"How Should the Next Administration Address Genetically Engineered Food Animals"

Forum with Industry Groups

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and Center for American Progress

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MODERATED BY:

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PANELISTS:

Scott J. Eilert, Vice President and Director, Meat Technology Department, Cargill

Michael Greger, Director, Public Health and Animal Agriculture, The Human Society of the United States

Gregory Jaffe, Director, CSPI Biotechnology Project

John Phillips, Emeritus Professor, University of Guelph and EnviroPig Developer

Michael Taylor, Research Professor of Health Policy, George Washington University

Jamie Jonker, Ph.D., Director, Regulatory Affairs, National Milk Producers Federation

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MR. JACOBSON: Good afternoon, and welcome. I am Michael Jacobson. I am the Executive Director of the Center for Science in the Public Interest, which is cosponsoring this event with the Center for American Progress.

CSPI is a non-profit consumer advocacy organization that focuses especially on food safety, nutrition, alcohol issues, and agricultural biotechnology. Most of our funding comes from the 900,000 subscribers to our Nutrition Action Health Letter.

The Center for American Progress is a non-profit think-tank here in Washington that has been more or less a caretaker of the progressive agenda over the past eight years and is very heavily involved in transition activities for the administration, though I don't know if our moderator today will let us in on any of the secrets.

It was only a dozen years ago that the first products of agricultural biotechnology were commercialized. Today, millions of farmers in the United States and throughout the world grow genetically engineered corn, soybeans, cotton, canola, and other crops on millions of acres of farmland. Overall, those crops appear to have
provided environmental benefits to our planet and economic
and health benefits to farmers. Nevertheless, those crops
are still steeped in controversy, especially in Europe, and
many potentially commercializeable engineered crops have not
been approved or planted due to that controversy.

Now a new application of genetic engineering is on
the bring of commercialization: farm animals. Numerous
companies and university researchers have engineered animals
with various traits, and with those animals come all kinds
of questions. What are the potential risks? What are the
potential benefits of genetically engineered animals, such
as the so-called "Enviropig" and, probably the most
prominent of these animals so far, the fast-growing salmon?

How should these animals be regulated? Which agencies?
How rigorous should the regulation be? How open, and how
will American consumers and our international trading
partners react to these high-tech animals and their entry
into the food supply?

As you know, the FDA recently issued a draft
guidance describing how it will regulate GE animals. Is
that guidance adequate? What should other Federal agencies,
besides the FDA, be doing to address issues surrounding
These and other issues will be discussed by our group of panelists who represent a wide variety of stakeholder perspectives.

I hope that this panel leads to a greater understanding and a more sophisticated understanding by everybody here.

To get us started, I am pleased to introduce our moderator, Rick Weiss, who will then introduce our panelists and get the discussion going.

Rick recently joined the Center for American Progress as a Senior Fellow. Before that, for 15 years, he was a science and medical writer at The Washington Post covering agricultural biotechnology, nanotechnology, and various other science and medicine-related issues, including the genomics revolution and personalized DNA testing.

So, after you have all turned off your cell phones and whatever else you have with you, let's welcome Rick Weiss to lead the discussion.

[Applause.]

MR. WEISS: Thanks, Michael.

Some watershed events get a lot of coverage. The
first black President-Elect for the United States gets a lot
of coverage. The worst economic crisis since the Depression
gets a lot of coverage. Even Virginia and North Carolina
going Democratic gets a lot of coverage. We are here today
because of a pending watershed that has not gotten a lot of
coverage, but that I think everyone up here would agree
deserves to have more of a public airing and more input from
the public.

Many of you probably recall that back in January,
the Food and Drug Administration released its final risk
assessment in which it concluded that meat and milk from
cloned farm animals was safe to eat and as a class allowing
them onto the market.

At the same time, the FDA emphasized that clones
are not genetically engineered, per se. They are procreated
in peculiar ways. They only have one parent, but once they
are born, they are a conventional animal in the FDA's view
at least, and that if the FDA were to consider allowing
truly genetically engineered animals into the food supply,
that is, animals whose DNA has been altered specifically to
change their traits, then it would require a more stringent
system for approval than that it used for clones, which are
now just under a blanket approval as a class.

Well, in September, the agency did, in fact, release its proposed guidance with regard to genetically engineered animals. It has invited public comments through November 18th, which is just over a week from today.

It is interesting to me that although the cloning proposal from FDA drew thousands of comments and actually that discussion went on for years, this proposal to allow genetically engineered animals into the food supply under certain forms of oversight by FDA has actually so far, if you look at the FDA website and the docket, they are received an order of magnitude less in the way of comments, I think more indicative of what has been going on in the world at the same time than a true measure of public interest or concern, since by many measures the introduction of genetically engineered animals into the food supply is more scientifically and potentially health and environmentally eventful than the introduction of clones. So our mission here today is to help educate the public about this interesting regulatory challenge.

Before introducing our panelists, very briefly, let me just very quickly review why these animals are being
made, what the issue is and what the FDA has proposed, for those of you who don't know.

As Michael noted, it is possible today. I won't say it is easy today, but it is getting easier all the time to introduce foreign snippets of DNA into animals to give them traits that they have never had before as a species.

Among the ones furthest along in development right now include changes in animal traits that would benefit the farmer, such as the salmon that Michael spoke of that grow much more quickly than conventional salmon; traits that would benefit the animal itself, such as cows resistant to mastitis, which is a pretty serious ailment in cows; traits that could benefit the environment, such as the Enviropig, which we will hear more about in just a few minutes because we have one of its developers here; traits that could benefit industry, goals, for example, that produce spider silk in their milk from which bulletproof vests, for example, can be woven; traits that could solve human medical problems, including pigs that have organs in them that may be transplantable someday into people; and traits that make for tastier or healthier food, for example, livestock with Omega-3 fatty acids which are normally only found in
significant quantities in fish, potentially making that
filet mignon almost as healthy as your filet of sole.

So all of the examples I have just mentioned are
already under development, and a couple of them which were
designed for human consumption, the fast-growing salmon and
the Enviropig, already have applications pending before the
FDA. So this is a field. This is not just a theoretical
concern that we are talking about.

As outlined in the agency's September 19th Notice,
the FDA has proposed regulating these animals as new animal
drugs; that is to say, they would have to be approved in
advance before they are allowed on the market. In three
sentences, I think it is interesting to hear their
rationale, and I know since we are in Washington, there is a
fair number of policy wonks in here.

So the rationale here is that a drug, as defined
by the FDA, is something that changes the structure or
function of the person or animal taking that drug. The
second step in this logic, a DNA snippet spliced into an
animal certainly changes that animal's structure or
function. So that DNA snippet is a drug, and since that
drug is inseparable from the animal itself, the entire
animal becomes a product to be regulated as though it were a
drug before it can be approved.

The system, as we will talk about, that the FDA
has proposed would require, just like a new drug requires,
premarket review for safety and efficacy, and the details,
we will get into later.

What are the questions that we need to address
today? I would suggest, first of all, what are the probable
benefits to be had from these animals, so we can fairly
balance the benefits against possible risks and minimize any
onerous oversight that really isn't necessary. Are there
any food products made from genetically engineered foods?
Are they safe to eat, and how would we know if they are safe
to eat or not? Would their mass cultivation and perhaps
accidental release pose environmental risks? Are there
ethical reasons, such as animal welfare concerns, that we
should be concerned about this technology, and what, if
anything, would be the impact of the FDA's plan on
international trade or on the all-important issue of
consumer confidence in the food supply?

We have got a terrific panel of experts here to
discuss all of these issues over about the next hour. I am
going to have each one give very brief remarks just to give his perspective, and I apologize that it is a bunch of "his-es." We really tried, but none of the women we invited could make it.

Just a quick introduction from each to discuss, to get their main points started. In the meanwhile, during the discussion that follows, if you would like to write questions on the index cards that are included in your folders, please do so, and pass them to the aisles. There are people who can pick them up towards the end of this roughly hour-long discussion we will have, and then we will have a half an hour or so to take your questions and entertain further discussion that way.

You have got their full bios in your folder. So I am not going to spend time on that, but let me just welcome and introduce them in order.

Dr. John Phillips, who is an Emeritus Professor of Biology at Guelph University in Ontario, one of the co-developers of the Enviropig, whose poop you will learn is better for the environment than conventional pig poop. I am wondering how we should really talk about this in this meeting, but I will let you come up with your own
In addition to this representative of the creator community, of people who are making these animals, we have two representatives of the food supply chain, essentially middle men who are beholding both to the developers of these animals and to the consumers who may or may not want to buy them. We have Scott Eilert, Vice President and Director of the Meat Technology Department at Cargill, and we have Jamie Jonker, Director of Regulatory Affairs at the National Milk Producers Federation, which represents something like 40,000 different dairy producers in the country.

We also have two representatives from the NGO watchdog community, Greg Jaffe, Director of Biotechnology Department at the Center for Science in the Public Interest, with a long history of keeping an eye on the biotech industry and in particular with the agricultural biotech sector, and Michael Greger, the Director for Public Health and Animal Agriculture at The Human Society of the United States.

And finally, someone with vast experience in sort of every community you could think of, Mike Taylor is currently at the School of Public Health at George
Washington University. He has also held high-level positions in FDA, so really knows the regulatory scene very well, did a stint at Monsanto, and so knows the industry side as well, and even spent some time at an NGO, Resources for the Future. So I know I can fall back on Mike to answer anything that comes up, if no one else can handle it.

So, with that, let me have each of you go ahead and speak for a few minutes and get a few talking points out there, and we will take it from there.

John?

DR. PHILLIPS: Well, good afternoon, everybody. My name is John Phillips, and I am glad to be here to talk about the EnviroPig which my colleagues and I have developed, started in development about 1988, the first publications on these animals, proof-of-principle publications in 1999, and we have been maintaining and testing these animals ever since. It is longer than I ever thought I would deal on this project, but we are still here.

The EnviroPig is developed to address a global problem with animal agriculture, and that is, namely, phosphorus pollution coming from pig growth and development.

This problem arises principally and very simply
from the inability of these animals to digest the principal phosphorus-containing molecule in their diet, namely phytate. That molecule, which is in high concentrations in most animal feeds, passes directly through the digestive track to produce a very high phosphorus-containing manure, which is then used as fertilizer.

That fertilizer is used to grow crops. Those crops will absorb much of the nutrient that is applied as fertilizer, but the phosphorus level is so high, the crops cannot usually use it all.

Year after year, the applications of pig manure to these fields manure to these fields will build up phosphorus residues in the soil, which will run off and pollute as an essential nutrient for microbial; as a matter of fact, for all live.

You will be into a cycle of aqueous groundwater and marine water pollution, rising from that phosphorus, again, coming from the simple inability of these animals to digest that phytate phosphorus.

Pigs that have domesticated over the centuries carry that innate inability. It is nothing that has been conferred to them by breeding. They simply cannot do it
because they are a monogastric animal.

There are many approaches, actually three discrete approaches that have been used to address this now globally pressing problem. All involve the utilization of an enzyme isolated from microbes, fungi or bacteria, that can digest that phosphorus-containing molecule and make that phosphorus bio-available to the pig.

That enzyme is called phytase. It is actually generated by E. coli that live in the human gut, as well as in the lower intestinal tract of most animals. That phytase can be produced by commercial-scale biotechnology utilizing transgenic microbes to produce a transgenic phytase which is optimized for use as a dietary supplement, and this can be rather effective. It can reduce phosphorus output in the pollution by increasing the dietary efficiency of phosphorus utilization.

Another approach is to generate transgenic grains that carry and express phytase-producing transgenes. These plants which produce phytase at high levels can be used as a dietary ingredient in the production, as feed for pigs, and that also can be fairly efficient in conferring a supplemental advantage to these animals with regards to
lowering their phosphorus level in their manure.

Both of these previous approaches are being utilized, particularly the former use of microbial phytase as a supplement.

A third possible way is to confer upon the animal itself, the capacity to make its own digesting enzyme that will supplement its own enzymes and allow it to utilize the dietary phytate. We have chosen that third approach.

Beginning about 1999, we began generating transgenic animals carrying and expressing a phytase transgene from E. coli that is designed to express in the salivary gland of pigs.

We first did these experiments with transgenic mice. We got our proof-of-principle from these transgenic mice. We then moved to transgenic pigs, and beginning in 1999, our first transgenic pig was produced.

We have now generated many lines of these transgenic phytase-producing pigs. The transgenic phytase is expressed only in the salivary glands. The saliva secreted during meals is then free to digest the dietary phytate in the low pH conditions of the stomach, and it does so virtually to completion. That is to say, virtually all
of the phytate in the diet is digested and utilized by these transgenic animals.

This then means that those animals don't have to be fed phytase supplements, nor do they have to be fed bio-available phosphorus supplements, as is required in many jurisdictions. No supplements. These animals carry their transgenic phytase wherever they go, whether they are bred and utilized in Canada, in the United States, in Europe, or in China, and in a lot of cases, that is where about half of the world's pig population is produced.

Now, just in my closing remarks, I would like to just give you a couple of pointers or insights into the progress that we are now making with regards to our application with the FDA.

MR. WEISS: John, do you mind, I want to get to that as part of our discussion. So I am going to ask you to hold off on describing the regulatory process, now that we have got your animal described.

DR. PHILLIPS: Okay. Very good.

MR. WEISS: We are going to go down the line, just to get the initial points in.

Scott?
DR. EILERT: Good afternoon. My name is Scott Eilert. I am here representing Cargill. Cargill, as many of you know, is a global processor of meat, egg, and poultry. Additionally, we are highly engaged in the animal production in different geographies across the world, as well as in the production of animal nutrition products.

We are also highly engaged and involved in the sourcing, distributing, and processing of both genetically modified and non-genetically modified grains and oilseeds.

So why are we here? As a member of the food industry, we don't have a particular portfolio of projects that are involved with the commercialization of transgenic animals today. What we are here, as described by Rick, as an integral middle man in this process.

We see that technology is evolving, as previously described, and we understand how technology is evolving.

We also understand the challenges of feeding a global population that will rise to somewhere around 9 billion people by 2050.

We also understand the consumer's right to choose, and we want to make sure that in the adaption and evolution of any technology, that we haven't lessened the consumer's
confidence in the food that they consumer; additionally, that we are still able to allow choice because consumers ultimately still would like to exercise their right to choose to consume or not consume products of certain technologies.

So why are we here? We are here and we will express in our comments in the FDA comment period, the critical need for a thorough and transparent review, premarket review of any transgenic technology that takes into account at least four primary principles around food safety, around animal welfare, around environmental impacts, and around health and nutrition.

So we are very concerned that that be done in a very thorough and scientific fashion to maintain the confidence of the public in our food supply.

Additionally, we are here to stress the importance that as technology evolves, whether it is transgenic or other technologies, that in order to enable that consumer choice, the importance of having the fundamental processes in place as an animal production system, to enable that choice, and that primary fundamental system that we are talking about is a national animal identification program,
one that allows us as this or other technologies, production
systems evolve, allows us to enable the choices that
consumers are going to wish to make.

I thank you for your participation today, and I
look forward to our discussion.

MR. WEISS: Thanks.

Jamie?

DR. JONKER: My name is Jamie Jonker, and I am
here representing the National Milk Producers Federation.

For those of you who are unaware of who the
National Milk Producers Federation is, we are a trade
association that represents 31 milk cooperatives in the
United States and their more than 40,000 dairy producer
owners. We work to advance the interests of those 40,000
dairy producers and the cooperatives that they own in the
regulatory and legislative processes here in Washington,
D.C.

Dairy producers have routinely been at the
forefront of technological innovation in reproduction to
enhance the genetic merit of dairy animals. Nearly 60 years
ago or actually over 60 years ago, the first
commercialization of artificial insemination in the dairy
industry began to occur.

Artificial insemination is now routinely used in the dairy industry. Although not as common as artificial insemination, in vitro fertilization and embryo transfer have nearly three decades of proven efficacy in our industry, allowing dairy producers to select their best cows to serve as a foundation for future generations of their dairy cattle.

Cloning has been used on a limited basis in the dairy industry for 20 years, initially in the form of embryo splitting which results in two or more identical offspring from the same fertilized egg to more recently the somatic cell nuclear transfer. That was the subject of the FDA risk assessment not too long ago.

Finally, genetically engineered animals containing heritable DNA is a future step in the technological innovation in the reproduction for dairy animals.

With that as kind of the foundation of where the dairy industry has been in the past on reproductive technologies, we do believe that in the future, our DNA animals may play a role in the dairy industry, but in order to do that, we believe that it is important to have a
comprehensive mandatory premarket approval process for GE animals, regardless of their intended use; that is, whether or not they are used for milk production, pharmaceutical production, or other applications.

We do support the use of the new animal drug application processes and appropriate mandatory premarket approval process for the regulation of GE animals. The dairy industry is familiar with the NADA process because it serves as a rigorous standard for the approval of animal drugs allowing the use of approved drugs by veterinarians and dairy producers. This process will assure dairy producers and their customers and consumers about the health and safety of the GE animal and any products that may be derived from their milk.

Setting that as a stage of support for the draft guidance that FDA has put out, we do have some concerns about where we go in the future. We think that it is important for FDA to include labeling guidance for those products that may not be distinguishable from GE animals versus conventional animals versus those products that may contain, say, enhanced nutrient profiles. That would be different from the milk that is currently available for
American consumers.

Another area where we have concerns are the marketplace impacts of transgenic animals when they come onto the marketplace, both domestically and internationally.

We currently export about 10 percent of our U.S. milk production out of this country. Our dairy producers are a major force in the international marketplace for dairy products and dairy ingredients, and that is a market that we wish to continue to maintain.

We do think that it is important to look at the potential implications as transgenic animals may be approved through the NADA process.

We also know that in the U.S., there is some consume skepticism about the appropriateness of having products derived from transgenic animals.

In the most recent International Food Information Council Survey, I think 22 or 23 percent of consumers identified that they would not purchase products that were produced from transgenic animals. While this has been decreasing, there is still consumer acceptance issues that are important for the dairy industry.

As has been stated before, we are kind of the
middle people in this process. We don't have technologies
out there that we are pushing forward in terms of specific
rDNA animals, and we will have consumers that will want
assurances that they can maintain product lines that may not
come from rDNA animals.
So, as we move forward as rDNA animals come to
market, we will have to examine what our producers can use
and what our customers will ultimately want, and I thank you
again for the opportunity.

MR. WEISS: Thanks, Jamie.

Greg?

MR. JAFFE: Thank you. My name is Greg Jaffe. I
am the director of the Biotechnology Project at the Center
for Science in the Public Interest.

As CSPI represents consumers, I guess the question
I am always asked is will consumers accept food from
genetically engineered animals, will they embrace this
technology.

The short answer is I think if the products were
on the market tomorrow, the answer would probably be no, but
I don't think consumers are adverse to technology at all in
the United States, and in fact, they will adopt technologies
where they are found safe and provide some benefits.

I would say consumers today are more aware than ever about where their food comes from and how it impacts their health and nutrition, and clearly, for some percentage of the U.S. population, this technology and the products will be looked at under a microscope.

So I think there are three things that I think need to occur if consumers are to look favorably upon products and this technology.

The first is I think we need a strong regulatory system overseeing the industry and ensuring safety. That regulatory system needs to, first and foremost, address whether the food from genetically engineered animals is safe to eat, but it also needs to look at what is the environmental impact from any of those animals if they go to commercialization, as well as ensuring that those animals are healthy and that they don't have any major animal welfare concerns from having those animals be produced.

I would say that the FDA guidance and the policy statements it made about how it is going to regulate genetically engineered animals is clearly a good first step because it addresses some of these issues head on, although
not necessarily all of them, which I am sure we will discuss in a little while. So I think that is the first thing is having a regulatory oversight that ensures safety.

The second is, just because something is safe doesn't necessarily mean we need to adopt it. There should be some societal benefit, some benefit to somebody along the chain, maybe not directly to the final consumer, but at least somewhere along the chain, and I think to date, the industry has not done a very good job of explaining to the public what are the potential products and what are the benefits that might accrue from those products.

We have John here today, and I am appreciative of that, and he has explained what the EnviroPig will do, but in putting this panel together, we tried to invite a number of different developers to participate, and for a number of reasons, they didn't participate.

This is an example of a forum where the public needs to begin to understand what are the benefits from these products and what products are coming out, and if the industry is going to just go ahead and develop their products and go to FDA without that public engagement, I don't think there is going to be an embracing of those by
the public.

With that, therefore, goes the idea of transparency, that the public needs to understand when these animals are coming into the market, what kinds of animals they are, and why they are being done.

So the final thing I would say is that there needs to be education here, education of consumers. The different stakeholders need to educate consumers about the technology, about its benefits, and also how it is going to be regulated, and I think that although we have some members of that food chain present here today, there are a lot of other members of the food chain out there who have not engaged themselves in understanding this technology, and if a supermarket doesn't know anything about this knowledge, how are they going to interact with the consumers who come into the supermarket and ask questions about this technology.

So I think in addition to safety and in addition to showing some benefits, there needs to be an education campaign that goes on around this.

MR. WEISS: Thanks, Greg, for making it clear that we are all part of a food chain now. I almost feel like I am going to get eaten here.
Go ahead, Michael.

DR. GREGER: I am the Director of Public Health and Animal Agriculture at The Human Society of the United States, honored to be here to voice on behalf of our 10.5 million supporters' grave concerns about the likely use of this technology.

The welfare of many farmed animal species in the U.S. is already so compromised by conventional genetic selection for production traits at the expense of animal welfare and well-being, that the use of biotechnology to further stress these animals towards their biological limits may be adding insult to injury.

Let me offer a few examples. Dairy cattle make the best cows. As Jamie talked about, over the last century, selective breeding has tripled the annual milk yield of per cow to about 18,000 pounds. It took the first half century to add the first ton increase, but then during the 1980s, the industry has been able to squeeze an extra ton of production per cow every eight or nine years or so, and turning cows into milk machines has led to an epidemic of so-called production-related diseases like lameness, mastitis, the two leading causes of dairy cow mortality in
We all remember the sick and crippled dairy cows being beaten and dragged to slaughter at the California slaughter plant earlier this year. Well, the loss of body condition that we saw in those animals is in part a direct result of this extreme selection for unnaturally high milk yields.

The turkey industry has so altered the natural order that the enormous breast meat mass of commercial lines has resulted in birds now being physically incapable of mating. They just can't do it. So 100 percent artificial insemination has allowed the industry to continue to select for increasing weight, and the selection is so intense that turkeys can barely support their own weight now.

So, unless you are choosing one of the slower growing heritage breeds, in a few weeks the bird on your table may have been on the verge of structural collapse, a painful dyschondroplasia, bowing of the legs, may not have been able to even stand by the end.

Today's egg-laying hens produce 10 times more eggs than their ancestors, leading to uterine prolapse and to broken brittle bones from the osteoporosis as the calcium is
mobilized for shell formation. In fact, egg-laying breeds have been so genetically manipulated through conventional selection that it is not profitable to raise male offspring for meat. So hundreds of millions of male chicks are gassed, ground up alive, or just thrown in dumpster to suffocate or dehydrate to death. Economically, it is not worth wasting feed on these animals because they are of the egg-laying type, because they haven't been bred for muscle productions.

Those birds, the so-called "broiler chickens," probably suffer the most. Broiler chickens now grow twice as big in half the time, outpacing their skeletal and cardiovascular systems, leading to lameness, joint deformed, and ruptured tendons. Heart failure is one of the leading causes of death. These are birds just a few weeks old dying of heart failure, but that seven times the mortality rate can just be factored in to the bottom line.

This has serious welfare implications. More than a quarter of broiler chickens in this country are in chronic pain, have gait abnormalities, difficult in walking. That means 2.5 billion animals are suffering every year because of this genetic selection for productivity, and now
agribusiness is considering stitching in growth hormone
genes into farmed animals in this country.

The Humane Society of the U.S. considers this
unacceptable, and I am glad that we are participating here
in the discussion today.

DR. TAYLOR: Thank you. I am glad to be here. I
am, I think as the introduction indicated, a professor at
the School of Public Health at George Washington University,
and I confess that notwithstanding the seriousness of the
issues surrounding this technology, I really haven't given
GE animal issues much thought since about six years ago when
I served on a National Academy of Science committee that
looked at science-based concerns around this technology as a
study requested by FDA. As I look at that sort of review,
that study, though, and look at the issues on the landscape
today, they really haven't changed much. So I hope that I
am, more or less, current.

I want to talk about the issue from the vantage
point of FDA and its regulatory role and really address and
put on the table sort of a broader public policy issue that
I think relates to GE animals, but also any of the examples
of dramatic new technologies that come along, and address
the question of whether our Congress on behalf of all of us
have really given FDA the tools it needs to regulate these
new technologies.

The first thing I would say is I share what I
think is the sense of this panel, that the guidance that FDA
put out on GE animals was exactly the right thing to do.

I would quibble a little bit with Rick that FDA
defines a drug as something that affects the structure or
function of the body. Congress has done that, and I see the
guidance simply playing out the logical understanding in the
law about what is a new animal drug, and so I think that
guidance is the right first step.

I think the question is, though, whether what FDA
is able to do under that law and with that guidance really
is going to be sufficient to meet public expectations with
respect to oversight of this technology, recognizing that
FDA is the gatekeeper to the marketplace, and so there is a
familiar set of issues, and we have alluded to, I think,
most of them already, where there is a real question about
whether the new animal drug authority and the statute really
is sufficient to permit FDA to answer the questions.

With respect to environmental risk, first of all,
yes, it does a NEPA review, but that is not a decisional statute for FDA. It can review environmental hazards. It can work with the sponsor on mitigation, but it is not a marker or controller of entry to the marketplace.

The standard under the law is whether the product is safe for the animals and effective for the animals. So what is the scope of FDA's authority to really address and regulate environmental risk, I think is a question that arises under the current law.

We have also heard about the issue of transparency and the lack thereof. This is a private confidential licensing process as a regulatory matter. It is between the sponsor and the agency.

There are things that FDA can do, as it has done in the human drug area, to bring some transparency to that through advisory committees and with the cooperation of the sponsor, getting information in front of the public, prior to the approval of a product, but in the law itself, there is no transparency. There is no public access to the decision-making process, and for a technology that is as novel as this, I think that raises a real question or potentially presents a real hurdle with respect to public
confidence in the decision-making process itself.

The last category of issues, which are well beyond FDA's recognized role but nevertheless will affect public acceptance of the technology, is this whole range of social, economic, ethical, and religious questions around this sort of technology. So, for FDA, it is not a question of making decisions about those sorts of issues at all, but there is a question of whether under FDA's law, it has the wherewithal through labeling and other means to empower choice, which is really the only way for society to deal with those issues.

So we have a regulatory tool, the new Animal Drug Authority, that is very strong for purposes of getting FDA to see the data, preapproval, to do an analysis, to make judgments about the safety and efficacy of the technology for the animals, but the question is, is that authority broad enough to meet public expectations.

There are other technology examples of where I think FDA has applied the law in a science-based and I think faithful-to-the-law sort of way, but where there is this question about is it enough, I think a lot of us bear the scars of the plant biotech decision-making and the policy there, which, again, I think has been fine with respect to
the products on the market being safe.

They have certainly been accepted by the agricultural sector, but that technology has yet to win public confidence to a level where food companies are actually willing to GM products in their branded products and reveal that they are marketing GM foods, and I think that is partly due to the fact that under the playing out of the current law, there is no mandatory premarket approval necessarily for GM plants. There is not even a mandatory notification regime. So, again, fitting brand-new technologies into existing statutes may not get us what we need in terms of vital concerns.

The final example of this, obviously, is still much more in the future, but nanotechnology presents a similar set. It is really dramatic, potentially, very powerfully beneficial technology, and certainly, in the food area, there are genuine questions about what is the premarket review that FDA will have, will it know about these technologies before they enter the market.

There is a need for FDA to put some guidance out about what current law provides, but if you look at the food applications, the cosmetic applications, the dietary
supplement applications of nanotechnology, FDA really doesn't even have a way to require developers to give it access to what is going on in the pipeline, so FDA can now it is coming and prepare for it.

So here is a technology like GM animals, like plant biotechnology, where FDA needs to prepare scientifically, but has no tools on the books to sort of drive the submission of information or to have the industry be transparent with the agency about what is coming.

So, again, I think there are a lot of important issues specifically, obviously, about GM animals, but I think it is sort of an example of a much broader question of FDA of are we giving it the tools it needs to regulate dramatically new technologies.

MR. WEISS: Thanks, Mike. Thanks to everyone on the panel.

So, for starters, I want to come back to John to talk a little bit about the pig because, for people who have been following this for a while, it has been something like 10 years since the first people started approaching the FDA, as far as I understand, to try to get some of these animals onto the market, very frustrating and near bankrupting for
some of them. The salmon people have expressed their frustration many times.

John, I am curious what your experience has been as you have tried to get the FDA to look at the products you have. I know that a large proportion, close to half of the pigs raised in Canada are imported into the U.S. So U.S. approval would be important to you.

What has your experience been? And I am particularly curious because you are coming at this a little bit differently than some developers. You are an academic. You developed this product through university research. You have said you don't anticipate really making any money on this, and you are pretty open to being very transparent about all of your safety data, where other companies may not have the same attitude that you do.

Tell me what your experience has been like at the FDA.

DR. PHILLIPS: Okay. Let me start off by telling you that we have had an FDA application in beginning about the middle of 2007. So it has been approximately a year.

We have submitted over 2,000 pages of data and documentation.
The process is an iterative process where we work with FDA, where if they need more information on a topic or want new experiments done or data reformatted in a different way, they tell us. We respond, sometimes grudgingly, but we do it.

So I must tell you that our experiences with the FDA have been surprising to me in that the level of detail, the intense scrutiny of our data has surprised me, not only in detail, but the comprehensive, the breadth of analysis, and I think that is great.

I think the most important thing to a developer -- and I don't really consider myself a developer -- is to have an extraordinarily rigorous, comprehensive review process, so that we feel confident that a third-party review can give the stamp of approval that we feel confident with about and that the public will feel confident about.

I will tell you that at the end of the review, I don't know what FDA's policy will be on this at that time. Whenever that is, we will make all of our data publicly available. All of the data that we have submitted to FDA will be available for scrutiny.

I will also add that we will insist on labeling.
We want people to know. I don't think we will call it "green pork."

[Laughter.]

DR. PHILLIPS: But nonetheless, we think people should have a choice. We understand that there are people that do not and may not want to at the time purchase or consume meat from these animals for whatever reason, and we say fine, we don't want to impose on you, but there may be people out there who do wish to have this product labeled as environmentally friendly pork, with data to back it up.

Have I missed anything?

MR. WEISS: That is good for now. That makes me want to go to Greg for a moment because, among other things, Greg, you have written in the past about your sense that FDA does not necessarily have the technical expertise to pull off the kind of review that you would like. In particular, there are issues beyond conventional FDA realms, including environmental review.

Would you take issue with John's take that this is getting a plenty good review?

MR. JAFFE: I have a couple of comments. I mean, I appreciate the fact that John is saying that FDA is taking
a very close look at that data, and that is great. I think
the public expects FDA to look at the data with close
scrutiny and to make sure that everything is safe and in
order, but there are a couple of concerns.

One is that FDA is primarily a food agency, and
the expertise of the Center for Veterinary Medicine is going
to be on the animal welfare, the safety of the animal, as
well as the safety of the food that is generated from that
animal.

But I think as Mike Taylor pointed out, the NAS
did a report a number of years ago that looked at the
different safety and risk issues surrounding genetically
gineered animals, and I think their major conclusion was
that environmental concerns may be the highest on the agenda
here for some of these applications. It may or may not be
for John's EnviroPig, but it may be for the salmon or for
other applications.

I think FDA may not both have the expertise in
that area, they may not have the ability to do the close
look at the data that is generated as to what are the
potential environmental risks or environmental management
options for that animal if it is released into the
environmental, either a controlled release or an expected release or an unexpected release, but also they may not have the legal authority to do that.

They are required to do some environmental assessments, but they aren't an environmental agency, and they don't have the legal authority to really make an environmental determination and act on that environmental determination. So I think that is a problem.

The other thing I wanted to mention -- and again, I appreciate the fact that John has said that when the review is done, he will publicly make all his data available, and I know another of other companies have said that, but I think that is not what the public is looking for here. I think making the data available at the end, when FDA has said it is safe, is too late. Then the public sort of sits around, waits. Some of the stakeholders here sit around waiting.

John has been nice enough to tell us that his application is at FDA, but that is not required either. So Scott and his company may not find out until after this product is approved. Then all of a sudden, they have got to now work with their management chain to figure out a product
that is going to be in the market that they haven't had a
c. chance to become aware of, and the public really hasn't had
an opportunity to review that data and give input to FDA
before the decision is made.

   So I think there has got to be a change if
consumers and the public are going to embrace this
technology or even consider it. There has got to be a
change in that balance, so that the industry doesn't control
when and what data gets released to the public, that the
public has some ability to chime into this process before it
is a fait accomplis.

   MR. WEISS: I want to talk more about the
transparency issue, which is difficult in this situation
since we are working within a framework that was developed
for drug development, and of course, the pharmaceutical
business is a very competitive business, and companies don't
tend to make their data public. That is one of the
attractions of the FDA system here, but before we get into
that more, I wanted to ask Michael Greger.

   Since, Greg, you mentioned that at least one of
the areas that FDA does have expertise in is animal welfare,
we are talking about the Center for Veterinary Medicine here
within FDA. Michael, would you agree that at least in that regard, we can trust the Federal regulators to make sure that animals are properly cared for?

I know I have talked to people in the agency, within CVM who are involved in this. They seem to care very much about animal welfare. It is very high on their list.

As you mentioned, for better or worse, animals have been manipulated by humans for a long time to keep us well fed. What do you think about how the agency is set up to deal with those issues?

DR. GREGER: I think one can look. A really illustrative example is kind of the FDA decision on the safety of cloned meat products.

So, for example, the European Food Safety Authority, when they were viewing the safety data, they came to the same conclusion as FDA in terms of the safety of these products, but realizing that there were broader issues at stake that they might not have the best expertise at.

They called in -- well, we don't really have a parallel in this country, which is the European Group on Ethics of Science and New Technologies, which is this 15 expert panel, which has kind of an advisory role to the
European Commission there, kind of an executive body that reports directly to the head of the European Commission, and they came to the opposite conclusion.

They said based on the animal welfare implications of cloning, they didn't think cloning should go forward. So I think we would like to see kind of a parallel process here in the United States where there would be people with expertise in these areas who kind of separate would be able to make these kind of determinations.

MR. WEISS: Right. My understanding is within FDA, there is no formal pathway for dealing with sort of social and ethical issues. So you are speaking to a different system in Europe.

Mike, I wanted to ask you, since Greg brought up the issue of transparency and labeling, I think you have talked before about the awkwardness of having to deal with this longstanding regulatory framework in the United States for dealing with biotech crops and now animals.

Is it time, and especially given this desire Greg is mentioning for more transparency, people have a lot of concerns about this? Does it make sense to keep trying to cram these new developments into the existing system, or is
it time to rewrite the whole thing, or would that just be
crazy to talk about starting from scratch now?

DR. TAYLOR: I think it is time to look afresh at
the law, particularly as it affects labeling, and not just
transparency of the decision process, but the empowering of
choice in the marketplace.

As FDA will point out to you, its law is not a
freedom-of-choice law. The law's intent is to prohibit
false or misleading claims on labels, and so it really
doesn't address the societal acceptance issue, which I think
is fundamentally embedded in the sense people have that they
can make a choice. As soon as people know they can make a
choice, then they relax, and if they have got the
information to make the choice, the technologies can go, and
people who want them can choose them, but if there is a
sense that something is being hidden or the public is being
disempowered by lack of information to make a choice, that
can kill off a technology.

Again, I would argue that it has essentially
killed off plant biotech as a direct consumer benefit
technology.

So, yes, I think the answer is there ought to be a
debate, and there ought to be a legislative consideration of
that.

I know I will throw some of my FDA friends off
balance here a little bit. I think the provision of law
that FDA relies upon to drive the issue of whether the mode
of production will be disclosed on labels is this provision
that says the withholding of information is false or
misleading because of the fact that there is some change in
the product and will have a material consequence for
consumers. Well, that is one element of the labeling
authority FDA has to provide affirmative disclosures.

There is also an even more basic element of the
misbranding laws, though, that says products have to be
identified by an appropriate name. You have to name the
ingredient, name the product, and I think there comes a
point where -- and again, I don't have the bright line here
or the answer to where it ought to be drawn, but I think we
ought to discuss whether and when because of the public
sense of products, the actual property identity statement
for meat from a genetically modified animal is, in fact,
something that discloses that fact.

I think in the plant area, from the public
standpoint, GM corn is different from corn that is not GM, and to think there is not an identity statement that should be devised to reveal that difference, it doesn't necessarily give full weight to current law, but because this is all about fundamentally empowering choice, which is not what the Food and Drug Act is about with respect to these more social issues, I do think it is a legislative issue, and I think it ought to be addressed.

MR. WEISS: It is interesting to me that, unlike the case with GE crops where the traits are mostly to help the farmer by providing pest resistance or resistance to herbicides, I think for these food animals, we are talking about traits largely that consumers are going to have a much more direct interest in; for example, healthier meat or environmentally friendly animals.

To that extent, I wanted to ask you, Scott, whether you think that consumer demand might actually start to alter what has long been sort of a discomfort with this technology.

I have noticed that in your testimony before Congress last year, you said, "Cargill is deeply committed to serving the needs of our customers."
So I wonder when it comes to the kinds of traits we are starting to talk about now, whether you have sensed some consumer demand or might anticipate having consumer demand, maybe even these things will end up being not only labeled, but sold at a premium, and do you see this as an opportunity, as much as a challenge?

DR. EILERT: It is a great paradigm shift, isn't it, that all of a sudden, instead of presenting a technology to consumers and having them run for the hills, as often is the case, actually presenting something that would be embraced?

I was intrigued by Dr. Phillips' comments that the EnviroPig, if approved, should be labeled because we should be telling the story of the benefits of a more environmentally sound production system.

So it is hard for me to imagine right now that a consume would ask for an advancement of greater technology because, oftentimes in today's more complex world, we more often hear the cries for something that is more closer back to nature, as it were, something that reflects the simpler times.

I don't say, though, that it would be outside the
realm of possibility that we could find the traits that would be asked for.

I have a daughter that is a diabetic, and she takes insulin four times a day. I read the statement on the box of insulin produced with recombinant technology, our recombinant-based insulin, and that gives me a sense of assurance. I know that every batch of insulin is going to be consistent time after time, and maybe not all consumers would be aware that originally we used pig-based insulin, it was much more of a natural product, and I don't hear cries for people to go back to that system of using pig-based insulin. If you have ever been around a diabetic, your focus is on controlling the blood glucose level.

So, as I see it, that is a user recombinant technology that gives me great assurance. It is not crazy to think that at some point, we could think the same way about the food that we consume.

It is hard for me to imagine today, but many things are possible.

MR. WEISS: Jamie, I am curious about your take on that because you deal with a product whose brand is wholesomeness. There is nothing true or false. Milk has
that label affixed to it in everyone's mine. I know the
milk industry is always concerned about anything that might
take a whack at its image.

And I also appreciate that, although milk itself
doesn't get exported to Europe, more and more milk products
are going there, and Europe is very sensitive about these
issues.

Do you feel like you are the animal getting wagged
by the tail here, or do you see a positive opportunity here?

DR. JONKER: I think it is a lesson for those who
are thinking about or who are currently developing
transgenic dairy animals to look at what could be learned
from what happened with first introducing transgenic crops
where the benefit was almost all exclusively at the producer
level.

I think you can look at that and what has happened
with, say, the Precautionary Principle in Europe, and maybe
a light goes on in a developer's head that perhaps we should
be looking for things that have a top-of-the-mind consumer
benefit.

If you get a consumer as your advocate for the
technology you are pushing, you probably will find your
acceptance of that technology a lot easier.

MR. WEISS: So I think we should get to one of the hearts of the matter here, which is safety. There has been talk of transparency so far and the public's desire to know sort of what is behind the curtain. I have to think that a lot of that is not because everyone really wants to look at the technical details of what this DNA construct is and so on, but what is the evidence that it is safe.

The FDA has spelled out in its proposed guidance the kinds of tests it would expect developers to do to prove safety. It includes showing that this animal has remained healthy and looks, two generations later, a lot like they did two generations ago, to show that this trait is stable.

I wonder if some of you could address the question, though, of how in the end you really can prove or at least make a convincing case to the public that this animal that has completely altered, something that would never happen in nature, is safe. What would it take, and is it plausible to actually demand that of developers?

Greg? Mike? Anybody want to weigh in on that?

DR. TAYLOR: Well, as the polysci major in the group, I am happy to offer an opinion.
[Laughter.]

DR. TAYLOR: First of all, I have confidence that the scientists at FDA can get their arms around the safety evaluation science associated with a technology like this and ask the right questions and get the right data, and without being able to sort of judge this scientifically myself, I have confidence that this guidance elicits that.

But any time there is a new set of questions -- and there is a new set of questions here when you are talking about a genetically modified animal. It is not like testing a chemical which we have such well-established protocols for doing. It does come back to the transparency point, but it is more than that. It is involving the external scientific community in the judgment about whether, in fact, these are the right questions.

I mean, again, while I can have confidence in what they have done, the public has no intuitive basis for having that confidence, and the way we get there is to have processes that involve the broader community and have a way of getting buy-in to the paradigm, to the framework.

So I don't know what the plan is. As I say, I have been away from this issue for six years. Maybe all
that has happened already, but if it hasn't, I mean, I think that sort of buy-in from the broader scientific community on the paradigm, on the questions, and do we have the protocols to develop the data to answer the questions that are properly asked, that has got to be a societal thing, not just an FDA thing.

MR. WEISS: Greg, are you satisfied with the outline the FDA has provided with regard to how to prove safety?

MR. JAFFE: I mean, I guess I have two comments on this.

One is I think the FDA guidance is a good first start. I think when you look at that FDA guidance in detail, about every paragraph or so, there is a statement that says come talk to us, come talk to us. I am not sure that gives me a lot of confidence that they know exactly what they are going go be requiring of developers yet.

Unfortunately, I don't think this is something unique to FDA, but usually, when new technologies come along, the government plays catch-up. You know, the developers are out in front. The research scientists are out in front, and the government is usually catching up.
I think we saw that in cloning where we had a four- or five-year moratorium, while FDA sort of caught up to decide whether these were safe or not.

We see that here in the sense that there have been a number of applications pending, and FDA is now coming out with a guidance document, and even though that guidance document gives us some general structure, there is still a lot of come talk to us, we will know it when we see it, or we will decide it at that time.

As Mike said, part of that is transparency. I think the public needs to know sooner, rather than later, what is being required of developers. I think it has got to be more set out.

The other comment I would just make is FDA, although has come to the table, but where are the other Federal agencies? Where is EPA? Where is USDA? Where is Fish and Wildlife? There are a lot of other agencies that might have expertise for genetically engineered animals and assessing whatever safety concerns there are, and they haven't come to the table yet. They haven't put out any policy. They haven't said if they are going to do anything here.
I am not necessarily advocating for a dozen agencies' review of every single product, but I do think that although I see an FDA policy here, I don't see a Federal Government policy about whether there is going to be some interaction among agencies where there is expertise for particular applications.

MR. WEISS: It is funny. When I first read these regs, I also was surprised by all the come-talk-to-us commentaries in there. At first, it does leave one wondering, well, do they really have this figured out yet, but I have to admit that part of me also concluded from that, well, let's be practical here, how else are you going to make this happen. It is new. People have to sit down and talk to each other, and in that regard, I thought it doesn't look that clean on paper as far as regulation goes, but maybe that is just what has to really happen.

And USDA, of course, has put out a request for people to start talking to them about what role they should play in this.

I am curious of all the agencies you mentioned, that one you didn't mention is the Centers for Disease Control. I know that Michael has raised an interesting
point in the past about not only that we have animal welfare
concerns here, but public health issues might get raised
through the creation of genetically engineered animals that
the regulators stuck in the bowels of FDA -- not to keep
bringing bowels up, John --

[Laughter.]

MR. WEISS: -- might not think about right away.

Do you want to talk about that for a minute, Mike?

DR. TAYLOR: Genetic manipulation for accelerated
muscle, milk, and egg production carries a tradeoff in
immunocompetence or disease resistance. This has been
empirically demonstrated in chickens, both beef and dairy
cattle, as well as pigs. It has been explained by what they
call the "resource allocation hypothesis." Essentially,
there is only so much energy protein entering into an
animal, and by diverting resources away from host resistance
to anabolic activities like breast mass production, for
example, at such kind of unnatural rates, one sees a
decrement in immune competence.

Indeed, when you look at these fast-growing
broiler chickens, for example, there is actually a shrinkage
of the lymphoid organs, of the immune organs as you
accelerate the breast mass.

So we see in chickens, for example, these fast-growing birds have increased disease morbidity, increased disease mortality, lower kind of antibody responses to disease challenges.

Now, from a human health standpoint, as a physician, if there is increased disease susceptibility in the dairy industry, well, from a human health standpoint, who cares? Right? So the cows have swollen, inflamed udders. So there may be more puss in the American milk supply. The cheese might taste not as good, but when the handful of corporate poultry breeders that essentially control the 50 billion global poultry flock decide to select growth above all else, they may be kind of policing the global human population at risk from a flu pandemic as chickens harbor this virus capable of infecting literally half the world's population in a few months' time.

So the immune competence of birds actually is a public health issue. The increased mortality of these birds can't just be swept under the rug and factored into the corporate bottom line. Regulators actually have to come in and raise some of these public health issues. How we raise
animals can have global public health implications.

MR. WEISS: John.

DR. PHILLIPS: Just two things. Michael, all of these horrors of the application or the over-application of traditional genetics, I agree with you. My sense is that the industry consume collaboration has pushed the animal too hard in general, but this is not connected at all to biotechnology. None of these things that you have put out here are directly the product of the application of biotechnology.

You say you fear the overloading of these animals until further with biotechnology, but that is not a necessity.

It seems to me like the first thing we have to do -- and I would subscribe to this -- is back off the application of traditional breeding, the pressure of these organisms to produce and to produce and to produce. I think we have gone overboard on that.

The second thing I would bring out here is in the discussions about biotechnology and regulation, I think we have to start to get specific about specific applications and don't talk about applications in general, and this
refers directly to the guidance document and these comments about "come to see us."

I think a lot of it is directed at that, where certain applications will require greater intensity and data to substantial claims than in other applications, certainly with regards to environmental problems as has been pointed out. The greater the reproduction of the animal is under the control of the grower, the producer, and so forth, I think the less is one aspect of environmental problem. As the producer is unable to control the breeding and so forth, for instance, in national populations, then that environmental issue does grow quite substantially, and I think you can go right down the line with the specific applications.

Let's focus on specific applications, stop talking about the benefits and horrors of biotechnology in general. I think we have done that for 20 years now. I think we really need to get specific.

MR. WEISS: Michael, do you want to respond to that?

DR. GREGER: I want to make clear that the genetic engineering of farm animals is not necessarily bad.
In fact, I can think of many uses of biotechnology that would dramatically improve the welfare of animals, but I think one has to follow the money, que bono or who benefits, who owns the technology, who is profiting from the technology.

Who can forget the promise of Golden Rice, the savior of humanity? In the last eight years since it has been developed, how many children have been prevented from blindness? Zero. In that same time, how many tons of Roundup Ready soybeans have been planted? A half-a-billion or so.

So I am concerned that the EnviroPig reminds me of Golden Rice, kind of this Trojan horse or Trojan pig, if you will, that the industry can hold up while they kind of slip past the really lucrative yet potentially damaging, dangerous developments.

MR. WEISS: I will get into a few more questions and then open it up to some of your own, but let me remind you now, if anyone has questions, please feel free to fill out a card and pass them to the end of the aisle. People will pick them up.

I wanted to talk a little bit about timing because
I am hearing two different perspectives. On the one hand, I hear enough points being raised that maybe we need to slow down and figure out what some of these issues are, maybe even have a whole new regulatory system. Plus, we do have a new administration that is going to be coming in very soon. There are questions one could raise about why we need to quickly get this finished before the Bush administration leaves, what is the hurry.

At the same time, we have heard some people have been trying to get this done for many years now, and I must say that in my position at Center for American Progress, where we are very focused on policies, that are under the next administration, we are going to really push to get the economy going again and focusing a lot on technology and the so-called "innovation economy," I don't see a lot of benefit in anything that is going to hold back progress that might turn into new lines of business where the United States in particular might be able to lead.

So I am left a little bit in a quandary with regard to whether we ought to get this going or sit back a little bit.

I don't know. Maybe some of our middle men here
who are going to have to live with it one way or the other
might want to speak to it, or anyone else on the panel. We
might want to wait and see what the Obama administration
wants to do or just get this thing on the road.

DR. JONKER: Boy, let's see how much trouble I can
get myself into here.

MR. WEISS: That's my job.

Laughter.]

DR. JONKER: I think from the dairy industry's
perspective, we want to make sure that there is a mandatory
premarket approval process. If the current paradigm that
has been proposed by FDA is seen fit as the appropriate
mechanism for that, with appropriate interagency
consultations, so be it.

If a new administration comes in and makes it a
priority to look at other regulatory mechanisms, then so be
it.

We just want to make sure that once a transgenic
animal arrives on the marketplace, that it has gone through
the appropriate process, so that we can ensure that its
products are safe and that it is safe to introduce that
animal into the larger dairy animal population.
MR. WEISS: Scott, anything to add?

DR. EILERT: It is pretty similar from our standpoint.

I mean, let's get it right. Quite frankly, I really don't care which administration gets credit for it or gets credit for killing it. I want to make sure that it gets correct.

At the same time, I don't think that we need to needlessly delay. The technologies are there. They are being developed, and so I would hope that there is not a needless delay on getting it right.

I would hope that if it is not in this administration, then it be swiftly addressed, maybe not swiftly, but correctly addressed, diligently addressed by the next administration.

MR. WEISS: So, assuming it gets done right, there is still always the issue of making sure the public appreciates that it was done right and that the confidence is there.

Mike, there is a question from the audience for you which is an interesting one, that maybe your knowledge of FDA authorities and so on would be able to answer.
The question is: Could the FDA encourage openness by expediting decisions on products for which companies make the safety data public? Is there a mechanism now, or could the FDA write something into the guidance here that might encourage companies, give them an incentive to be more open than technically they are required to be under the new animal drug provisions?

DR. TAYLOR: There is no explicit authority to do that.

I mean, clearly, in the human drug area, if FDA expedites reviews of products that have an important health benefit or therapeutic benefit and properly so, it would be a different sort of angle in this context, but I think if there is a good social purpose, I think FDA could sustain doing creative things like that.

I don't think, though, that that sort of case-by-case inducement begins to address the transparency and public participation in the judgment about whether we have got the right paradigm and are doing the right safety evaluation with the right data. So I think it is a nice idea. I don't think it really solves the problem.

MR. WEISS: The public has had 60 days in this
process, and from what I have heard from FDA, there is a commitment on the part of the agency for at least the first one or first few applications to go through the process, commitment from the FDA to do this in a more public venue than it would normally do with the permission of the applicants using the Veterinary Medical Advisory Committee and so on.

DR. TAYLOR: Again, that is all to the good, and I think this is FDA working within the confines of the law that it has got. I think it deserves credit for making those efforts, but FDA, its incremental efforts within its current law to address these big social issues just may not be enough, and that is my point is that society needs to figure out is this really the way needs will be met in this process.

MR. WEISS: Greg?

MR. JAFFE: I will just give another example. The cloning example, I think it is something we have to be very careful about. While FDA was looking into the safety of cloning, they had a voluntary moratorium, and the public and consumers needed to just rely upon the goodwill of the industry while the agency made a determination.
Then they came out with that determination, and now there is still a sort of gentleman's agreement that these animals aren't going in the food supply, while USDA tries to work on a transition plan on how to deal with our international partners on some of these things.

I think the more we have those kinds of voluntary transitions and voluntary moratoriums, things like that, I think the public loses confidence in the overall regulatory system and the ability to address the issues, and the lines blur as to the safety determination with some of these social and economic developments.

So I agree with Scott. Let's get it right. Let's get it right the first time through, and I think that may be requiring something broader than just FDA's guidance and FDA's involvement from a Federal Government point of view because FDA may say this is safe, but Scott or Jamie may have all kinds of problems with international markets and what kinds of segregation is going to go on in their businesses. If something is safe here and farmers want it and even consumer want it, will it get killed because the Europeans don't want it, and we live in a global economy?

So I think there has got to be a way to have a
discussion about those broader issues on the front end before a determination is made and then everybody else plays catch-up.

MR. WEISS: It is interesting that you bring up the issue with international traders, too.

I know one of the issues with GE crops has been how do we even identify this stuff if it is in a place where it is not supposed to be, and certainly, with regard to crops, it is the companies themselves that own the rights to and the licensing rights to the tests you would need to use to identify the gene you are looking for, and FDA has had to sort of cajole companies in the past to share those tests when a contamination event happens to be able to identify these things.

So, whether the companies involved in these animals would be equally willing to share their testing methods and the specifics of the gene constructs they are working with would be an issue.

Scott, I think you wanted to respond to something Greg was saying.

DR. EILERT: I have a question for either Greg or Mike because a couple of times today, it has been mentioned
about having greater interagency work on this. Let's use EPA as an example.

How difficult is the change, if as a part of this process, EPA plays a more active role to make sure? I mean, one of the comments that I made at the beginning was we have to study the environmental impact.

So is this a huge change for FDA to have greater interagency involvement in something like this, or is this something that we can kind of change on the fly?

DR. TAYLOR: Go ahead.

MR. JAFFE: I mean, agencies work together all the time. Before I came to CSPI, I worked at the Environmental Protection Agency, and they do it sometimes very formally through memorandums of agreement, and sometimes they do it very informally.

Right now, we don't know for genetically engineered animals, how they are going to interact and if they are going to interact, and sometimes even agencies have to interact because they may have statutes that require them to do something, but for the purpose of the developer or for the purpose of the public, they want to coordinate their review, so you don't have two sets of review.
So I think the issue here is that for some applications, clearly I think EPA would probably have some added benefit. Whether they have legal authority that requires their involvement or whether that is more of a policy determination, I think remains to be seen, but right now, I think a lot of us who follow this, as you have known for years, there has been an attempt to have some sort of interagency coordination and interagency policy come out on genetically engineered animals, but we haven't seen anything.

When you are asked, it is, oh, next month or next year or the following year. Again, it feels from the public's point of view like we are playing catch-up.

MR. WEISS: A couple of questions from the audience that are related, let me put them together, John or anybody, to answer. One asks how will GE animals impact the diversity of our food supply, this prospect of having this mono-culture of genetically identical animals perhaps, susceptible to some epidemic.

And a related question, making the point that you can't always predict what the impact of things is going to be, what is to say that as hog producers switch to
EnviroPigs, they don't, because of the ability to do so, also increase the number of pigs they are cramming into these operations, and so in the end, you have a net wash in terms of the environmental impact of all this hog manure?

DR. PHILLIPS: The latter is a good question, and that just depends on regulation and management, as it does now, whether it apply to transgenic animals or traditional commercial animals. It is the same.

I can make an analogy here that I like to make with regards to the EnviroPig. Basically, what we have done is installed a pollution control device, a catalytic converter in our animals.

Now, when that was installed in the automobiles back in the 1970s, no one wanted it. The public did not want it. The manufacturers did not want it. It was legislated.

Here is an introduction of a technology for an environmental cause or a purpose that nobody wanted. Now very few people I know would agree to buy a car that did not have that on it.

Now I have forgotten why I was making that point.

[Laughter.]
DR. PHILLIPS: Anyway, the story still lingers out there.

What was the first part of that question?

MR. WEISS: The question of whether we are going to have GE-identical --

DR. PHILLIPS: Oh, reduction of genetic diversity.

MR. WEISS: Right.

DR. PHILLIPS: No reason whatsoever because you are producing a commercial animal. If you are going to produce a food animal that is going to compete in the marketplace, it is not just some transgenic trait that is going to do it. It has to stay competitive with other animals. That is a whole genomic, a whole genetic approach.

Traditional breeding will still apply to these animals to make them fit for the conditions in which they are being produced. I don't see that impacting that whatsoever. That has nothing to do with cloning and producing identical sets of individuals. These things segregate and are inherited like Mendelian genes.

MR. WEISS: Another question here, making the point that in a free market, although it may not be obvious to consumers, there are benefits to the consumers, even
though the producers may be really the ones taking best
advantage of some of these traits. So there are hidden
benefits the consumers are benefitting in terms of
availability and affordability of different kinds of foods,
and that polls, according to this questioner, show that
consumers are not really thinking so much about food
technology. Maybe this is not such a big issue after all.
Maybe we didn't have to spend our lunch hours here.

Is there a sense that maybe we or somebody is
making too much of this, and that the consumers in the end
want tasty, good, healthy food at the cheapest possible
price, and don't tell us too much about how you are getting
it? I mean, God knows people mostly don't want to know how
today's food is being made. Maybe it is just more of the
same.

Michael?

DR. TAYLOR: Well, I can just speak from in terms
of consumer interest in animal welfare issues. I can think
of no better example than six days ago, the landslide
victory for Proposition 2 in California, with a healthy
25-point spread of consumers voting to essentially,
potentially increase the price of their animal products by
eliminating cages and crates for egg-laying hens, veal
calves, and breeding sows.

So, by a large margin, they voted beyond their pocketbooks and took on these other social issues. In fact, if you do look at the American Farm Bureau, they did a poll last year that found that the majority of Americans are opposed to these kind of intensive confinement systems. Three-quarters are in favor of passing legislation to improve the humane treatment of farm animals. A Gallup poll of 2008 found a very similar thing. About two-thirds of Americans want national laws improving the welfare of farm animals.

So I think this is really something that Americans will not only advocate for at the ballot box, but with their forks and their retail dollars.

MR. WEISS: Keeping in mind, of course, that this does not co-segregate perfectly with biotech versus non-biotech because some of the traits we are talking about, arguably, will benefit the animals themselves. So it will be interesting to see how that shakes out.

Here is an interesting question. Whose responsibility is it to fund health impact studies on short-
and long-term human consumption of genetically modified food products?

This has come up online in the FDA's docket where you can look at the comments that have been submitted so far, in several cases too, concerns that we have got a serious conflict of interest when it is the companies who are producing the data in the first place on which this decision is going to be made by FDA. FDA does not do its own research, of course. Then there is this big open-ended question of post-market approval or follow-up studies.

Who, if anyone, is going to try to keep track of whether there are any unexpected effects here?

Mike, is there any?

By the way, with regard to drugs, of course, we have all been watching the news over the last year or two, as so many safe and effective drugs have gotten either pulled off the market or gotten black box warnings because down the road, we have had some surprises.

DR. TAYLOR: Well, on the first part of the question concerning who should be investigating the research to understand the safety of these products, I think it is a joint public/private duty. There ought to be public
research that enables the regulators to know enough to ask
the right questions and to be able to validate the tools
that are used to answer the questions.

It is the model for FDA premarket review of
particularly drugs, whether human or animal, that the
companies generate the data, but it has to be within a
scientific context, the tools that, again, have been
validated in a way that is publicly acceptable. So that is
a dual thing.

The post-market issue, I haven't given this any
thought really at all until now, but in the human drug area,
we make decisions all the time at market entry where we know
it is a risk-benefit balance, and there is a human
therapeutic benefit, and we can never test enough to really
fully understand drug safety. So it is very legitimate, and
the new authority FDA has when empowered to do this, to
require a post-market data-gathering, to validate safety, to
better understand safety, you are going to have to show me
the GM animal that is conveying a sufficient benefit, so
that you are going to let it into the market with enough
uncertainty about safety that you would know what data to
try to collect post market.
To the extent that ever happens, it is obviously the company would have the duty to make that investment, but I see that as a very, very different issue and much less likely to be part of the debate for GM animals than human drugs.

MR. WEISS: You know, that actually plays into very well another question from the audience and gets back to a point that Scott had raised, that this audience member is asking you to go into in more detail, and that has to do with the possibility of actually tracking these animals, where they came from, from birth to the end of their cycle. It is obviously one of the things you would want to be able to do to some extent, if you were going to figure out at all what impact some of these animals are having on consumers because right now there is no such segregation, at least with regard to plants in this country.

Can you talk a little bit about what you mean by an ID system and what would be entailed, what would the benefits be?

DR. EILERT: The benefits, I would position the benefits in the context of the conversation today, but the benefits for a national animal identification program, one
in which from birth through harvest and processing of the animals, that we understand where the animal has spent his time, not just cater to or to enable marketing programs, but to monitor the health of the animals and to make sure that in cases of animal health issues, animal disease issues, that we can adequately control that.

So there is a great motivation to have a national animal identification program well beyond the advent of transgenics, and so what would that entail? What does a national animal identification program entail? It can entail a lot of things, but probably base some real principles around premise identification, much in the same way under USDA inspection, every facility that a food product is processed in, a meat or poultry product is processed in, there is a premise ID, there is an establishment number.

So we need to get into the point of having those premise identifications, having a chain of custody that is verifiable, so that in the cases of an animal health issue or in the case of a marketing claim or a supply-chain segregation claim, we can maintain the identification of those animals. That mandatory animal identification system
has been implemented in Canada, and it is something that we believe that long term is quite necessary, regardless of the evolution of biotechnology in the U.S.

MR. WEISS: And we are talking about, in some cases, what, tags that can respond to a radiofrequency ID?

DR. EILERT: Sure. Yes, the technology. Whether it is radiofrequency ID or bar codes, the technology is the tool. The enabler is really having the system, a premise ID in the chain of custody documentation, and having the responsibility on everyone in the supply chain to maintain those records.

MR. WEISS: It is just about 2:30, which was when we are going to end. I am going to squeeze in a couple more questions, and we will wrap it up.

I just wanted to follow up on that with you, Jamie, because it occurs to me that an animal ID system like that runs into complications with regard to the way our milk supply works in this country because there is a lot of pooling going on.

Is there a way that the milk industry has thought about that might be able to track back where milk was coming from, whether it is from genetically engineered animals in
an equivalent system, or is it just impossible the way we deal with milk in this country?

DR. JONKER: Well, I do want to say that National Milk has been in favor of mandatory national animal identification system as part of our collective insurance policy for our dairy industry in the event of particularly a foreign animal disease outbreak.

You do bring up interesting points about what happens with the pooling of milk. We have pooling of milk on the farm from all of the cows into one tank on the farm, and you can have pooling of the tank on that farm with several other farms into one trailer-load, and then that trailer-load can be off-loaded into a milk silo that may have another 10 milk-loads on it. So you can have this commingling.

I do think that as the market dictates the types of products that the consumer wants to have, that we will transform the way that we operate our abilities to provide consumers what they want.

We have seen that with the advent of the increase in the desire for RBST-free products.

MR. WEISS: Right.
DR. JONKER: There have been altering of pick-up patterns, so that you don't get the commingling of milk from cows that are from farms that use that technology versus farms that don't use those technologies.

MR. WEISS: Which then gets to the next question, not a question but a point that has come up with regard to other claims on food. We will see how the FDA and USDA, which regulates labels, deals with the issue of to what extent those agencies will allow labels that make claims such as non-GE, and of course, that is one area, we won't get into it now, where organic could become a big issue because transgenic animals and plants are not allowed to be considered organic under the organic rules here.

I am going to finish with one last question from the audience that I may direct to someone in the audience with the FDA, if you would like to deal with it. It just asks: FDA has published a draft guidance. What are the next steps in the regulatory process? Will there be a rulemaking, or is this it?

Does anyone here from FDA want to say just what is going to happen next, what we should expect?

DR. RUDENKO: Sure.
MR. WEISS: Let me introduce Larisa Rudenko who I have now flushed from her rear row, who is from the Center for Veterinary Medicine at FDA.

DR. RUDENKO: Thank you very much.

The next steps are to gather all of the public comments, to read through them all very carefully. We are monitoring them as they come in and taking a good careful look at them to attend meetings like this, hear what the public has to say, and then to finalize the draft guidance, which as you know, the draft guidance is simply a set of our best thoughts at this time as for recommendations to how industry can best meet their obligations and responsibilities under the Federal Food, Drug, and Cosmetic Act, the National Environmental Policy Act, and their implementing regulations.

At that point, a decision will be made as to whether or not we go final with the guidance. I don't know when that determination will be made or when the guidance will go final, and then we will stop and see where we are.

So we very much appreciate the opportunity to attend meetings such as this and to hear from everybody and
look forward to people's comments.

MR. WEISS: Thank you, Larisa.

I am just going to allow a last, maybe a half-a-minute each, if people on the panel want to make any closing points or comments, and then we will wrap it up.

John, anything left to squeeze in?

DR. PHILLIPS: I think I said all I need to say.

I would only close in saying that the opportunity to come and bring our animal data to the FDA has been a real pleasure. They fly the flag of approvals around the world.

I am not saying that because they are sitting in the back.

MR. WEISS: Yeah, this from a supplicant.

DR. PHILLIPS: As a supplicant, yes.

[Laughter.]

DR. PHILLIPS: So keep up the strong and rigorous analysis. We all need that.

MR. WEISS: Scott?

DR. EILERT: First of all, I just appreciate everyone's engagement and attention to this important topic, and secondly, I wanted to stress that while it may appear on the surface there would be competing interests and there would be even adversarial positions on this panel today, I
want to just make sure everyone understands what they heard because what I heard was that every one of the panel members had pretty much the same objective, ensuring a safe food supply, ensuring animals that are cared for and have not had a reduced quality of life, and ensuring an ability to feed an ever-growing population.

So I appreciate the chance to be in a dialogue like this and to work with the NGOs, the agencies, and other parts of the supply chain to achieve those goals.

Thanks for your time.

MR. WEISS: Jamie?

DR. JONKER: I would like to say ditto.

MR. WEISS: You can.

[Laughter.]

DR. JONKER: Just to reiterate, the dairy industry from the National Milk Producers Federation perspective is interested in having a mandatory premarket approval process, so that we can be assured in the event that a transgenic dairy cow comes to market, that the animal is healthy, that any products that may result from the animal are safe, and then we can let the marketplace decide where that role of that animal in the dairy production system is.
MR. JAFFE: I also want to thank everybody on the panel for coming today, and I guess my final comment is that people who aren't on the panel that might have helped in this discussion today, there were other developers who were invited that were retailers and other members of the food chain who weren't yet ready to talk publicly about this topic, and I think that says something. I think if this technology is going to move forward, the discussion has to get broader, and I hope that everybody here today will start that process of broadening the discussion in the Washington community and also bringing in the different interests that you all represent because I think that is a key to understanding the benefits and risks of this technology, ensuring proper regulation of it, and if these products reach the market, giving them a chance.

MR. WEISS: Michael?

DR. GREGER: I wanted to note that if anybody didn't get it, there is a stack of our white papers in the back or on the outside paper on our thoughts on GE animals, and for more information, you can go to FarmAnimalWelfare.org, which has my contact information as well, and we are very much looking forward to working with
industry on this issue.

   Thanks, everyone, for coming.

DR. TAYLOR: Well, I guess this session has
compromised for me that the issues really haven't changed too
much since 2002. I don't know of that is good news or bad
news. I am not sure what it means.

   I do, again, commend FDA for taking a step it
took. This issue of FDA having the tools it needs includes
statutory authorities and procedures that gain public
confidence. It also has to do with resources, which are
finally beginning to hear about, and FDA is getting some
additional resources.

   I am not sure what CVM is getting, but it takes
the investment to have the scientific capacity to do this
and to act promptly and all of that, all things we expect of
FDA, but I think society has been a little negligent over
the last decade or so in giving the resources. So I think
that has got to be seen as part of the picture to getting it
right here.

MR. WEISS: That is a great closing point. We can
all hope that the next four years, whatever your persuasions
are and wherever you are coming from do make our agencies
stronger and better able to do the jobs that we all ask them
to do for us.

Thank you all for coming to listen and be part of
this, and I hope you will keep talking about it and keep the
public education process going.

[Applause.]