would provide. The pet food purchaser would have a more informed choice of pet food quality, as indicated by truthful labels. Veterinarians would have far more meaningful guidance about what foods to recommend to their clients.

There can be no doubt that the present system of pet food regulation is in need of meaningful reform. This reform can be achieved, as a first step, by a "truth in pet food labeling initiative" that would stimulate America's best pet food makers to provide and prove the quality and safety of their foods. This is no less than what pet owners desire and deserve, and what will be required to regain faltering public confidence in the industry.

Thank you.

Senator KOHL. Thank you, Dr. Hodgkins.

Mr. Nelson.

STATEMENT OF ERIC NELSON, PRESIDENT, AMERICAN ASSOCIATION OF FEED CONTROL OFFICIALS

Mr. NELSON. I appear today as president of the Association of American Feed Control Officials. I would like to thank the Committee for the opportunity to provide testimony on this important issue.

The safety of all animal feed, including pet food, is AAFCO's number one priority. I'm going to share some background on AAFCO, partnerships between States and FDA, and AAFCO's plans for added oversight of the animal feed industry.

AAFCO is a international association, with members consisting largely of State feed-control officials responsible for the administration of State laws and rules, as well as portions of the Food, Drug, and Cosmetics Act, which pertain to the distribution of commercial feed and feed ingredients for livestock, poultry, and other animals, including pets. AAFCO counts as its members all 50 States, Canada, Puerto Rico, and Costa Rica.

While AAFCO has no regulatory authority, it guides States through the development of model laws and regulations and program guidance tools, such as inspection and labeling guides. Individual States adopt those model elements, sometimes modifying them to meet local needs or issues. The AAFCO model pet food regulations have become the de facto national program for regulating the marketing of pet foods.

While this current regulation primarily controls the formulation, distribution, and labeling of dog and cat foods, there are also safety components, since ingredients used in animal feeds must be defined by AAFCO. Part of the AAFCO definition process is a review of ingredients' safety and utility, as determined by FDA's Center for Veterinary Medicine, Division of Animal Feeds.

Most States participate in partnership with FDA. States provide the—use the overarching authority of FDA to inspect and investigate feed manufacturers. FDA furnishes training and other support items, while States provide the manpower and coordination.

In addition, FDA supports AAFCO in State programs through its scientific review activities, providing guidance and insight into technically sensitive issues. This guidance may include review of product labeling to determine suitability of label claims.

Since the connection of animal feeds to BSE, AAFCO has directed its focus to the safety of animal feeds and the potential effects that unsafe feed may have on human health and animal health. The current system is focused primarily on postproduction controls, such as labeling, licensing, and marketing. However, AAFCO has identified gaps in this system. These gaps and their related risks would be best managed through controls on the processes used to produce and distribute animal feeds and feed ingredients wherever they occur.

AAFCO has been working on their Model Feed Safety Program for several years. The intent of this model program is to provide regulatory direction and oversight for all manufacturers of animal feeds, including ingredient processors, livestock feed and pet food manufacturers, and manufacturers of feeds on farm. AAFCO's initial step was to provide guidance for self-regulation through quality assurance programs. However, AAFCO feels that simply guidance and self-regulation has not gone far enough to accomplish our goal of safe feed.

Consequently, AAFCO has chosen to develop model process control regulations, which would be adopted and enforced by States. The areas addressed by the process controls include procedures to manage the receipt and storage of ingredients; responsibilities and training of personnel; processing; suitability and maintenance of facility and equipment; storage of finished products; testing of ingredients and finished products for contaminants and quality; and the transportation and distribution of both ingredients and finished products. These regulations would be enforced through product testing and inspection by State authority.

It would be pure speculation to say that process controls would have prevented this terrible incident from happening. However, the intent of such process controls, as proposed by AAFCO, would be to do just that. The pet food industry and animal feed industry, as a whole, are very quality conscious and very responsive to known hazards. More needs to be done to identify the potential hazards, reduce their impact, and still provide affordable feeds and food.

PREPARED STATEMENT

The status quo will not provide the security upon which our citizens rely. The reestablishment of consumer confidence is not going to happen overnight, and it will take great efforts by both the industry and those charged with their oversight. I encourage you to support FDA, AAFCO, and their State partners by ensuring that the necessary controls are developed, implemented, and funded for effective enforcement.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF ERIC NELSON

My name is Eric Nelson and I appear today as the President of the Association of American Feed Control Officials (AAFCO). I would like to thank the committee for the opportunity to provide testimony on this important issue. The safety of all animal feed, including pet food is AAFCO's number one priority. Strengthening both State and Federal feed control programs to address gaps in the current system has been paramount to our membership.

I am going to share some background on AAFCO, partnerships between state and Federal agencies and AFFCO's plans for added oversight of the animal feed industry. AAFCO is an international association with membership consisting largely of state feed control officials responsible for the administration of state laws and rules, as well as portions of the Food, Drug and Cosmetic Act, which pertain to the distribution of commercial feed and feed ingredients for livestock, poultry and other animals, including pets. AAFCO counts as its members all 50 States, Canada, Puerto Rico, and Costa Rica.

While AAFCO has no regulatory authority, it guides States through the development of model laws and regulations and program guidance tools, such as inspection and labeling guides. Individual States adopt these model elements, sometimes modifying them to meet local needs or issues. The AAFCO model pet food regulations have become the de facto national program for regulating the marketing of pet foods. While this current regulation primarily controls the formulation, distribution and labeling of dog and cat foods, there are also safety components, since ingredients used in animal feeds must be defined by AAFCO. Part of the AAFCO definition process is a review of the ingredient's safety and utility as determined by FDA's Center for Veterinary Medicine's Division of Animal Feeds.

Most States participate in partnership with FDA. States use the overarching authorities of FDA to inspect and investigate feed manufacturers:

—for compliance with the medicated feed Good Manufacturing Practices (GMPs),
—for compliance with the (Bovine Spongiform Encephalopathy) BSE feed ban to prevent the establishment and amplification of BSE in the U.S. cattle herd,
—and for incidents of feed adulteration.

Thirty five States currently have formal agreements with FDA to inspect feed manufacturers using the highest risk category of feed additives (Type A/Category II drugs) and those manufacturers and animal production sites that provide feeds for ruminant animals. FDA furnishes training and other support items, while States provide the manpower and coordination.

In addition, FDA supports AAFCO and State programs through its scientific review activities, providing guidance and insight into technically sensitive issues. This guidance may include review of product labeling to determine suitability. FDA also provides additional support to States in the evaluation of label claims that may have health effects other than nutrition.

Since the connection of animal feeds to BSE, AAFCO has directed its focus to the safety of animal feeds and the potential effect that unsafe feeds may have on human and animal health. The current system, with the exception of medicated feed regulations, is focused primarily on post production controls, such as: labeling, licensing and marketing. However, AAFCO has identified gaps in this system. These gaps and their related risks would be best managed through controls on the processes used to produce, and distribute animal feed and feed ingredients wherever they occur.

AAFCO has been working on their Model Feed Safety Program for several years. The intent of this Model Program is to provide regulatory direction and oversight for all manufacturers of animal feeds, including: ingredient processors, livestock feed and, pet food manufacturers and manufacturers of feeds on-farm. AAFCO's initial step was to encourage the production of safe feed by:

—providing guidance to industry through a framework of best business practices;
—and supporting industry developed and implemented Quality Assurance programs.

However, AAFCO feels that this guidance and self-regulation process has not been fully adopted nor has it shown results indicating our goal was accomplished. Consequently, AAFCO has chosen to develop model process control regulations, which could be adopted and enforced by States. The areas addressed by the process controls include procedures to manage:

—the receipt and storage of ingredients,
—responsibilities and training of personnel,
—ingredient processing,
—suitability and maintenance of facilities and equipment,
—storage of finished products,

—testing of ingredients and finished products for contaminants and quality, and
—the transportation and distribution of both ingredients and finished feed products.

These regulations would be enforced through product testing and facility and record inspections by the State authority.

It would be pure speculation to say that process controls would have prevented this terrible incident from happening. However, the intent of such process controls, as proposed by AAFCO, would be to do just that. The pet food industry and animal feed industry, as a whole, are quality conscious and very responsive to known hazards. More needs to be done to identify the potential hazards, reduce their impact and still provide affordable feeds and foods.

The status quo will not provide the security upon which our citizens rely. The reestablishment of consumer confidence is not going to happen overnight and will take great efforts by both industry and those charged with their oversight. I encourage you to support FDA and their State partners by ensuring that the necessary controls are developed, implemented and enforced.

Senator KOHL. Thank you, Mr. Nelson.

Mr. Ekedahl.

STATEMENT OF DUANE EKEDAHL, EXECUTIVE DIRECTOR, PET FOOD INSTITUTE

ACCOMPANIED BY DR. ANGELE THOMPSON, CHAIRMAN, NATIONAL PET FOOD COMMISSION

Mr. EKEDAHL. Thank you, Mr. Chairman.

My name is Duane Ekedahl. I'm the president of the Pet Food Institute.

Hello. Thank you.

My name is Duane Ekedahl. I'm the president of Pet Food Institute, which represents the manufacturers of cat and dog food in the United States.

I have—our testimony has been submitted, and I'll just summarize it here for you, at this time, if that's all right.

I think I entirely understand the urgency with which you approach this pet food recall. In our family, we have a 12-year-old cat, Gus, and a 4-year-old dog, Sven. And I think I know where I stand in the family hierarchy. And I've got to tell you this, if anything happened to Gus or Sven, we would be devastated. And our heart goes out to those people who have been affected by this pet food recall. And I'm here to tell you that our industry intends to work with this Committee and with the Food and Drug Administration, as we have, and will continue to do, until this issue comes to a close.

Pet foods are, in fact, very highly regarded in the marketplace. They rank among the top products in the supermarket shelves, in terms of respect by consumers. A Gallup poll, this week, said that consumers continue to have confidence in pet foods, in spite of the confusion in the marketplace, and they're confident that pet food manufacturers will do the right thing and make this right, and we're determined to do that, at any cost.

Today, we're going to announce—we have announced the formation of the National Pet Food Commission, which brings together the best minds, authorities in the fields of veterinary medicine, toxicology, pet nutrition, and government regulators into a commission to examine how this happened, and what we can learn from it, to be sure it doesn't happen again. This was announced, as you might have seen, in early newspapers today. This announces the formation of this National Pet Food Commission.

And with me, if I may, Mr. Chairman, is Dr. Angele Thompson, who has 26 years of cat and dog nutrition experience. And she—Dr. Thompson will be serving on the Commission, and serving as its chair, and she's here to answer any questions that you might have.

Now, I must insist—and I think some people are surprised to know this; perhaps you're not—that pet foods are, indeed, a highly regulated product. They are perhaps the most regulated product on the supermarket shelf. You pick up a package of cat food or dog food, and you'll see more information on that package than you're likely to see on any other package—any other package in the stores. And these—this information is required by law. The nutrition declarations on those products must be substantiated—must be substantiated and proven. And they are verified, by the State—chemists in the various States, to meet the claims that are made on those labels. There's no other produce like that. And these are a complete nutrition requirement for the cat and dog—the complete requirement. All the requirements are present in that product, the results of years of nutrition research by the—by these companies.

Pet foods are—they come under many of the same regulations of human foods. Pet food plants are inspected, often by the same people that inspect human foods. Pet food ingredients are subject to very exacting analysis when they come to the plant. Many pet food ingredients, that are also human food ingredients, receive even more analysis in pet foods because of the sensitivity, sometimes, of cats and dogs to certain foods. So, that's the system in which pet food companies operate. It is a highly regulated product. And there is not confusion in the label claims. The nutrition claims are very specific, the various life stages of the cat or dog specified on the product, meeting the State regulations.

What about ingredients from overseas? Our association, represented by Nancy Cook and other industry officials and government regulators, are working with the World Health Organization, its Codex Feed Ingredient Task Force, working toward the establishment of international standards for feedstuffs. We think this is an important goal. We work with other organizations. It's a major commitment on our part.

I'd like to close with one statement, one final point. There is—the numbers of fatalities of cats and dogs is all over the place. And a recent—a Banfield report, just this week, cited that during the past 3 weeks they've seen 237,000—what—a little over 237,000 cats and dogs; and, of that group, there were five cats and one dog affected by products in the recall. That's in their recent press release. Now, five cats and one dog are five cats and one dog too many. But that does suggest that this industry acted very responsibly once they learned that this substance, melamine, which is a contaminant, a contaminant of wheat gluten—wheat gluten is not the issue; wheat gluten is used in human food more than in pet food—this contamination is the issue. And once the companies learned of the contamination, they acted promptly to remove the product from the marketplace, at considerable disruption to their operations.

We think what we're hearing from the Food and Drug Administration is that this thing is fairly close to being sure that this—that

the products are out of the system, and that that part of it's been done, and that the second phase of this is to examine what caused it—what caused this to happen. And our Commission will be working on helping and augmenting the FDA to get the facts out there as to what caused this contamination, and then to report to industry and to government its recommendations, the steps that can be taken to assure that we maintain the very high standards that exist today.

PREPARED STATEMENT

So, we're very hopeful that this is close to being behind us, so that consumers can really select, with confidence, the products that they choose to feed their pets in the marketplace, because, as we know, cats and dogs are not just pets, they're family. We believe that very definitely.

Thank you, Mr. Chairman.

[The statement follows:]

PREPARED STATEMENT OF DUANE EKEDAHL

Mr. Chairman, members of the committee. Good afternoon. On behalf of the pet food industry, I wish to thank you for the opportunity to appear before this subcommittee to provide information and counsel and answer any questions that I can during this difficult time for America's pet owners. My wife and I have a Cockapoo dog, named Sven, and a Persian cat, named Gus, and our hearts go out to those affected these by foreign substances in pet food.

Mr. Chairman, since the very first evidence surfaced that something might be wrong with some pet food, our industry has been working closely with the Food and Drug Administration to determine the cause and to reassure pet owners around the country. I am here today, as part of that continuing cooperation with authorities and officials, to answer any questions lawmakers have about the industry, how it is organized and how the industry in general responded to the situation that first came to our attention the afternoon of March 16. These recent weeks have been difficult ones for pet owners concerned and confused about the recall. The industry is working diligently with the FDA to determine how a basic food ingredient was adulterated with a substance our industry has never seen and never would have expected to find in our products.

The industry is committed to working tirelessly to continue our efforts to keep America's pets safe and healthy.

For nearly 50 years the Pet Food Institute has been the voice of U.S. pet food manufacturers, representing the companies that make 98 percent of all dog and cat food in the United States. Our member companies are large and small and range from America's best known and oldest brands to small family owned companies. Our members make both dry and wet foods as well as biscuits and treats for America's 150 million dogs and cats.

Pet food has one of the highest consumer confidence ratings of any product in the grocery store today. Our recent polling, and that of Gallup, indicates consumers have confidence in the industry even in this time of confusion and concern. They have faith the industry will take the right steps in the coming weeks. We see our cooperation with Congress, and with FDA, as just one of those steps.

Pet food is perhaps the most highly regulated product on store shelves. In addition to companies' own high standards and proprietary recipes that dictate appropriate levels of nutrition, vitamins, minerals and flavor, pet food manufacturers are governed by the U.S. Food & Drug Administration, the U.S. Department of Agriculture, as well as authorities in all 50 states.

—Pet foods are required by law to provide on their labels more information than most human foods, and must, in fact, guarantee their nutritional information, unlike "typical" analyses for human foods.

—State Departments of Agriculture and Regulatory Agencies provide standards and enforcement policies for the regulation of pet foods resulting in safe foods, through an internationally recognized and respected body of regulators, the Association of American Feed Control Officials. That body's "Official Publication", revised annually by them and widely distributed among regulators and indus-

try, is recognized by many countries around the world as the leading authority in pet food regulation.

—Ingredients in pet food must be acceptable to State and Federal authorities.

—The same FDA employees who inspect human food facilities may also inspect pet food plants.

—Pet foods are wholesome and truthfully labeled and meet all FDA requirements.

—Pet food ingredients undergo significant testing for safety and quality assurance including screening for mycotoxins (including aflatoxin), bacteria (including Salmonella and E.coli) and nutrient content. Furthermore the finished product is analyzed to ensure appropriate nutrient levels, which include evaluation of protein (including 12 amino acids), fat, fiber, vitamins, and minerals for the appropriate stage of the pet's life.

Despite all of these requirements, at the end of the day, no regulations are as stringent or standards as high as the ones the companies set for themselves. They do everything possible to ensure their products deliver on their brand promises. It just makes good business sense that happy pets and pet owners mean happy customers.

With respect to the current recalls, neither the investigators nor the industry know the exact reason why animals were sickened. But while the FDA continues its investigation, the pet food industry is taking steps to examine and, if necessary, enhance the safety and security of the manufacturing process.

To that end, today I want to announce that the Pet Food Institute has formed an industry-government partnership called the National Pet Food Commission. This Commission is composed of government officials, veterinarians, toxicologists and nutritionists who are committed to maintaining and enhancing the high standards we have set in this country. It will include such individuals as Dr. Angele Thompson, nationally known pet nutritionist, who will act as Chair; as well as Dr. Murl Bailey, Professor of Veterinary Medicine from Texas A&M University; Dr. Fran Kallfelz, Professor of Veterinary Medicine, Cornell University; Dr. Rod Noel, of the Indiana State Chemist's office and AAFCO; Randy Gordon, National Grain and Feed Association; Christopher Cowell, Chair of Pet Food Institute's Regulatory Affairs Committee, and an advisor from FDA's Center for Veterinary Medicine.

The purpose of the new Commission is two-fold:

—First, to investigate the cause of the current pet food recall.

—Second, to recommend steps the industry and government should take to further build on the safety and quality standards already in place.

At the conclusion of its work, the Commission will issue a report outlining its findings and offering its recommendations to industry and regulators. The details of this Commission, and ultimately our full report, will be posted to the PFI consumer website www.Petfoodreport.com

Now, let me share PFI's actions with respect to the recalls. The association first became aware of the recall on Friday March 16 shortly after 2:00 PM EDT when a call came into our offices to an associate of PFI charged with member relations. Menu Foods called to alert us that in about an hour they were issuing a recall of 60 million containers of "in gravy" pet food produced in two of their four plants. Upon confirmation of the scope of the recall, we e-mailed an alert to our Board of Directors and every one of our members explaining what we had been told. We were on the phone with members around the country seeking to determine if any other companies were seeing similar issues, but found none at that time.

PFI members have since participated in frequent conference calls for updates on the status of the recall and have cooperated fully with FDA in its investigation. We do feel that if FDA had been able to specify earlier-on what ingredient was under investigation that we could have assisted them in finding and removing affected products from commerce in a more timely fashion.

Much of the rest of the case is well known by people who have followed the headlines in recent weeks. The determination by the FDA is that melamine, a substance completely foreign to the pet food manufacturing process, was present in wheat gluten, an ingredient used widely in both human and pet foods. This is both a puzzle, because we don't know how it got there, and is also a reassurance in that we seem to be getting closer to a conclusion.

Regardless of assertions to the contrary, pet food produced for the United States is among the most regulated products on store shelves today. But, this was not a problem we believe more regulations can fix, because it was outside the parameters of any known contamination. Our industry routinely tests ingredients for at least as many, and in many cases for more contaminants than done for human food because of the known sensitivity of pets to certain substances, such as aflatoxin.

For instance, we use the same grains as used in human food. However, where testing requirements for human food may only search for aflatoxin, the pet food in-

dustry testing regularly includes those for fumonisin, vomitoxin, zearalanone and ochratoxin, as well as other mycotoxins or potential contaminants that do not affect people, but which do affect pets. This also holds true for many other ingredients.

Make no mistake; the pet food industry feels the FDA has done a superb job handling this recall. But early on, when information surfaced about suspicious pet illnesses and deaths, the industry could have been a more valuable partner in the process sooner than it was allowed to be. At that point, the industry should have been allowed the same access to critical information, in the same timeframe, as was the news media. If the industry had access to the same information to which FDA was privy, we could have cross-referenced that with lot numbers, shipping information and other data that perhaps could have helped reduce the confusion the public felt because of multiple announcements. If you take one thing away from my remarks today, please understand this. The answer to this problem is not additional regulation, rather it is enhanced communication.

The FDA's investigation is ongoing and has not yet reached any conclusions regarding how any foreign substances entered the process. Only when we have this information can we make an accurate and informed decision about the best course of action going forward. It is our commitment that the members of the National Pet Food Commission will bring their considerable experience to bear and work to give pet owners peace of mind that every reasonable and possible safeguard is in place to protect pets in this country.

In regards to the use of imported ingredients and the regulations in place that govern them, Pet Food Institute staff participates in both the U.S. government delegation led by FDA for the World Health Organization's CODEX Alimentarius Commission's Animal Feeding Task Force; and in the Agricultural Trade Advisory Committee (ATAC) for USDA and USTR. The CODEX Task Force works to establish uniform standards for feedstuffs around the world, and educates member states about the necessity of reducing and where possible, eliminating contaminants that pose a danger to human or animal health.

The pet food industry is very concerned about the health of pets and strives to do the very best job it can to protect it at all times. The vast majority of pet food was never affected by the recall. According the Banfield Veterinary Hospital group which has been working with FDA, of the 237,844 pets seen by them since the onset of this issue, 5 cats and 1 dog have been shown to be tragically affected by products included in this recall.

This is far fewer animals than the public has been led to believe, while the very responsible pet food industry has incurred significant disruption of its operations while taking extraordinary steps to prevent any further loss of life to pets.

Mr. Chairman, the industry is dedicated to supporting the health of dogs and cats, and will continue to cooperate fully as we move forward. There is every reason for consumers to feel confident in the products we produce.

I want to thank you again, Mr. Chairman, for this opportunity to testify before you today. I am happy to answer any questions you may have to the best of my ability.

Senator KOHL. Thank you, Mr. Ekedahl.

Before we proceed to questions, again, I'd like to thank the members of the FDA who appeared here today. And we know you have a conference call coming up, for which you may have to leave at any point. And whenever you have to leave, we understand.

Mr. Nelson, you spoke at length about AAFCO's Model Safety Feed Program and its goals. How long has this AAFCO program been working? How long have you been working on this program? And why don't you think that these strictest self-regulations have been fully adopted?

Mr. NELSON. We started the process of developing the Model Feed Safety Program in 2001. Like I said, initially we developed best business practices for companies to adopt and to use to evaluate their own quality assurance programs. And there has been some—you know, some adoption of that. Clearly, not enough. At that point, we decided to move on to actually develop model regulations, because the—with—outside of the medicated feed good manufacturing practices, there are very little process controls available for enforcement of the industry.

Senator KOHL. Do you think you would have had more success if the FDA had mandated these regulations?

Mr. NELSON. FDA actually is working on a similar—you know, a parallel path right now with their Animal Feed Safety System Program, which, of course—you know, that would be Federal—it would be a Federal program, as well, but I think, you know, process controls are—give it an ability to pinpoint problems in a quicker manner and potentially limit types of actions, like recalls, like this.

Senator KOHL. Thank you.

Dr. Kirk, we know that you previously worked as a research scientist for a pet food company that used the Menu Foods plant located in Kansas. We know that one of the things that people are learning and being surprised about is that so many brands of pet food were made at the very same plant. Can you talk us through how that works? Are they really all very much the same?

Dr. KIRK. Thank you, Senator Kohl.

The products can be very much the same if they've been contracted to the—to Menu Labs, and the nutritionists are providing their formulas. However, the products can be vastly different. For example, major manufacturers will come in and essentially rent plant time, because the equipment that is available at Menu is unique to the industry, in terms of making formed meat chunks. So, a major manufacturer, kind of like Coke, will protect their formula, come in with their own ingredients, generally, and manufacture their own product over a short period of time. And they'll bear no similarity to some of the other products. So, the—they can be vastly different or remarkably the same.

Senator KOHL. Well, what we read is that many people are not very comfortable, to say the least, with the pet foods that are being sold in stores today. What advice would you give these pet owners? Should they try to cook their own pet food? And what should they do if they are as concerned as they are and, nevertheless, have to find food for their pets?

Dr. KIRK. Certainly, we've received a number of those very questions from our own clientele. As a veterinary nutritionist, we have numerous calls, and calls for recipe and formulation individually for dogs and cats. Generally, I don't normally recommend people cook for their dogs and cats, just because the consistency of the product and their ability to provide a balanced diet over a prolonged period of time seems to wane. I feel that the products that are on the market now are generally safe, since the recall. I've added an extra caveat that's not necessarily popular, that, in the short period of time while we're still trying to determine whether all the wheat gluten has been removed, that the consumer check the actual label and the ingredient list to determine whether wheat gluten is used. And that's been my current recommendation for my clients.

Senator KOHL. That's a good point. Thank you.

Dr. Hodgkins, in talking about the AAFCO label guarantees on pet food, you say that they are not based on routine testing of individual ingredients. Could you give us a little bit more thinking on that, expand on what you said?

Dr. HODGKINS. Yes, Senator, thank you.

I think the current situation illustrates a very good example of that, that, in fact, ingredients are not being tested individually before they're incorporated in pet food, and wheat gluten would not be the only one. I think the regulators in the room would agree that every ingredient batch that comes from overseas or from local suppliers is not tested. That would be a daunting task, I realize. But my concern, as underscored in my testimony, about the implicit and explicit safety claim on the pet food label, would lead consumers to believe that it is. I think that we can only ask human beings, whether we're dealing with our own food or we're dealing with our pet's food, we can only ask a certain level of perfection from human beings. And I understand that. But I do believe that there is an unwarranted sense of safety in a pet food label that contains an AAFCO guarantee. And there is an issue of fairness to the pet food purchaser here, in my view. Are people led to believe that their pet foods are safer than they really are, safer than they can be, perhaps? And do we need to reexamine how we label pet food so that they, in fact, tell the consumer what to expect?

Senator KOHL. Following up on that, in this case melamine does not appear to be an ingredient that ever would have been tested for. So, how do you think the situation could have been prevented?

Dr. HODGKINS. That's correct. I do not believe that—melamine might now be on a list. In my fantasy world, where pet food manufacturers—the better pet food manufacturers who wish to access safety claims might very well test for melamine, going in the future. And, as time goes on, perhaps they would add additional substances to the already substantial list—aflatoxin, E. coli, salmonella, all of those things—so that list can become more safe, and more complete over time. But today we do know that melamine would not have been checked for, 2 months, 3 months ago. But a pet food label that identifies those foods that undergo no safety testing at all, versus those foods that are at least undergoing safety testing that is as comprehensive at the time as is humanly possible, is more fair to pet owners. I have the same concern that the subcommittee has about wrapping up this investigation and making sure that all of the food is out of the marketplace, no more pets are exposed to this particular toxicity, but I am personally a good deal more interested in going forward and fixing what is a sieve of safety inadequacy assurances. And that is my focus.

Senator KOHL. Thank you.

Mr. Ekedahl, we have heard, and will continue to hear, that the pet food on the grocery shelves now is safe, but that there are plenty of available options. But the recall continues to expand—that's the point I'm making—which obviously shakes consumer confidence. What can you say to consumers to reassure them? Have companies not affected by this recall done additional testing to be certain that their products are safe?

Mr. EKEDAHL. Yes. I'd like—on the matter of safety, I'd like to cite what Dr. Sundlof said here just a few minutes ago. Pet foods are safe. And it's because of the safety record of pet foods that their resources are applied elsewhere, as necessary. So, the safety issue with pet foods is something—and the consumer sees that. The consumer has a very high confidence level in pet food products. As to what the consumers can do now, I think it's been said that there

are many products out there that are safe. The list of recalled products is very clear. Retailers have to be vigilant in getting their product off the shelves. Industry has pretty well gotten that—those products back and out of circulation, out of distribution. I think that part of it, FDA suggests, is pretty much resolved.

So, there are many, many safe products on the market, and the consumer is really in a position—and the retailers—to assure that the products they select for their pets are safe products.

Senator KOHL. Thank you.

Senator Bennett.

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

Dr. Hodgkins, I'm interested in your proposal to take labels off and then let the marketplace see the cream of the manufacturers rise to the top as they put their own labels on, under the watchful eye of the FDA to make sure that they don't put a false label on. Have I accurately summarized what you're recommending?

Dr. HODGKINS. I believe so, Chairman, yes.

Senator BENNETT. Okay.

And, Mr. Ekedahl, your folks are in the business. Would they feel that would be—that would, in fact, create a competitive advantage for some of the better manufacturers, and help the consumers?

Mr. EKEDAHL. I think there's a level playing field out there. I think consumers have very clear declarations as to the level of nutrition in that product, like no other product. We're always open to something that would improve the system, but we think we have, now, a system that works. These are really remarkable products. They're tested. They're tested by State chemists. We supply products to the highest requirements of every State. Our products meet the requirements of every State.

Senator BENNETT. So, I think what I'm hearing you say is that there would probably be no—probably be no changes on the part of those who manufacture pet food if the labeling situation went in the direction that Dr. Hodgkins has described.

Mr. EKEDAHL. I think the companies manufacture to the highest requirement out there, and that's what they will do. They'll have to do that.

Senator BENNETT. So, their labels would be sufficient—would be roughly equivalent to each other. Her complaint is that the labels are all the same now, and, therefore, meaningless. And if I hear what you're saying, they would put their own labels on, and they would all be roughly equivalent, because they think they would stay at the same level they are now.

Mr. EKEDAHL. The labels really are not equivalent. It's a very, very competitive marketplace, and companies are able to describe to the consumer the advantages that they perceive in their products. They each have their own nutrition theories, their own research, and they are providing products on the marketplace, and that is described in their products and in their advertising.

Senator BENNETT. All right. I will disappoint you both by saying that, when we had dogs and cats, and we had a multitude of both throughout our family career before I came to Washington, I never read the label. I would go to the grocery story, and I would buy what the dog was used to eating, and I would continue to buy that same thing. And I can't tell you what advertising move me in one

direction or another, or one label or another. Fortunately, all the dogs and the cats survived just fine. So——

Dr. Kirk, would you—you were asked by the chairman to walk through one process—would you walk through another process for me, the process of typical screening of both suppliers and products?

Dr. KIRK. Yes, thank you very much, Senator Bennett.

I certainly can't speak to all companies' process. I can speak to the process I used when qualifying an ingredient. We would source ingredients from suppliers that we felt were reputable and that had a history within our company of providing consistent, high-quality ingredients. We would inspect the quality—the analysis statement. And, on that statement, it would not only describe the nutrient content, but the degree of toxin testing, which included microbial contamination, antibiotics, other contaminants, including heavy metals, aflatoxins or mycotoxins. An ingredient that we would suspect could be contaminated with something else—for example, fish—would go through additional heavy-metal screening and evaluation for rancidity, because those products can go rancid. We would have to test three different lots, three different shipments, and a large quantity of sampling from each individual shipment, so that would essentially be nine samples, and to evaluate not only product batch-to-batch consistency, but overall safety and nutritional quality. That would occur before we would ever agree to put that new ingredient into a product.

Senator BENNETT. Now, the FDA requires that Hazard Analysis and Critical Control Points, which I understand in the trade is called HACCP—we always have to acronyze—create acronyms for everything in government—the FDA requires that the HACCP systems be in place for some human foods. Would you think that HACCP plans required for the pet food industry would be a good idea?

Dr. KIRK. That certainly is out of the scope of my expertise, but certainly there were those particular plans implemented within the plant that I was involved with; and truck-side testing, as well as testing throughout the manufacturing process was, indeed, employed.

Senator BENNETT. Would any of the other witnesses at the panel want to comment on whether or not HACCP systems in place for human food be a good idea or a bad idea?

Mr. NELSON. If I may address the——

Senator BENNETT. Surely.

Mr. NELSON. Committee, actually I believe right now some components of the pet food industry do require HACCP plans—low-acid canning covers pet food too, if I'm not mistaken. The process controls that AAFCO has been developing are essentially ones that would be put together on known hazards, suspected hazards, of individual plant, based off of what type of activities they do. Very similar to HACCP, people tend to try to shy away from that word, because of, maybe, you know, expense nor a lack of expertise on some of those people. But that's the type of process controls that we're looking at, similar items.

Senator BENNETT. Would you agree with Mr. Ekedahl, that the industry is highly regulated?

Mr. NELSON. I think the industry is highly regulated, on a postproduction process. Product labeling, we've talked about—you've talked about several questions here. Requirements, most of the rules or regulations that deal with product labeling restrict labeling. The required labeling is probably about a 2-square-inch panel on the side of the bag. The other information is advertising——

Senator BENNETT. Sure.

Mr. NELSON [continuing]. And consumer information that is highly regulated by AAFCO and FDA to make sure it's true and not misleading.

Senator BENNETT. Dr. Kirk and Dr. Hodgkins, would you agree with Mr. Ekedahl, that this is highly regulated?

Dr. KIRK. I would agree that a large number of aspects are highly regulated, as I described in my testimony. Certain other areas are self-monitored.

Senator BENNETT. I see.

Dr. HODGKINS. The industry has a great deal of regulation. If you look at the layers, there's a whole bunch of stuff happening and a whole lot of groups of people involved. It's not effectively regulated. As I outlined in my statement, we don't have products that are as safe as the labels suggest, or as safe, perhaps, as we want them to be. And we certainly do not have adequacy testing that confirms that a pet can remain on the food for 6 months, 6 years, 2 decades, and not suffer harm. And there are examples in our own experience with pet foods that suggest that this is the case.

Senator BENNETT. Okay. Did you want a final rebuttal, Mr. Ekedahl, before I——

Mr. EKEDAHL. Yeah, I'm fine with it. I know—I can simply tell you that cats and dogs are living longer, healthier lives than ever before, and it's the nutrition in the product, and it's veterinary care. Better than ever before.

Senator BENNETT. Thank you very much.

Senator KOHL. Thanks, Senator Bennett.

Senator Durbin.

Senator DURBIN. Mr. Nelson, one thing I'm not clear on. Who funds the American Association of Feed Control Officials?

Mr. NELSON. It's self-funding through publication of the official publication of AAFCO.

Senator DURBIN. So, who pays for the publications?

Mr. NELSON. The industry, State officials, our department buys those for all field agents.

Senator DURBIN. So, some of your funding comes from the industry that you are involved with, correct?

Mr. NELSON. Industry—actually, AAFCO is a fairly open process. Membership is limited to people who have actual charge of enforcing feed regulations. The industry does provide, you know, advisors, of a lack of a better term——

Senator DURBIN. What——

Mr. NELSON [continuing]. And they come in and work with us on developing regulations. One of the paramount focuses of AAFCO is, we want to develop regulations that are understood and accepted by the industry.

Senator DURBIN. So, what percentage of your budget for your association comes from the industry that you are overseeing?

Mr. NELSON. Oh, boy, I would have to get back to you on that. I really don't know.

The association—we hold, you know, several meetings a year, we have one employee. So, our—you know, our budget is not——

Senator DURBIN. You have one employee?

Mr. NELSON. One employee. She's the assistant secretary/treasurer.

Senator DURBIN. And that employee is——

Mr. NELSON. Everyone else is volunteer.

Senator DURBIN [continuing]. Is determining the nutritional safety of all the pet foods in America?

Mr. NELSON. Well, it's done on a volunteer basis, through committees. And actually, the AAFCO——

Senator DURBIN. We know all about committees.

Mr. NELSON. No, all—well, the AAFCO nutritional statement that's required on product labeling is a statement of nutritional adequacy. There is no implication to safety.

Senator DURBIN. That's a point I wanted to make. First, before I hold up this can of dog food, let me say, it is not on the recall list, it does not include wheat gluten. I am not suggesting that there is anything wrong with this brand or this can that I'm holding up. I've got to say that for Jack Danforth.

This is Alpo, made by Ralston Purina. And there is a statement on the back of the label, which says, "Purina Alpo Classic Chunky With Beef is formulated to meet the nutritional levels established by the AAFCO Dog Food Nutrient Profiles for Growth and Maintenance of Dogs." Is that a pretty common statement/declaration made——

Mr. NELSON. It's the absolute——

Senator DURBIN [continuing]. For AAFCO?

Mr. NELSON [continuing]. Required statement, yes.

Senator DURBIN. So, what you are talking about when you say that AAFCO is interested in safety, is nutritional safety.

Mr. NELSON. Nutritional adequacy. Safety, long-term effects—you know, individual animals are going to be—they're individuals——

Senator DURBIN. So, this doesn't mean that any ingredient in this can is not contaminated.

Mr. NELSON. No. And, actually, the—all ingredients used in animal feed, including pet foods, have to be defined by AAFCO. And there's a definition process, and FDA has—there's AAFCO investigators. I'm one of them. And we look at items. And typically they're nonfood items. These are things that come as byproducts and——

Senator DURBIN. And so, is it fair to say that, if I look at the long list of ingredients—I won't read them, but the AAFCO employee, or committees, have taken a look at those ingredients and decided this is nutritionally sound, in your opinion, for feeding dogs?

Mr. NELSON. That's correct.

Senator DURBIN. Okay. So, when the word "safety" is used, that's what you're talking about. You're not talking about whether the plant that produced it is safe. You're not talking about whether the

ingredients in the can are safe. You're just talking about, in general terms, these ingredients, fed to a dog, are nutritionally safe.

Mr. NELSON. When I've been talking about safety, I am talking about prevention of the contamination of adulteration outside of the formulation of the product.

Senator DURBIN. But AAFCO makes no inspection of pet food-producing facilities, is that correct?

Mr. NELSON. Our member States do. Wisconsin does inspect pet food manufacturers.

Senator DURBIN. But not your association.

Mr. NELSON. Not my association.

Senator DURBIN. Okay. Fair enough.

Let me, if I could—Mr. Ekedahl, I think you've, kind of, used a term, which I'm going to challenge. And several people on the panel have agreed with it. And I'll tell you why I'm challenging it. You referred to dog food—pet food as a "highly regulated product." Mr. Nelson was very clear in his statement that "AAFCO has no regulatory authority," and I quote him. Is that correct, Mr. Nelson?

Mr. NELSON. Right.

Senator DURBIN. Okay. We've been told by the FDA that there is no premarket approval of this product sold to consumers. We know that there's no regular inspection of the facilities that make these products. What we are told is that 30 percent of these facilities will be inspected once or twice over a 3½ year period. We also know that there is no penalty for failure of a company, like Menu, to report if they know that their food is contaminated. At least we're going to check into that, but it appears they waited 3 weeks, and I haven't heard of a penalty being assessed.

We know that there is no Government authority to recall a contaminated product. We know that there was no mandatory State inspection standards established by the Food and Drug Administration across the United States. We know that the claims being made on the label here about this dog food are beyond the claims that can made about human food. And we are told, at least Dr. Hodgkins has told us, that it's questionable as to whether or not a company that makes a contaminated pet food has to report to anyone about adverse events in a timely fashion, whether a dog has died or dogs are dying.

When I go through that long list of things, it's hard to conclude this is a "highly regulated product." What is it about this product that I have missed?

Mr. EKEDAHL. Well, your first point, really, is that AAFCO is not a regulatory body. That's absolutely correct. It's not a regulatory body. But the members of AAFCO are regulators in their States, in each of the States. And they're not supported by industry, they are, typically, employees of the State Departments of Agriculture.

Senator DURBIN. Agriculture.

Mr. EKEDAHL. That's right. And they have the responsibility for these products in their States.

Senator DURBIN. And does each State have the same standards for inspecting?

Mr. EKEDAHL. Yeah. And that's the purpose of AAFCO, is to develop a model——

Senator DURBIN. So——

Mr. EKEDAHL [continuing]. That applies to all the States. Now, all States haven't adopted the model.

Senator DURBIN. Okay. And, in this case, in Emporia, Kansas, we're told, there was never an inspection. So, does that mean the Kansas AAFCO inspection standard requires no inspection of production facilities?

Mr. EKEDAHL. That—those inspections would be FDA inspections.

Senator DURBIN. No, but——

Mr. EKEDAHL. Yeah——

Senator DURBIN [continuing]. We've just been told by the FDA——

Mr. EKEDAHL. The plant——

Senator DURBIN [continuing]. That those——

Mr. EKEDAHL [continuing]. Plant facility—of the facility would be——

Senator DURBIN. But the FDA has told us what the inspections amount to.

Mr. EKEDAHL. Yeah.

Senator DURBIN. Thirty percent of the facilities over a 3½ year period of time are inspected once or twice?

Mr. EKEDAHL. But there—but there are very specific rules and protocols established by FDA with respect to assuring the safety in those plants. And companies take that very seriously. I mean, if you fail with that, you fail. There's a big price to pay for that.

Senator DURBIN. But they never show up. They come and inspect 30 percent of the plants over a 3½ year period of time?

Mr. EKEDAHL. Well, the system suggests that you don't have to have a cop standing at your shoulder to do the right thing and to produce a good product, because the marketplace will deal with that.

Senator DURBIN. Well, the marketplace has dealt with it, and a lot of consumers across America aren't going to buy Menu pet food for a long time. That's how the marketplace deals with it, because there are animals that died as a result of this pet food. That's how the marketplace responds.

Mr. EKEDAHL. Well, that was a contamination that came in—a foreign contamination of an ingredient that—all the regulation in the world would not—would not really have captured that——

Senator DURBIN. The point—what I'm——

Mr. EKEDAHL [continuing]. That foreign substance in an ingredient.

Senator DURBIN. All right, let's go to that point. We are increasing our importation of foreign agricultural products. I think it's——

Mr. EKEDAHL. Right.

Senator DURBIN [continuing]. Some $7 billion a year. So, do you have confidence that the next shipment of wheat gluten from anywhere around the world is not going to be contaminated?

Mr. EKEDAHL. No, wheat gluten—you know, there's 100-percent examination of wheat gluten coming from either China or The Netherlands, which are the two largest suppliers of that product. Yeah, I——

Senator DURBIN. Excuse me, 100 percent inspection?

Mr. EKEDAHL. Inspection of the product coming in now—of wheat gluten coming in now. That's——

Senator DURBIN. You're saying that every shipment of wheat gluten into the United States from China is being inspected?

Mr. EKEDAHL. By FDA, yeah.

Senator DURBIN. For——

Mr. EKEDAHL. That's what they've said, yes.

Senator DURBIN. Is that since this contamination of pet foods?

Mr. EKEDAHL. Yes.

Senator DURBIN. Okay.

Mr. EKEDAHL. That's right. So, I think we're comfortable with wheat gluten. Wheat gluten, from one plant in China that contaminated that product, is the problem. Not wheat gluten. It's the contaminant that got into wheat gluten.

Senator DURBIN. I understand.

Mr. EKEDAHL. Adulterating of food substances is serious—a serious offense. And that happened.

Senator DURBIN. Let me go, specifically. Do you think—is Menu one of your——

Mr. EKEDAHL. Yes.

Senator DURBIN [continuing]. Clients companies? Do you think that they met the standard of care for pet owners across America by failing to report their suspicion of contaminated pet food for 3 weeks?

Mr. EKEDAHL. I have no direct knowledge of the timing——

Senator DURBIN. I'll tell you the timing.

Mr. EKEDAHL [continuing]. Of that situation.

Senator DURBIN. I can read it to you. Believe me, it was 3 weeks, from the first notification or the first suspicion at Menu until they reported to the Food and Drug Administration that the product was dangerous. Do you think that that is the standard of care which pet food manufacturers should live up to?

Mr. EKEDAHL. I don't know that that is a standard, no. I don't know the facts in that case. I can tell you that once the melamine was determined to be the suspected agent, and once companies were made aware of the fact that that found their way to their plants, those products were recalled at once.

Senator DURBIN. They were——

Mr. EKEDAHL. That was a very responsible thing to do, for the——

Senator DURBIN. Now, wait a minute. Now, wait a minute. Let's get the record straight. Menu waited more than 3 weeks after finding out that the dogs wouldn't eat their food and were getting sick. They waited 3 weeks before they reported it to the FDA. The FDA, within 48 hours, recalled 95 products, or at least announced that they should be recalled.

Mr. EKEDAHL. Yeah.

Senator DURBIN. So, the FDA made a timely decision, once being notified by Menu. But Menu waited 3 weeks, or more. Now, let's——

Mr. EKEDAHL. I——

Senator DURBIN [continuing]. Make sure the record's straight on that.

Mr. EKEDAHL. Well, that's——

Senator DURBIN. And I'm asking you about Menu.

Mr. EKEDAHL. I don't have the facts on Menu, Senator. I don't have——

Senator DURBIN. I'd think——

Mr. EKEDAHL [continuing]. Have the direct information.

Senator DURBIN [continuing]. Before you came to the hearing, you would have the facts.

Mr. EKEDAHL. Well, I think that's a matter between Menu and FDA. I do not—we do not have the direct information as to the circumstances surrounding that—the timing of that recall.

Senator DURBIN. Mr. Chairman, let me say I think Dr. Hodgkins is onto the right suggestion. We need more timely reporting of anything that's suspicious so we can take a look quickly, before damage is done to pets, or even to humans. In this case, that was one of the fears. We have expanded the law for adverse-event reporting to the Food and Drug Administration for a number of things, including dietary supplements.

I think, clearly, we need to expand and strengthen this law so that companies, whether it's Menu, in Canada, or other companies, know they have a responsibility—a corporate responsibility—to their customers to respond in a timely fashion, any adverse event so that there can be a reaction, an appropriate reaction, perhaps a recall of product.

Thank you very much, Mr. Chairman.

Senator KOHL. Dr. Kirk, can you explain how a plant, such as Menu, prevents cross-contamination as it moves from one product processing to another's product processing?

Dr. KIRK. I cannot specifically speak to how Menu prevents cross-contamination, but I can speak to the individual plant with which I worked, and that is that, generally, a run of ingredients, of dummy ingredients, would essentially wash out the line, and then the line would be hand-cleaned to remove product and product contamination between the next product run. So, it's very standard to clean the line, where ingredients are going to be mixed and batched and cooked and bagged.

Senator KOHL. And is it your expectation that all plants proceed in this manner?

Dr. KIRK. No, it's not. And I personally have found, you know, Kibbles 'n Bits in my, you know, Cat Chow occasionally, so certainly those do pop up here and there. But, in general, I would expect that most of the major manufacturers do clean the lines between major shifts and changes in formulas.

Senator KOHL. Any comment from any other panelist on the danger in this procedure as they move from one brand name to the other, in terms of——

Yes, sir, Mr. Nelson.

Mr. NELSON. May I address the Committee?

Cleanout or cross-contamination is actually an item that is covered in detail by both State and Federal inspectors when they do medicated feed manufacturing. And it's actually—it's each individual system. So, it's a complicated process. But there is no requirement for that in current regulations, about clean outs between production, other than medicated feeds.

Senator KOHL. There is no current requirement? Say it again.

Mr. NELSON. There is no current requirement for the clean out of equipment prior to manufacturing other feeds, other than medicated feeds.

Senator KOHL. All right.

Yes, Dr. Hodgkins.

Dr. HODGKINS. This would be an important consideration, just as we are concerned about peanut contamination for people who have allergies to peanuts. I'm sure plants that handle peanuts have to be very careful about either not manufacturing any other types of products or being very clean. Certainly, food allergies occur in dogs and cats, as well, and there are even products that are marketed for allergic pets and pets allergic to certain ingredients. So, this would be an important consideration. And it is a concern that there is a laxity in the amount of regulation that looks at that particular problem.

Senator KOHL. Yes. Thank you.

Any other comments or questions from Senator Durbin? Comments from the members of the panel?

The subcommittee has received a statement from the Honorable Rosa L. DeLauro which will be placed in the hearing.

[The statement follows:]

PREPARED STATEMENT OF HON. ROSA L. DELAURO, U.S. REPRESENTATIVE FROM CONNECTICUT

Mr. Chairman, I want to commend you for calling this hearing and thank you very much for the opportunity to present testimony.

The recent pet food recall has raised very serious questions about the safety, not only of our food, but of our pets as well. It is very unfortunate that not even the family pet is immune from the food safety problems that are plaguing our country. In response to the letter that Senator Durbin and I sent to the FDA, Mr. Chairman, the agency claims that it is not ignoring its responsibility in the pet food area. However, to the many Americans who have lost their pets to contaminated foods, the initial evidence would suggest that the FDA is failing its responsibilities to protect pets from unsafe food as much as it is failing to protect American consumers.

As Senator Durbin has stated, the FDA's response to this situation has been tragically slow, and pet owners deserve answers. The uncertainty about which foods have been recalled and what is safe to feed their pets has gone on far too long. I want to know how often pet food manufacturing plants are being inspected, and whether we need to force the FDA to modernize its regulations to protect our pets.

Early in the process, I also was troubled by FDA's underreporting the number of pets affected by the contaminated foods. At one point, the agency reported that only 16 pets had died when in fact, the number was significantly higher than that.

And of course, I do not have to remind you Mr. Chairman that the FDA has no authority to mandate recalls and instead relies on information submitted by companies. We saw yesterday how problematic this arrangement can be when Menu Foods admitted that a "clerical error" caused the company to overlook a shipment of potentially contaminated wheat gluten from one of its plants in the United States to one in Canada. This gap delayed a recall of some cat food made in Canada.

We are all aware of the disturbing statistics related to imported foods. The United States now imports far more foods than it exports, but there are fewer inspectors for imported foods. Currently, FDA inspects less than one percent of the food imported into this country that it is responsible for regulating. Also, the FDA does not require that exporting countries to have food safety regulatory structures that are equivalent to the U.S. standards. Given that the contaminated pet food appears to be connected to wheat gluten imported from China only heightens my concern about the agency's ability to inspect imported products. It is this aspect of the pet food recall crisis that I am particularly troubled about and intend to examine further in a follow-up hearing before the House Agriculture Appropriations Subcommittee.

It very well may be that FDA lacks the resources to adequately inspect pet food facilities and imported products. And this is an area, Mr. Chairman, where we could work together to make a direct impact.

However, we also should examine whether this is a management issue. In its response letter, the FDA says it has not determined whether changes in current law or resources are necessary based on the pet food recall. I find it mind-boggling that this agency always refuses to even consider requesting additional authorities or resources to help it do its job. As we all know, that is unheard of in Washington.

The FDA likes to demonstrate its commitment to food safety by pointing out that "food" is the first word in its name. However, its actions suggest otherwise, highlighting the need for legislation that would create a single food safety agency—a bill that Senator Durbin and I have worked on for quite a long time now, Mr. Chairman.

I look forward to FDA's analysis of their oversight of pet food manufacturing facilities and the final report on the actions that the agency took once the crisis finally ends. I think it will play a key role as we determine the best steps to take in moving forward.

Thank you again, Mr. Chairman for allowing me to present testimony at this hearing and I look forward to continuing to work with you on this issue.

CONCLUSION OF HEARING

Senator KOHL. Well, we thank you all for being here today. This is obviously a really important topic. It's very timely and something of concern to people all across our country. And your coming here today has helped us a lot to shine the light on the problem, and also, hopefully, to look for answers and solutions as quickly as possible.

Thank you so much.

[Whereupon, at 4:01 p.m., Thursday, April 12, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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