

Transcript of FDA Press Conference on FDA Announcement on Final Cloning Risk Assessment

**Moderator: Kimberly Rawlings
January 15, 2008
11:00 am CT**

(NOTE: Because of transmission issues, the Opening Remarks are not included in this transcript.

They are located in the 1 p.m. media telecon transcript)

Ms Zawisza: Thank you Under Secretary Knight, and thank you Dr. Lutter and Dr. Sundlof. Ladies and gentlemen at this time we'll open it up to your questions but before we begin a few things.

We have as I've mentioned we have technical experts in the front row and I'd like to introduce them now. Dr. Larisa Rudenko is Senior Advisor for Biotechnology with FDA Center for Veterinary Medicine. Dr. Adele Truzillo is an animal physiologist with FDA Center for Veterinary Medicine and Dr. Eric Flamm is a Senior Policy Advisor for the FDA.

And when we call on you we have folks with handheld mics, when we call on you please keep in mind that there are folks listening on the phones so please speak directly into the microphone and state your name and affiliation.

Okay, let's take the first question, gentleman on the, on my right.

(Phil Brasher): (Phil Brasher) with the Des Moines Register, I don't know if this question is for Bruce or someone else, but could you go and describe

this transition time in which this vol -- do you want this voluntary moratorium to continue, how long is going to be, what its transition time going to consist of?

Bruce Knight: The voluntary moratorium as it stands today is an industry lead effort that resolved out of the initial time that FDA requested to be able to move forward. We will be convening the industry leaders as well as expanding the universe of folks to talk about what are the concerns that folks have, what are the steps that are needed in order to be able to move forward.

And it's very important to keep in mind that this moratorium is being, we've requested that the industry continue with it as an aspect of allowing the marketplace to adjust.

And this is about market acceptance because with the FDA announcement, the food safety issues have been resolved.

Ms Zawisza: Question? Yes, sir, can we get a mic over there please.

Dennis Powell: Hi, Dennis Powell with ABC News, this is for I assume Dr. Sundlof. Dr. Sundlof, you've said that there are very strong opinions about the use of cloned meat and dairy, yet in the same breath you've said that you're not going to ask for labeling of this meat. Why not?

Stephen Sundlof: Thank you, as I said in my opening remarks that the FDA does not require labeling if there is no food safety issues, that labeling would provide information to the consumer that would be helpful in making their determination.

(TRANSMISSION ISSUES)

Bruce Knight: Sounds good, will now have a debate within themselves whether or not to offer consumer lead or commercially lead labeling alternatives.

But that's their choice that's out there much as has already been raised in the previous instance with milk.

We have a very robust system in the United States where when the consumers request a particular thing that the industry is able to respond and provide in a common sense way the ability to respond and provide them that which they are demanding.

And it doesn't necessitate a regulatory intervention.

Man: Do you have any indication how long the moratorium, the voluntary moratorium would continue, how long the producers want it to continue?

Bruce Knight: We need to be working with the industry, with the consumers bringing them to the table to work through that and from that will evolve quite naturally the length of time that will be necessary for the moratorium.

Ms Zawisza: Thank you, for those on the phone that was Under Secretary Knight on the last two questions and before that Dr. Lutter.

Next question, let's see, who haven't we gotten yet, Val.

Val Willingham: Val Willingham from CNN. In these focus groups there were three things that the public were most interested in. Safety, which you've

already addressed, (ethically), which you haven't addressed, and the price.

If you go into organic food, organic food is more expensive. What is this going to mean to the consumer when it comes to pricing?

Ms Zawisza: Dr. Sundlof will take that.

Stephen Sundlof: My recollection of the focus groups, and we did conduct focus groups, there have been a number of different focus groups that have addressed this very issue.

And just let me tell you what my summary of all of those are including ours, is that when you ask people how they feel about this technology, there's about a third of the people that you ask say that under no conditions would I want to consume food from animal clones.

About a third said they had no concerns about that at all, and another third were in this middle range where they were movable in their opinions if they thought that they had good information that would allay some of their concerns about, primarily about food safety.

We certainly did receive a lot of feedback indicating that people were uncomfortable with it, whether it's from an ethical standpoint or just something about it didn't feel right.

We hope that the information that we're providing through this risk assessment and other documents will help allay some of those concerns as well.

But that's kind of the overall lay of the land in terms of all the surveys that have been done, pretty much have reached those similar conclusions.

Val Willingham: I have a question, is it going to be more expensive because these cloned animals are very expensive.

Stephen Sundlof: The whole purpose I think of introducing cloned animals into a herd is to improve the overall value of the herd itself so that they produce higher quality products, higher quality meats, higher quality milk.

Those may in fact garner some premium prices, I don't know about that, but certainly the technology has been traditional in agriculture as agricultural technology improves, generally the prices go down.

Ms Zawisza: Next question please?

(Iguchi): Hi, my name is (Iguchi), I am a reporter with a (digibus) Japanese news reporter. How do you know sir that the US government is now negotiating with many trading (personnels) like Japan or other Asian nations, so in order to open up their beef market, so my question is so do you think that today's decision to impact on that this is an (international) trade negotiation?

Bruce Knight: Today's decisions should have no effect on the international trade negotiations on reopening the market with Japan, that had to do with a different set of health issues.

As an aside however, we have tapped into experts around the globe from France to Japan on the safety and the soundness and, of this technology.

Ms Zawisza: Thank you, that was Under Secretary Knight. We have time for just a couple more questions, is there anyone who I haven't called on yet?

Okay, let's go to the gentleman in the back and then the front.

Man: Hi, thanks again. This is probably for Mr. Knight, once you do achieve your transition of products into the marketplace, what products or what product areas do you expect would be the first where these products might show up, the cloned products might show up?

Bruce Knight: I'm very hesitant to outcome, to prejudge the outcome of the work with the consumers and with the industry and farmers and processors as you go forth with this.

However, as you look at the data on cloning, you will see that the largest number of clones, there's about, only about 600 in the entire United States today, I think 570 of those are cattle.

And so you could assume quite logically from that at the rate of adoption that that would be the first places where people would be looking at the acceptance of these new (unintelligible) products.

Ms Zawisza: Thank you, question in the front. Do you still have a question sir?
Okay.

(Phil Brasher): Again from the Des Moines Register. I've got a follow up question for Bruce, two questions actually. Is there, as a producer yourself, is there any possible consumer advantage to these products in terms of the quality or cost from products that are produced, from animals that have been cloned?

And just a second question, this is more of a scientific question, is there any way to test the meat or milk from animals who, or offspring of clones to verify whether they have or whether they have not been produced from clones?

Bruce Knight: The, first off is, fellow had asked about for a producer what would be the potential advantage and then on to the customers. This is one of the exciting things about the advancement of this technology is what it can do.

I've been ranching for well over 20 years and in that time, building the genetics in my particular herd for palatability, cutability, for the health of that particular product to meet a consumer demand.

Assisted reproductive technology in my case what I've used primarily is artificial insemination, allows one to be able to take the best genetics and be able to do those.

The other case where you're going to see a farmer or rancher want to utilize this is if they want to save a particular genetic line that is nearing its natural life.

You know and I think about one of the best bulls I ever had on my ranch that was injured in the middle of the breeding season, in a fight with the other bulls.

And this is the kind of example where this assisted reproductive technology will allow farmers and ranchers to be able to preserve a particular genetic line that may in the long run provide benefits to the consuming public as well.

I'm going to let the remainder of the question go to FDA.

Stephen Sundlof: Thank you, the question was would it be possible to detect the food from an animal who's the progenitor was a clone, and the answer is no. These animals are indistinguishable, both the animal and any food produced from those animals is absolutely indistinguishable from any other food source.

Because there's nothing new added, and so there is no technological way of distinguishing the food as being from an animal that had a clone in its ancestry, it's not possible.

Ms Zawisza: That was Under Secretary Knight and then Dr. Sundlof. Question in the center there, on the end of the row.

Ms Zawisza: (Try) to address this, but I, but you talked about a process that has to go forward now with consumer groups and producers, all of those things but can you give us any idea of some kind of an expected time frame when these kinds of products might show up on grocery, in grocery stores?

What you reasonably think this kind of process might take, what time?

Bruce Knight: As a farmer I learned a long time ago, there are natural time frames that guide things, and it applies equally well as a policy official. But the, as you look at the pool that's out there, about 500 to 600 animals that are out there, pregnancy in the case with cattle take about nine months.

Then growing to sexual maturity takes about two years. Then from that, those progeny would be giving birth to other calves moving through that.

And so from that time line you can see that there is a fairly natural timeline of the evolution of the genetic material that's out there.

And I will be trying to make sure as we guide this acceptance process that we're matching with that, so that there can be clear decisions for folks before the milk and meat from those animals that are already in the community reach the marketplace.

You're talking about a process that you have to match with the biological processes, and what's already out there.

Ms Zawisza: Thank you Under Secretary Knight. Are there more questions? There's another question in the back from Val. Okay.

Val Willingham: ...consumer awareness campaign after these years, are you going to say hey, cloning is now out there, is that what you're going to be telling the people or is it just going to show up?

Ms Zawisza: Could you say that again, I just want to make sure I understand that.

Val Willingham: It was a follow up to her question, is that how long will it take to bring cloning food, cloned food into the marketplace, and we're assuming years. But once those years come into months, into days, are you going to put out a public campaign letting people know the cloned food is now on their grocery shelf?

Bruce Knight: As I stated earlier, I'm not going to prejudge the outcome of this partnership that needs to emerge between consumers, interest groups and the technology providers.

However, given the emotional nature of this issue, it makes a great deal of sense to have as much transparency in the process as we possibly can. Thank you very much.

Ms Zawisza: Thank you. Do we have any questions from the phone lines yet? Not yet, okay. Getting that organized, so I'd like give people chance to ask questions on the phones if that, if they have them.

Okay, gentleman in the back.

Man: Do I understand correctly that there was something different about very young calves that gave scientists some concern and therefore it's not recommended that any food product from very young calves would included (here), did I understand that correctly?

Could someone clarify that and explain why that is?

Ms Zawisza: Dr. Sundlof.

Stephen Sundlof: Yes, generally we're talking about cattle here because cattle are the, one of the species, or the only one of the species that we see, because if we really see some early, some effects early in life on some of the animals, certainly not all of the animals.

But on some of the animals they have some developmental issues that require additional medical care, generally things like they are not able to regulate their body temperature quite as well as a normally born calf.

But we see these same kinds of problems in cattle that are bred through other assisted reproductive technologies like in-vitro fertilization and even in naturally occurring animals.

These animals outgrow this early on in their life usually within the first couple weeks to a month or so, and then are in every respect a very normal animal.

Now those animals generally would not be going into the food supply anyway, but just as animals that have the exact same problems that are produced through other reproductive technologies, there are systems in place to keep unhealthy animals out of the food supply.

And those same programs would apply to any animal that was a clone that was visibly ill or unhealthy.

Man: If I could supplement that with a couple of bits of information that may help you. Your average steer or heifer is harvested at the youngest about 14 months of age up to 25 to 30 months of age for what you'd normally buy at the grocery store as a steak or something like that.

For those folks that purchase veal, probably the youngest age of that calf would be around four months up to around six months of age so that, just so you can put in to context what the previous speaker mentioned as opposed to what's on the store shelf.

Ms Zawisza: Thank you. Pardon me, we had hoped to take some questions from the phone but we're having some technical difficulties, so I'd like to announce the teleconference line for people who would like to dial back in at one o'clock to participate in so they can hear some of the discussion and some of the presentations that were made earlier.

The number is, for domestic calls 1-800-857-1694, I repeat domestic calls 1-800-857-1694 and for international callers, 210-839-8004, that's 210-839-8004 and the pass code for both of those numbers is FDA.

At this time I'd like to conclude this briefing and thank our speakers Dr. Lutter, Dr. Sundlof, Under Secretary Knight, Dr. Dunham on stage and our technical experts in the front row Dr. Rudenko, Dr. Turzillo and Dr. Flamm.

This news conference was taped and it should be available on instant replay in about an hour, let me quickly give you those numbers if you'd like to dial in and listen to the replay, 1-866-419-8655 and 203-396-0874.

If you haven't picked up the press release grab a copy on the way out, it has those same numbers I just said and we'll have a lot of documents on our Web site if they're not already posted that you may want to check out.

We will not be doing any follow up interviews after this briefing, but if you have questions please call my office at 301-827-6242.

I'd like to thank you all for your participation, have a great afternoon.

END