

Transcript of FDA Press Conference on Cloning Risk Assessment – Afternoon Media Telecon

**Moderator: Julie Zawisza
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Julie Zawisza: Good afternoon and welcome. I'm Julie Zawisza, Assistant Commissioner for Public Affairs with the Food and Drug Administration.

Understand that we had a lot of technical difficulties on our 12:00 briefing. We apologize, too, for that and hence we're having this call now so that you have an opportunity to hear our speaker's remarks and an opportunity to ask questions.

Today we're discussing FDA's release of three documents on animal cloning for agricultural purposes and we have three individuals here today who will provide remarks – make remarks.

Randall Lutter, Deputy Commissioner for Policy with FDA, Dr. Stephen Sundlof, Director of FDA's Center for Food Safety and Applied Nutrition and Mr. Bruce Knight, Undersecretary for Marketing and Regulatory Programs with the U.S. Department of Agriculture.

And we also have with us Dr. Bernadette Dunham who is the Director of FDA Center for Veterinary Medicine, newly appointed on January 7th.

And then we have some other folks here who'll ask – who'll take questions later in this briefing.

At this time I'd like to turn it over to Dr. Randall Lutter. Dr. Lutter.

Randall Lutter: Thank you very much. Good afternoon. Today we're releasing three final documents on animal cloning for agricultural purposes – the risk assessment, the risk management plan and a guidance for industry.

After years of detailed studied analysis, the Food and Drug Administration has concluded that meat and milk from clones of cattle, swine and goats and the offspring of clones from any species traditionally consumed as food are as safe to eat as food from conventionally bred animals.

All of these documents as well as others that help explain cloning are the results of our peer review and others that we'll talk about a bit later are available on our Web site.

FDA's mission is to protect the health of the American public and to use the best available science to make sure this happens.

In our work related to food and feed, we often use risk assessments to determine whether new substances or technologies pose any unique risks to people or animals.

This is an exhaustive process. It includes evaluating peer review research, primary research, seeking evidence of guidance from scientists in academia, the National Academy of Sciences and other

sciences involved in this area as well as seeking feedback from members of the public and industry.

From this process, the FDA makes a decision based on the best available scientific evidence. FDA is not recommending any additional measures be applied to the food or feed derived from these specified animals because foods derived from these clones is no different from conventionally bred animals.

In other words, the risk assessment concludes the meat and milk from cattle, swine, and goat clones are as safe to eat as the food we eat everyday. These conclusions are in broad agreement with conclusions of the New Zealand Food Safety Authority and the conclusions in the European Food Safety Authority's draft opinion for (common) and the 2002 report of the United States National Academy of Sciences.

At this time the FDA does not have sufficient information to make a decision on food consumption risks from clones and species other than cattle, swine and goats and so we continue to recommend edible products from sheep clones or other species not be introduced into the human food supply.

Now I'd like to turn this over to my colleague, Dr. Stephen Sundlof, who was the Director of the Center for Veterinary Medicine during the time that this assessment was performed.

Earlier this month he became the Director for the FDA's Center for Food Safety and Applied Nutrition. Dr. Sundlof.

Stephen Sundlof: Thank you Randy. Now turning to the specifics of the animal cloning for agricultural purposes, because clones will primarily be used for breeding, they are not expected to enter the food supply in any significant numbers.

Clones will be used in the same way as other lead breeding animals are. In other words, the risk assessment concludes the meat and milk from cattle, swine, and goat clones are as safe to eat as the food we eat every day. (Recording missed words. Inserted from prepared opening remarks)

The FDA is not recommending any additional measures such as labeling for foods from these animals if companies wish to market them.

In general, FDA requires specific food labeling if there are safety concerns that labeling could adequately address or if there is a material difference in the composition of the food.

However, based on an extensive review of the scientific information, FDA scientists have determined that no material difference exists between food from clones of cattle, swine and goats or the sexually reproduced offspring of clones and food from any conventionally bred animals, and therefore cause no additional safety concerns.

These three final documents were originally released in draft form in December, 2006. Since that time, the risk assessment has been updated to include new scientific information that reinforces the food safety conclusion of the drafts, which were based on an extensive multi-year review of all the publicly available on clones, their offspring and food from these animals.

We also collected comments from the public that were submitted to the FDA dockets. More than 30,500 comment were received, many of them which has multiple signatures.

Let me just say a few words about the comments themselves. Each comment was carefully reviewed by a member of our scientific staff. In many cases, we found (some of) the recommendations or concerns expressed in them helpful to us as we updated the risk assessment.

Many pointed us to additional references and some indicated places in which we could improve the clarity of our presentations.

We have prepared a summary of these subsequent comments as well as our responses to them and we posted these – the summary and our responses – on our Web site for all to see.

We understand that some members of the public may have strong opinions about animal cloning for agricultural purposes. The FDA's mandate, however, is to make science based decisions based on data and the American public counts on that.

We take our commitment to ensure food safety very seriously and will not stop our review of animal cloning with the release of these documents.

We will continue to monitor the technology and if we see anything that causes us to have concerns about the safety of the food supply from these animals, we will take the appropriate action.

We further recognize and respect that although some people may accept the science, they do not feel comfortable with our decision.

Finally with regard to animal care, I'm proud to say that the FDA has taken a leadership role in developing a set of animal care standards for clones that are designed to provide clone producers with the information to help minimize the potential for adverse outcomes in these animals.

These standards will be released by the sponsoring organization, the International Embryo Transfer Society, some time in 2008.

And with that, I will turn it over to Bruce Knight, the United States Department of Agriculture's Undersecretary for Marketing and Regulatory Programs to discuss important efforts that USDA is undertaking. Undersecretary Knight.

Bruce Knight: That you Dr. Sundlof. Good morning to the participants on this phone conference.

The USDA fully supports and agrees with FDA's final assessment that meat and milk from cattle, swine and goat clones poses no safety concerns and these products are not different than food from traditionally bred animals.

Now that FDA has evaluated the scientific data and public comments and issued its final risk assessment, USDA will join with the technology providers, producers, processors, retailers and domestic and international customers to facilitate the orderly market of meat and milk from clones.

We'll be working closely with stakeholders to ensure a smooth and seamless transition into the marketplace for these products. At the same time, we understand that there are currently only about 600 animal clones in the United States and most of these are breeding animals, so few clones will ever arrive in the marketplace.

Further, USDA has encouraged technology providers to maintain their voluntary moratorium on sending milk and meat from animal clones into the food supply during this transition time.

Many farmers and ranchers routinely use other assisted reproductive technologies such as artificial insemination, embryo transfer and in vitro fertilization to produce superior animals for milk, meat and breeding purposes.

Cloning is another breeding technique that has evolved and has now been demonstrated to be safe. It is helpful in creating genetic twins of the very best animals who can transmit superior characteristics and genetics to their offspring and quickly improve a herd.

In conjunction with FDA, USDA will also be implementing the report language contained in the 2008 omnibus appropriation bill, suggesting that we study domestic agriculture and international trade economic implications of commercializing milk and meat from animal clones.

Thank you very much.

Julie Zawisza: Thank you Undersecretary Knight and thank you Dr. Lutter and Dr. Sundlof. Ladies and gentlemen, before we begin the question and answers for the segment of this briefing, I'd like to introduce several

other FDA officials who are around the table with us. They're here to provide technical expertise and available for questions.

Dr. Larisa Rudenko who is our Senior Advisor for Biotechnology at FDA. Dr. Adele Turzillo, an animal physiologist with FDA's Center for Veterinary Medicine, and Dr. Eric Flamm, a Senior Policy Analyst Advisor for FDA.

And before we begin the questions, I'd like to ask Dr. Rudenko to address a question that we weren't able to answer, didn't have time for on the 12:00 briefing which is on ethics and animal welfare. Could you take that Dr. Rudenko?

Larisa Rudenko: Sure. I think the question that was put forward was whether or not the FDA was doing anything at all about ethics in cloning. And I want to reiterate Dr. Sundlof's comments a little bit earlier that we care very much about the health of these animals and animal care.

And because of that we've been working extensively with a group of international scientists, veterinarians and other folks who are primarily interested in animal care and husbandry to develop a set of care standards for animals involved in the cloning process including guidelines on what to do if you detect early problems so that the animals don't experience undue discomfort and suffering.

Those guidelines or recommendations will be published by the International Embryo Transfer Society, the professional scientific group that's been responsible for coordinating those a little bit later this year and will be posted on their Website.

Julie Zawisza: Okay, thank you very much. In one moment we're going to go to the phone. I just would like to remind you all that there are a number of people on the phone so please limit yourself to one question and a follow up. State your name and affiliation.

And for those of you who attended the 12:00 briefing, please hold your questions so that others who are on the phone who weren't able to ask questions earlier now can.

Thank you and let's take the first question.

Coordinator: First question is from Andrew Martin, the New York Times.

Julie Zawisza: Hi Andrew.

Andrew Martin: Hi, how are you? I'm totally confused by the request that this voluntary moratorium continue. I'm – given that, what exactly happened today and why – can you explain again why you're asking for this moratorium to continue?

Julie Zawisza: Undersecretary.

Bruce Knight: From the perspective of the Department of Agriculture, we had heard soundly some aspects of agriculture both domestically and internationally about a need for time to go through the transition period making sure that the food and fiber that we produce in the United States, which is the most wholesome in the world, that folks have the time to assess the risk assessment, the implications of that as they look at what are the opportunities that may be out there for meat and milk and other products that may result from cloning technology in the

future. This is simply allowing the time for that orderly transition to occur.

Andrew Martin: So I mean this – this report today isn't significantly different from the one a year ago. Haven't we already had plenty of time to sort of think about this?

Bruce Knight: Well I'm going to defer to the folks from FDA to respond to the outcome of today's risk assessment which is significant as to the response to your question.

Larisa Rudenko: Yes, thanks for that. You know, part of our process – as part of our process, we vowed that we would be as transparent as possible with the American public with respect to how we handle the risk assessment.

You saw a draft about a year ago, published in December, 2008, which we then had a public comm – 2006, I'm sorry – on which we had a public comment period.

We had lots and lots of comments. Some of those of those were substantial and very, very helpful to us. We updated the risk assessment. And now what we're doing is publishing the final risk assessment. In the past what you saw was the draft.

So there's been a little over a year for everybody to understand what happened in the draft and now we've published our final conclusions on this.

Andrew Martin: Okay but, I mean, from my perspective, the FDA said three times that food from cloning is safe in various ways, or draft, tentative, now it's final and three times they've asked for a voluntary moratorium. And I'm still totally confused by your asking to extend it.

Larisa Rudenko: The first time we asked, it was – when we first met with folks in the late 1990s who were cloning, we asked them not to put food from clones into the food supply until we had a chance to complete an assessment.

At that time, we asked the National Academy of Sciences to help us define what the science based concerns were. We then followed up on that with a very rigorous draft risk assessment during which time we asked again for folks not to put food from clones into the food supply.

And now that we've issued a final risk assessment, we have no further safety concerns about food from the three species that we specified or the (prodigy).

What we're doing right now, and I'll pass you back to Mr. Knight, is to work with USDA to make sure that we address some of the non-science based concerns that come more from marketing issues or public concerns so that we are addressing all of the needs of the public at this time.

Andrew Martin: The USDA perspective is quite simply to assist folks in the orderly market transition that is now before us now that the FDA has come to scientific conclusions on the safety of cloned products in food supply.

Julie Zawisza: Thank you. That was Undersecretary Knight and then Dr. Larisa Rudenko and then it was back to Dr. – to Mr. Knight. Next question please.

Coordinator: Next question is from Rick White from Washington Post.

Julie Zawisza: Rick, go ahead.

Rick White: Hi, thank you. First to Dr. Sundlof please. You know, the FDA has been clear that it's not going to demand labeling on this because you don't believe in asking for labeling if you don't think there's any safety concern or difference.

So along the same lines, can you tell me plainly whether the FDA supports the call for an ongoing voluntary moratorium or is this an Agriculture Department move?

Stephen Sundlof: From the FDA standpoint, we have no further safety concerns. That was the reason that we asked for a voluntary moratorium so we could fully evaluate the safety of this technology as it applies to food.

We've come to that conclusion. We are aware that there are concerns about transitioning this technology into the market and I believe that as Undersecretary Knight has just indicated that that is the primary reason that the USDA is working with the technology providers on this voluntary moratorium.

Rick White: But just to be clear, you're saying the USDA is doing that. So this – the ongoing voluntary moratorium, it sounds to me, like is now being called for by the USDA not by the FDA.

Bruce Knight: This is Bruce Knight. That is correct. We have encouraged the technology providers to continue their voluntary moratorium.

Rick White: And as a follow up to either one of you, I was just talking today to a cattle raiser who's been selling his semen from clones for quite a while now and suggested that he knows a lot of other people who are doing the same.

Can either of you give me any sense of the extent to which you think the voluntary moratorium has been effective to date?

Randall Lutter: This is Randy Lutter. Let me offer one preliminary comment on that and that is it's important in thinking about the effectiveness of a voluntary moratorium, the bottom line of our findings here, and that is with respect to food products for the three species – cattle, swine and goats – they are as safe as other foods that people have already been consuming and the same is true for progeny of all species.

So in that sense, from a safety perspective, our findings today is that there're not safety concerns posed by these products.

With respect to the voluntary moratorium, I don't think FDA has ever received any specific information about compliance or non-compliance apart from press reports that have surfaced from time to time.

Julie Zawisza: Thank you Dr. Lutter. Let's take the next question.

Coordinator: Next question is from Luran Neergaard of the Associated Press.

Julie Zawisza: Lauran, go ahead. Lauran Neergaard?

Lauran Neergaard: Hello, can you hear me now? Okay. Have the manufacturers actually agreed to continue the moratorium? Have they told you that they will?

Bruce Knight: This is Undersecretary Knight. We have been in contact with the three companies in the United States that are active in cloning and have encouraged them to continue the moratorium as have sectors of the agriculture production processing value chain encouraging them to continue with the moratorium.

Many – several of those companies more recently announced on their own, a tracking system in order to be able to make sure that each and every cloned animal is identified and is able to be tracked as it moves through its natural life.

And so we are anticipating a very favorable reply from the sector on continuing the voluntary moratorium.

Lauran Neergaard: Okay, so you just asked them and they haven't had a chance to reply. Is that basically it?

Bruce Knight: We have not received an official reply from them.

Lauran Neergaard: Okay, how long – I mean, you all have been asked this a couple of times now and you've not given an actual answer – how long do you anticipate this transition period to need to take? And I know you can't be too specific, but are we talking weeks, months, years?

Bruce Knight: And I believe, Luran, you may have heard, I made reference to some of the natural biological processes that are out there as these animals mature and that we have to keep an eye on those things.

I, of course, will be doing everything we can to have this transition period be orderly and would certainly have a personal goal of having it be over in months rather than years.

Julie Zawisza: Thank you. Let's take the next question.

Coordinator: Next question's from Marian Falco at CNN.

Marian Falco: Hi there. Thanks for doing this. It was extremely frustrating not to be able to ask during the original press conference.

The question that some folks have is, given – you say everything is safe, which is comforting, but what if we discovered there is a problem with cloned food?

After it's in the food supply and it's not labeled, the FDA won't be able to recall it like it did Vioxx, for instance.

The food would already be tainted. So, I mean, what happens if down the line something pops up?

Julie Zawisza: I'm going to ask Dr. Sundlof to answer that and then turn that over to Dr. Dunham.

Stephen Sundlof: Thanks. Well first of all, this – we've done a very extensive job of reviewing anything that could possibly result in the food safety hazard, and to be quite honest with you, we found nothing in the food that could potentially be hazardous.

They – the food in every respect is indistinguishable from food from any other animal so it is beyond our imagination to even find a theory that would cause the food to be unsafe.

So the likelihood that anything would go wrong from a food safety standpoint is unimaginably small. However, this is a technology that is developing. We haven't seen the last iteration and I'm going to ask Dr. Dunham, who's now the Director of the Center for Veterinary Medicine to respond on what the Center for Veterinary Medicine will be doing in the future.

Bernadette Dunham: Thank you, Dr. Sundlof. Yes, with the scientists that we have and the evaluations of everything to date that led to the risk assessment, we will continue to do just that to be able to evaluate any modifications in the science technology of this process.

And with that, if we do find anything, we would immediately continue to share that with our counterparts, in this case, USDA, and the public.

Marian Falco: But how would you get it out of the market? It's not like pulling a drug off the shelves. What if somebody had consumed something already and then you find out there were – was – a problem?

Bernadette Dunham: In the case right now with our progeny that you're looking at, we have already shown indications that everything in those tissues is the same as what you're seeing with our natural conceived animals.

And we would then refer, as you would to any animal that has an adverse reaction to something right now, and we would make an announcement to have that pulled.

Marian Falco: But I'm thinking back to Mad Cow, sometimes it can be very difficult to track down these cattle or these progenies, so is the system fool proof?

Bernadette Dunham: I would say with our track record that we have right now of making sure we do keep any animal from which you're going to have a human food product generated, our monitoring of that -- from production all the way through to processing to then go to market -- has really been tremendous.

And the safety of our food supply as we've known it in the United States has been just that. I think everybody works together and we do exchange open communication and transparency.

I do believe that we would be able to respond if we did see anything of an adverse nature.

Julie Zawisza: Thank you Dr. Dunham and Dr. Sundlof. Let's take the next question.

Coordinator: Jane Zhang, Wall Street Journal.

Jane Zhang: Hi, thanks for taking my call. I have two questions. The first one is that -- a follow up on an earlier question, do you have any evidence at all

that, you know, the products from current animals are not already in the food supply, I think, you know, you said earlier that FDA hasn't received any compliance or non-compliance to report, but are they supposed to report compliance or non-compliance to the FDA?

Stephen Sundlof: This is Dr. Sundlof. Just to recall, it is a voluntary moratorium. We've asked producers, there are only a few tech – a few companies that actually produce this technology. We work very closely with them. We've been working with everybody that's been involved in this technology so we think we have a pretty good indication that food from these clones, at least to our knowledge, has not been introduced into the food supply.

Remember also that there are probably some 30 million cattle that are processed every year. There're only around 375-some cattle, period, that are cloned. So even if that was to occur, the numbers would be extremely, extremely small compared to the entire food supply.

Julie Zawisza: Thank you.

Jane Zhang: I have a second question.

Julie Zawisza: I'm sorry, Jane, go ahead.

Jane Zhang: What do you think, you know, this analysis – what do you think it's impact will be on trade, especially talks with the E.U. or Japan?

Bruce Knight: This is Undersecretary Knight. This is one of the reasons why we had asked for the voluntary moratorium, to allow time for our partners around the globe to complete their own risk assessments, to make

their own policy, guidance, decisions and determinations on the utilization of the products of cloning in their own countries as well as the movement of the products of cloning in the international trade arena.

We're very cognizant that we have a global environment as it pertains to the movement of agricultural products and have to be very sensitive to those acceptances as we move forward.

And that's why we're looking forward to working with our customers, both domestically and abroad on the next steps on the acceptance and adoption of these products.

Julie Zawisza: Thank you. We have time for one final question.

Coordinator: There are no other questions at this time.

Julie Zawisza: Okay, ladies and gentlemen, that concludes today's briefing. And I'd like to thank you for joining us and my – our sincere and deepest apologies for all the problems. We appreciate your patience here with the technical difficulties.

I'd like to thank our speakers, Dr. Lutter, Dr. Sundlof, Dr. Dunham, Dr. Rudenko and Undersecretary Knight, and let you know that we are not doing follow up interviews, so if you have any outstanding questions that we weren't able to cover today, please call the press office at FDA at 301-827-6242.

And please check our Web site. We have a number of documents on the Web site that are very informational and will be helpful to you.

Thanks again for your participation and have a pleasant afternoon.

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