## Transcript of FDA Press Conference on the Pet Food Recall April 5, 2007

## **FTS-HHS FDA**

Moderator: Julie Zawisza April 5, 2007 12:00 pm CT

Coordinator:

Please continue to stand by. Your conference call will begin momentarily. Please continue to stand. This conference call will begin momentarily.

As a reminder to ask a question while on today's conference call please press star 1 on your touch tone phone. You will be limited to one question. Once again to ask a question while on today's conference call you may press star 1.

You will be limited to one question. Please continue to stand by. This conference call will begin momentarily.

Welcome and thank you for standing by. All participants will be on listenonly until the question and answer portion of this call. To ask a question at that time please press star 1 on your touch tone phone.

This conference is being recorded. If you have any objections please disconnect at this time. I would now like to introduce your host Ms. Julie Zawisza. Please begin

Julie Zawisza:

Thank you (Terry). Good afternoon ladies and gentlemen and thank you for your participation today. Today we're going to update you on FDA's investigation of the pet food recalls. And we have two speakers today and we have other folks available to answer questions later on in the briefing.

Our first speaker will be Stephen Sundlof who is the Director of our Center for Veterinary Medicine here with FDA. And he will provide an update on our findings to date.

And Michael Rogers who is the Director of our Division of Field Investigation will provide more information on the investigation. We also have David Elder, Director, Office of Enforcement here to answer questions.

And with that we will begin with Dr. Sundlof.

Stephen Sundlof: Thank you Julie and good afternoon. I would like to update you on our investigation of the contaminated pet food manufactured with imported wheat gluten.

Our investigation is still ongoing but we hope to tie up any remaining loose ends in the near future. I want to report on where we are to date. We have identified some additional pet food products that are being recalled today.

The manufacturer is Sunshine Mills of Red Bay, Alabama. And that company has identified some pet treats particularly dog biscuits that were manufactured with contaminated wheat gluten. We will have the names of all of the different products that are affected by this later on this afternoon.

And I want to announce that Menu Foods Incorporated is amending its recall to extend the production date on some of the recalled products. Both firms are issuing press releases shortly.

To recap the investigation so far three weeks ago FDA first learned of a problem with pet food manufactured by Menu Foods after the company

reported illnesses and deaths in cats and dogs who had eaten some of its products.

We immediately launched an investigation into the problem. FDA investigators arrived at the company's Emporia, Kansas plant the next day and searched for possible sources of the contamination.

At the same time FDA consumer complaint coordinators around the country began taking calls from consumers and veterinarians who reported illnesses that may have been associated with the contaminated pet food.

FDA has received over 12,000 such reports in the last three weeks. And this is more than twice the number of complaints that we typically receive in a year.

Through testing of samples of finished product and raw materials our field laboratories confirmed the presence of melamine a product used in fertilizer and other industrial chemicals in commercial uses in shipments of wheat gluten that had been received from China.

FDA's examination of import records and records obtained during follow up investigations identified the distributor of the contaminated wheat gluten ChemNutra of Las Vegas, Nevada.

FDA worked with the firm to trace the suspect product and identified its Chinese manufacturer. FDA has asked the Chinese government to help us with this investigation. The investigation continues to determine how the melamine may have gotten into the wheat gluten.

FDA is currently sampling 100% of all Chinese wheat gluten being offered for import into the United States. At this time there is no evidence that any wheat

gluten contaminated with melamine has entered the food supply to humans and human food supply.

To date recalls of pet foot products have been conducted by Menu Foods, Hill's Pet Nutrition, P&G Pet Care, Nestle Purina Pet Care Company, and Del Monte products.

While a number of firms have been affected these recalled products represent approximately 1% of the total pet food industry and there remains an ample supply of safe cat and dog food available at stores throughout the United States.

Understanding the role of melamine in each of the dog and cat illnesses will require an extensive analysis of the information, assistance from outside sources, and perhaps future research. This is a major undertaking that the agency is currently carrying out.

Now I've been asked repeatedly about the total number of cats and dogs that may have been affected by this current outbreak and we still don't have any firm numbers. And I want to just talk a little bit about the process and why that is.

When there is a food borne disease outbreak in humans FDA receives help from the Centers for Disease Control and Prevention and state departments of health to trace outbreaks of the human illness and to determine the cause.

The Centers for Disease Control with its partners uses dedicated resources and infrastructure to collect, store, and analyze samples and to conduct the epidemiologic investigation into the cause of the outbreak.

When dealing with food borne outbreaks in animals however in addition to removing the contaminated products from the market so they can no longer cause harm FDA assumes the responsibility for the epidemiologic part of the investigation.

So we - the FDA is really responsible for carrying out what would normally be carried out by the Centers for Disease Control with the help of state departments of health.

So right now our priority is still ensuring that all contaminated product is identified and removed from store shelves. We have traced all the contaminated wheat gluten and identified all the pet food manufacturers who received contaminated raw ingredients.

We are going back to analyze complaints that we've received, analyzing the results of blood and tissue samples, and conducting research to learn as much as we can about what caused the outbreak and what we in the industry can do to avoid this type of problem in the future.

All along we have been working with the Banfield Pet Hospital -- a nationwide network of veterinary hospitals -- the Veterinary Information Network, and the ASPCA -- the American Society for the Prevention of Cruelty to Animals, universities and others to help us assess the extent of the outbreak.

The Banfield Pet Hospital's extensive database of the animals it treats has been very helpful in assessing the prevalence of acute renal failure in cats and dogs during the outbreak period. And we will be relying on this information as well as others as we try and determine the extent of the outbreak.

The American Veterinary Medical Associations and other professional organizations have also partnered with us to provide advice and communicate important information to the public.

This investigation has been a massive effort drawing from many parts of the FDA and involving thousands of dedicated professionals across the country. We appreciate the extraordinary cooperation of our federal and state partnered health authorities, veterinarians, members of public, and others who have helped us with this investigation. We also appreciate the prompt action and cooperation of the firms who have been affected by the recall.

Once again I'd like to thank you the members of the media for helping FDA get the information out to the public. We encourage the public to continue to monitor FDA's website and should new information arrives we will get it out to you as soon as possible.

Thank you. That concludes my remarks and I will now turn it back over to Julie Zawisza.

Julie Zawisza:

Thank you Dr. Sundlof. At this time I'd like to turn it over to Michael Rogers who will give us further information on the investigation to date.

Michael Rogers: Thanks Julie. As Dr. Sundlof mentioned this has been an unprecedented national response to this event that involves all of our 20 districts, over 400 people, 4 of our FDA labs with all of them on standby, and an incredible coordination effort with all of our state and local public health counterparts.

> In response to this the agency has conducted numerous inspections and investigations of importers, manufacturers, and warehouses that have been

identified as companies that potentially received suspect product. And all of this is in an effort to identify the scope of this incident.

In doing so we've inspected all the firms that received suspect product. We've worked with these firms to initiate the appropriate follow up action including recalls, market withdrawals and sub recalls as well as notifying their customers. And these firms we're happy to report are cooperating.

The agency has taken more than 12,000 calls and assisted in the development of a number of recalls and market withdrawals. And while it is expected that this may represent one of the largest pet food recalls in history it does not represent a percentage of the market share that would cause any shortage concerns at this point and that there remains plenty of safe pet food products available to consumers.

During this investigation which began the day after FDA was notified on March 15 we've inspected the importer and all firms that received suspect products.

We've identified the contaminant as melamine which has no approved use in human or animal food. And we've worked with all the firms on the appropriate follow up action as we've said which includes recalls, market withdrawals, and notifying their customers.

The inspections and investigations and the evidence that they have generated allow us the confidence at this time to declare that there is no evidence at this time that any imported wheat gluten contaminated with melamine has entered into the U.S. human food supply.

In a proactive effort the agency has implemented an import alert focused on the suspect foreign supplier and initiated an import sampling effort designed to cover all imported wheat gluten from China.

We've activated our emergency operations response center. And we've conducted over 430 analyses carried out by the various FDA laboratories.

The FDA will continue monitoring the ongoing recalls to ensure the effectiveness and to support the safety of all food and animal feed in the U.S. and will continue to work with our state and local counterparts as well as commit to properly inform the public of any additional findings regarding the recent outbreak associated with this incident.

Julie?

Julie Zawisza:

Thank you Mr. Rogers. Ladies and gentlemen and (Terry) our operator we're ready now to take questions. Let me remind you to ask one question and follow up. I think we're going to have a lot of questions today. And also to state your name and affiliation please.

Coordinator:

Thank you. At this time to ask your question please press star 1 on your touchtone phone. You will be asked to record your first and last name. I will announce you prior to asking your question. To withdraw your question press star 2.

Once again to ask your question please press star 1 on your touchtone phone. One moment please for the first question.

Our first question will come from Katie Zezima, New York Times.

Katie Zezima: Hi. Thanks for taking my call. You know, there's still some confusion

surrounding exactly where this wheat gluten came from. China apparently is saying it has no record of any agricultural products - sending any wheat gluten

to the U.S. that could have been tainted which obviously contradicts, you

know, what you just said.

Is this true? As far as you know is this in fact from China?

Michael Rogers: What we can say is that our investigation and the records that we have been

provided has led us to a common importer that identifies the country of origin

as China.

But as we mentioned our proactive efforts are focused on sampling all wheat

gluten from that particular country and that sampling effort includes testing

for melamine.

Julie Zawisza: That was Michael Rogers.

Katie Zezima: So you're saying this product is from China then?

Julie Zawisza: I'm sorry. Say that again Katie.

Katie Zezima: So there is in fact wheat gluten being imported from China despite what the

Chinese government is saying - that they're not shipping any in?

Michael Rogers: According to our import records that is a correct statement.

Katie Zezima: Okay.

Coordinator: Thank you. Our next question will come from Tracy Potts, NBC.

Tracy Potts:

Thank you. Could you give some advice for people who at this point are just concerned about all of the food that's on the market. I know that you said that those involved in this recall are very small part of the market.

But a lot of people at this point are just concerned that, you know, as things continues to develop we've got more recalls now than we did yesterday. That perhaps what they're feeding their pet today could be the source of a recall tomorrow.

Could you address that concern?

Stephen Sundlof: Well let me just say that we have - we believe we have found out all of the material that came from the one supplier from China. We think we have this all traced out.

> And so, you know, barring any new information that we are unaware of at this point in time we think that we pretty much are coming to a conclusion on this. And that those products that are not on the recall list with the exception of those that are going to appear today -- the dog biscuits and increased extended time/date window for the Menu Foods Cuts in Gravy products.

But other than that I think, you know, the public should feel secure in purchasing pet foods that are not subject to this recall.

Julie Zawisza: That was Dr. Sundlof. Next question please.

Coordinator: Deidra Henderson, Boston Globe. Deidra Henderson:

Hi. Thanks a lot for doing this call. Dr. Sundlof I'm hoping that we can get a little bit sharper on this. If you're a concerned pet owner and you're hearing today's news and you're also hearing that the FDA thinks that they've traced out all of this tainted wheat gluten will today probably be the last day they'll see a recall notice?

Stephen Sundlof: We hope so. We don't know of any others that are potentially pending. I mean, obviously we're, you know, in an investigation, new information becomes available to us so we can never say again with 100% assurance that it won't.

> But all of the information that we have, the thoroughness that we've tracked all this material down my recommendation to consumers is that again barring any unforeseen new information that we should have it all wrapped up.

Julie Zawisza:

Thank you. Next question.

Coordinator:

Julie Schmidt, USA Today.

Julie Schmidt:

Thank you very much. Just one quick one. Was the FDA actually notified by Menu Foods or someone else on the 15th?

Stephen Sundlof: I believe it was Menu Foods. Yes.

Julie Schmidt:

Okay. And then you talked about wrapping up the loose ends? How do you address the fact that, you know, melamine is not considered highly toxic?

Stephen Sundlof: That's an issue that we are going to be pursuing. And when I was talking about loose ends I was talking about getting the wheat gluten - anybody that manufacturers with wheat gluten getting those products off the market and

making sure that consumers know which products are under recall. So that was pretty much the loose ends.

Yes we still have a lot of work to do in understanding why melamine is involved as a relatively non-toxic substance how that relates to the conditions that we're seeing.

But we are certain - relatively certain that there is a connection here some place whether it's the melamine or some other contaminant that is traveling along with the melamine.

All of the cases of disease and deaths in animals seem to be tracking only to the product which we know contains the melamine.

Julie Zawisza: Thank you. Next question.

Coordinator: Andrew Bridges your line is open with Associated Press.

Andrew Bridges: Hi. Thanks for taking my question. The agency says it's collecting and analyzing samples of dry dog and cat food in response to calls from veterinarians and pet owners. What do those analyses show so far?

And across the whole pet food spectrum are you continuing to look for possible other contaminants? Or is the melamine it as far as you're concerned.

Stephen Sundlof: We are focusing on the melamine right now because we believe that even if the melamine is not the causative agent it is somehow associated with the causative agent an so it serves as a marker.

Yeah, you know, we will as time allows look for additional toxic substances. We are analyzing dried dog food and cat food because we have heard from a number of callers and consumers that they believe their pet may have been affected by that. To date we have not found any melamine in those samples.

Julie Zawisza: That was Dr. Sundlof. Next question please.

Coordinator: (Jim Spellman).

Julie Zawisza: With who?

Coordinator: Jim Spellman CNN your line is open.

(Joe Johnson): It's (Joe Johnson) and Jim Spellman with CNN. I realize that the numbers are difficult for you but there seems to be a really huge disparity between the 14

deaths that you're reporting and some of the claims out there. For example in

Oregon alone there's twice that number that's suspected.

Is there any way you can give us a better feel for how many animals are likely

to have died because of this. And do you want to update that 14 number at

least?

Stephen Sundlof: No. And let me just say that, you know, we are aware of 14 confirmed cases.

But we're not saying that we think that's an accurate number. We know that

there are a lot more animals that have been affected this (unintelligible) and

have died.

Trying to put an estimate to it at this time is just not something that we can do.

We have to define and we are in the process of defining some of the criteria

that we're going to need to actually call it a confirmed case.

For instance, you know, was one of the pet food products involved that we

know to have caused disease in other animals. Is there a veterinarian involved.

A lot of the calls that we're receiving are from pet owners and it's hard to get

good clinical evidence to rule in or rule out whether the pet food may have

been the cause.

If they did go to a veterinarian did the veterinarian run blood work. And is the

blood work consistent with the findings that we know from animals that were

known to have died or been affected by this pet food.

And so, you know, each of these steps strengthens the case. The best - the

absolute perfect conditions would be if we had - if the animal unfortunately

died but they had done a thorough autopsy and we can review the results of

the autopsy. And if there's any food left and we can analyze the food.

So there's a number of steps that give us greater levels of assurance. And so

far we're in the process of putting together information from what you heard

earlier today over 12,000 calls to start grouping some of these calls into likely

suspects that we will pursue further and unlikely suspects that we can set aside

at least for the time being and zero in on the ones that we think are most likely

to be the result of the pet food.

But just again we have no good information as to what that final number

might be. It is going to take us a while to get there but eventually, you know,

we will have a much better idea of the extent of this tragedy.

Julie Zawisza:

Thank you. Next question.

Coordinator:

(Frank Presthill), MarketWatch.com.

(Frank Presthill): Thank you very much for taking the call. You said - Mr. Rogers you said

earlier there's no evidence that any of the wheat gluten contaminated with

melamine has entered the U.S. food supply. Is that an indication that that

portion of the investigation has concluded?

And if there were to be melamine within the food supply because, you know,

it is considered non-toxic what would the FDA think that the effect might be if

this - is there a worry that the causative agent might cause similar symptoms

in humans?

Julie Zawisza: Your question is have we stopped investigating the possibility in humans and

if it were to be found in humans what would it look like? I don't want to put

words in your...

(Frank Presthill): Specifically with Del Monte and Nestle because they produce products that do

include gluten.

Julie Zawisza: Okay.

Michael Rogers: And in your recharacterization of my statement let's clarify we're talking about

the human food supply first.

(Frank Presthill): Yes.

Michael Rogers: Second we're not aware of any leads that warrant follow up that would suggest

that it might relate to an investigation or a manufacturer that manufactures

products for human purposes. But again this is an ongoing investigation.

All along one of the objectives of the agency was to ensure the effectiveness of the recall, to conduct our inspections and investigations but certainly in an effort to notify the public and be as transparent as possible disclose the fact that we know at that time. And those are the facts that we have presently.

(Frank Presthill): Okay. Thank you.

Julie Zawisza: That was Michael Rogers. Next question.

Coordinator: Brian Hartman, NBC News.

Brian Hartman: Hi. ABC News. But thanks. I just want to make sure I've got this correct here.

So melamine is not necessarily the contaminant - the culprit in these poisonings but it is a contaminant.

It has no business being in pet food. You found it in there. And there's a good chance that it's just a market that's somehow related to whatever the poison really is. And there's a good chance that you still don't really know what the poison is. I want to make sure if I've got that correct.

And then the follow up question is, you know, the folks from PETA yesterday and earlier in the week were trying to get us and others to look at vitamin D3 as a potential culprit. And just wondering if you've looked into that at all.

Julie Zawisza: Dr. Sundlof?

Stephen Sundlof: Yes. We've looked at all the likely suspects such as vitamin D, ethylene glycol which is antifreeze, and some derivates of that diethylene glycol and propylene glycol. We've already - that was our first undertaking was to look

for the most likely suspect and compounds that might cause acute liver

disease.

And in addition to those substances I just mentioned we looked for heavy

metals such as cadmium and mercury which are very toxic to the kidneys as

well as lead and arsenic and zinc and others.

We looked for things like mold toxins, fungal toxins that are specifically toxic

to the kidneys. And in all of those cases we were unable to find anything. And

so when melamine did show up it was not - it would not have been a chemical

that we would normally have suspected as causing kidney disease.

And the limited information that's out there in the scientific literature indicates

that it's fairly non-toxic. Whether - but there is a very strong association

between the finding of melamine in the wheat gluten and the disease in those

animals all trace back to that same wheat gluten.

So our job now is going to be determine whether or not it is the melamine

itself which is the most likely suspect at this point, whether it's some other

contaminant that carried through with the melamine, whether cats and dogs

are more sensitive than the rodents that all of the literature talked about in

terms of the toxicity of melamine.

And so we'll be spending a considerable amount of time trying to understand

this with the hope that we can prevent anything like this from occurring in the

future.

Julie Zawisza:

Thank you. Next question.

Coordinator:

Mary Fergus, the Chicago Tribune.

Mary Fergus:

Yes. Hi. Thanks. I have a question that you may have explained before but I'm trying to catch up. Have you explained what Menu Foods was doing between February 20 when they first started - when I think you said they first started hearing complaints about some consumers and March 15 when they contacted the FDA?

And also do you know if Menu Foods is destroying the recalled food that they're getting?

Julie Zawisza:

Hold on a second. Michael Rogers would you like to take that one?

Michael Rogers: I think that based on the question it's probably something that should be

directly addressed with Menu so I don't want to speculate on their efforts. It's important to mention that the activities i.e. recalls and product withdrawals and notification of customers to date has all been voluntary by the firms

involved. So it might best be directed to Menu.

Julie Zawisza: What was your second question?

Coordinator: I apologize. Let me reopen up her line. One moment please.

(Mary) your line is reopened.

Mary Fergus: Thank you. I was wondering what's being done with the recalled products?

We're hearing that Menu might be destroying the recalled products. I was

wondering if they know anything about that.

David Elder:

This is David Elder. In the general course of a recall we would expect products like this that are (unintelligible) that can't really be reconditioned into good products to be destroyed.

It's the burden of the recalling company to handle the destruction appropriately to ensure all product that was removed from the market is appropriately disposed of. And in this case destruction would be the appropriate disposition. And to do so in accordance with state and federal environmental laws.

Julie Zawisza:

Thank you. Next question.

Coordinator:

Amy Birnbaum, CBS.

Amy Birnbaum: Hi. Thanks for taking my call. Back to the melamine could you discuss a little bit what - how much was found in product in kidneys, in urine of the - that the labs tested and if that has any impact in terms of what available - or I guess it's fairly scanty literature on the effects of melamine?

Stephen Sundlof: Okay this is Steve Sundlof. I'll try and answer that. There hasn't been any quantitative evaluation of the amount of melamine in the urine or kidneys of cats just the fact that it is there. So at this point we don't have any quantitative information on that.

> But in the wheat gluten itself we found in some cases very high concentration of melamine. I think the highest one so far has been 6.6% and that's a lot. That means that, you know, getting close to - between 5% and 10% of the product that was sold as wheat gluten was in effect melamine. That's a lot.

Now take that into consideration. But also take into consideration that the amount of wheat gluten actually used in the manufacture of pet food is relatively small - 5% or less.

So we have a high concentration in the wheat gluten - at least in some of the lots of wheat gluten that were analyzed. But it represents a small portion of the pet food. And then trying to extrapolate that into what animals - dogs and cats might actually receive in the diet it generally comes to a number that's less than what is reported in the scientific literature as being toxic to rats and mice.

Julie Zawisza: Thank you. Next question.

Coordinator: Barry Muller, Gannett.

Barry Muller: Hi. I want to get a little more information on something that Dr. Sundlof said

twice and maybe I just don't understand how these investigations are done. And Dr. Sundlof you said -- I'm paraphrasing here -- that all these cases track melamine. That there's a strong association. There's melamine in the wheat gluten and the diseases in those animals all trace back to wheat gluten.

You've only got a pool a 14 animals. Is that a - how can you make a statement that this is all related to wheat gluten if you only have 14 subjects that you have investigated closely to confirm the connection?

Stephen Sundlof: Well we are relying on those numbers - those 14. We are also analyzing other products - other wheat gluten for the presence of melamine. And again everything to date seems to point back to that one company's wheat gluten containing melamine.

Barry Muller:

So without -- if you'll allow me a follow up -- without investigating dozens or hundreds of other dead pets you can't or you can conclusively say that they were killed by wheat gluten and melamine.

Stephen Sundlof: Well we can't say conclusively anything at this point. But it is the strongest association that we have to date. And we have found no other - evidence that points to any other product except the ones that we're talking about right now.

> As I indicated earlier we are looking at dry pet foods to determine whether or not that might be affected. So far we've not found any melamine in the dry pet food with the one exception of the cat food that was recalled.

But other than that it still seems to be the very strongest link. So we are pursuing that route of investigation. If we find out in the course of this investigation that there's evidence there may be something else involved we will adjust accordingly.

Julie Zawisza:

Thank you. Next question.

Coordinator:

Sandra Eckstein, Atlanta Journal Constitution.

Sandra Eckstein: Hi. Thanks for taking the call. I just wanted to double check. So you have accounted for all 792 metric tons of the wheat gluten that was imported by Nutricam.

> And also Dr. Sundlof if you could just - you've said that you've gotten 12,000 calls which is more than 2 times the number of complaints is that on pet foods or all across FDA compliance?

Stephen Sundlof: I'll answer the second part. That's of all FDA complaints. So in the last three weeks we've had as many complaints as we would normally receive in two years for all of FDA's regulated products.

> And I'll ask Mr. Rogers to respond to the first part of the question about the total number of pounds of wheat gluten that we have accounted for.

Michael Rogers: Okay I'm not going to attempt to reconcile all of the supposed tons or bags or quantity of products that may be reported coming into the country. I think the headline is the agency as part of its follow up investigation and inspections and interacting with the firms has identified the source of the materials, the initial import of record as well as where all the subsequent (unintelligible) reside

> And we have visited either conducting inspections or investigations in each of the firms that received some of the suspect product. And we have outcomes associated with those inspections and investigations. Presently we're not following up on any lead of a firm that directly received suspect product from the suspect manufacturer in China.

Julie Zawisza:

Thank you. Next question.

Coordinator:

(Curtis) (unintelligible) of Star Newspaper.

(Curtis):

Hi. Yes could you confirm your investigation with the Chinese government authorities? Do I understand it right that you've asked the Chinese government to help with the investigation? Just wonder what the cooperation is there and whether you've been able to have your investigators inspect that plant in China personally.

And the second question relates to the Canadian - does the Canadian situation mimic what's going on in the states pretty well?

Michael Rogers: Let's go last first. I'm not aware of the Canadian follow up. So someone else may want to address that. I can tell you that we've been in close contact with the agency's office of international programs who has reached out to the Chinese embassy as well as ultimately to the Chinese government.

> One should certainly recognize that different from a domestic firm in the U.S. there are challenges with respect to FDA's authority for firms in foreign arenas. And so our follow up efforts certainly require a formal process to interact with the Chinese government.

Having said that we fully expect that the Chinese government will cooperate and will assist in our further investigation and understanding about this particular Chinese supplier.

Julie Zawisza:

That was Michael Rogers. Next question please.

Coordinator:

Cindy Wolff, The Commercial Appeal.

Cindy Wolff:

Hi. I was wondering since veterinarians are on the front line of this and I've been getting lots of calls from pet owners and vets is there no way to gather information from the veterinarians and use them as a legitimate source of - to confirm numbers of illness or death and set up some sort of protocol for them to report to you and have them on the front line?

Because 14 is such a low number compared to what I just have anecdotally here in my city alone. And it just seems strange to report such a low number when there is other numbers available. And I was wondering when that might be elevated - that number or updated?

Stephen Sundlof: Okay. Yes we are working with a number of sources. There are two main ones that I indicated in my opening statements. The first is Banfield Pet Hospital.

This is a network of veterinary hospitals that span throughout the United States.

They maintain in a single database all of the medical records for all of the animals that they see throughout the country. And this represents I think it's somewhere on the order of about 6% of all veterinary visits are to these Banfield Hospitals. So it's a substantial database.

The other one that we are working with is called the Veterinary Information Network. And in that system veterinarians can call into the Veterinary Information Network and report suspect cases. And they have been doing that. So we are seeing lots of different numbers from different places.

There are some limitations to all this obviously. With the Veterinary Information Network there's not a consistent kind of reporting because veterinarians, you know, just call in and basically report what they have. With the Banfield data it's a very structured database so we have all of the same information on each case.

One of the things that we don't have is whether or not in many cases there was - the recalled pet food was associated with that. And in fact the Banfield Company has decided to put additional fields in their database to allow veterinarians to input that information.

So we're working with those groups. We're working with the information - the 12,000 calls that we've had in trying to sort all of that information out and come up with a final number. But again that is some ways off.

Julie Zawisza: Thank you. That was Dr. Sundlof. Operator we have time for just one or two

more questions.

Coordinator: Thank you. Diane Lade, Sun Sentinel your line is open.

Diane Lade: Yes. Hey good afternoon. I have one quick clarification and then a question.

My clarification is I know - in the past I've also heard 16 confirmed cases versus the 14. Wanted to know if indeed it is 14. And if it is 14 how many of

those are cats?

Stephen Sundlof: We think it's 16. I think our official number is 16. Again this is a number that

we recognize is nowhere near the reality and that there are many, many more

animals that have been affected.

Julie Zawisza: I just want to make sure people do understand and appreciate what it would

take. Dr. Sundlof talked through the criteria that we're developing that we

would have to use to establish cause and effect if you will and why that's labor

intensive, takes a long time, and it's not easy to do, and in some cases can't be

done because we don't have all the parts - everything that we would need to

sort of connect those dots.

And I don't know if you want to repeat that again but it seems like this keeps coming up that we don't have a good number. And we don't. But there is a

good reason why we don't which is what you described earlier.

Okay. Next question. Actually this will be our final question for the afternoon. Please?

Coordinator:

Wendy Dager, Ventura County Star.

Wendy Dager:

Hi. This question was somewhat asked but on a broader scale how is it possible for the FDA to monitor raw ingredients in pet food if those ingredients originate from a country that's outside the U.S.?

Stephen Sundlof: Well just like most products that come into the United States from foreign ports the suppliers are generally required by the buyers to produce some certificate that indicates that the product contains certain properties or information.

> For instance in the case of wheat gluten these products come in with a laboratory analysis certificate that indicates that they've been tested for a number of different things such as protein and fat and carbohydrates and those kinds of things as well as for any toxic substances that may have entered into like pesticides and mold toxins and those kinds of things.

> And in this case the importing company ChemNutra did receive certificates of analysis that indicated that the product was free of these substances when in fact it wasn't.

> So with the millions of imports that come into the United States every year the systems that are generally used are those in which the suppliers certify to the importers that their products meet certain standards.

We require that all products coming into the United States be declared. And we have the authority and through the bio terrorism act we require that they notify us within a fixed time period before those ever enter the United States.

So we have better control over those than we did a few years ago. But again it is largely the responsibility of the importer to ensure that those products are safe. And if they are found to be unsafe then the FDA gets involved in making sure that those products are removed from the market.

Julie Zawisza: Thank you. We have time for one more question. We have about one minute.

Coordinator: Thank you. Bo Petersen, Boston Carrier.

Bo Peterson: Thank you. Gentlemen two things kind of related the recall this afternoon going to extend the biscuits. And wondering what kind of percentage of the pet treats the biscuits was going to be involved in this thing. And second if

you've all but ruled out dry food how did biscuits get in this recall?

Stephen Sundlof: The answer to your first question is I don't know. I don't what percentage of the dog biscuit market this new recall will affect. What we did in this case was we traced the wheat gluten to that particular manufacturer and found that that manufacturer had used the affected wheat gluten in producing dog biscuits.

Similarly we traced the affected wheat gluten to another plant that made prescription diets for cats. And so this is not the first dry product that has been involved. There is on the recall list a dry cat food that was recalled as well for the exact same reason.

Julie Zawisza:

Thank you Dr. Sundlof. Ladies and gentlemen at this time I would like to conclude this briefing and would like to thank our speakers Dr. Sundlof, Michael Rogers, Captain Elder, and thank all of you for joining us today.

Also I'd like to thank pet owners around the country who have submitted information and called our complaint line and the veterinarians and the state and local governments and associations and authorities that are working with FDA and with industry to help us on this investigation.

We will put something on our website later this afternoon summarizing essentially what was discussed this afternoon so you may like to check that. We invite you to check our website periodically any way for updates. And if you need to listen to this call again it will be available on replay in about two hours.

With that we will conclude and have a pleasant afternoon.

**END**