

## PANEL 2

### REGULATION OF GENETICALLY MODIFIED FOOD -- PROTECTING CONSUMERS OR HAMPERING INNOVATION?

**MR. DELACOURT:** Good morning. Thank you for joining us for what promises to be a very interesting panel on the regulation of genetically modified food.

As you all know, advances in biotechnology have led to the creation of a number of remarkable agricultural products, including crops that are resistant to disease, insects, and certain types of herbicides. To some the advantages of such products are evident. To use Kent Walker's image from the prior panel, these would be advocates of golden rice to feed the Third World.

To others, however, the risks seem to dictate that regulatory authorities should take a more cautious approach. These would be -- again, borrowing one of Kent's images -- critics of so-called "Frankenfoods."

Hopefully, all of our panelists today will have insights into what we can do to bridge the gap here. That is, how we can chart a sensible course with regard to regulation while still enjoying all of the benefits that biotechnology has to offer.

Before introducing our panel, I would like to start by introducing myself. My name is John Delacourt. I am an Attorney Advisor with the Office of Policy Planning of the Federal Trade Commission. Prior to assuming that position, I was an attorney with Covington & Burling where I worked on a variety of antitrust and intellectual property litigation matters, including matters involving significant biotechnology licensing issues. I am also currently the Chairman of the Biotechnology Subcommittee of the Federalist Society.

Now, on to our panelists. Our first panelist is Dr. Sally McCammon. Sally currently serves as Science Advisor to the Animal and Plant Health Inspection Service of the United States Department of Agriculture.

In addition to numerous other responsibilities, she is head of the APHIS Biotechnology Policy Group and serves as the USDA's project contact on biotechnology to the National Academy of Sciences.

On the international front, Sally is the head of the delegation to the OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology. She has been involved in regulatory review and biosafety policy issues for over ten years, and we are very happy to have her with us this morning.

**Dr. McCammon.**

**DR. McCAMMON:** Thank you very much, John.

It is a pleasure to be here. I thought I would briefly cover the regulatory system in the United States, a little bit of the philosophy behind it, and the approach to its development.

The good news is that we have a sophisticated and complex system in which we review biotechnology products. The bad news is that it's very difficult to explain to people, both to the U.S. public and to explain internationally, because it is sophisticated and complex.

We do think we have a strong regulatory system. It was developed in the early eighties and articulated in 1986, with the publication of the Coordinated Framework for Regulation of Biotechnology. The coordinated framework took a couple of years to develop and its development was stimulated by concern over the first field tests. There were pictures in the national press of people in moon suits in California protecting themselves from the first field test of a small bacterium to prevent frost damage.

Concern over this test set up a chain of events in which the scientific community asked the federal government to look at how we might proactively set up a system to evaluate these field tests and the products that would evolve out of them. I say 'proactively' very determinedly because the U.S. government has been extremely proactive in developing a regulatory framework in this area. One of the reasons for this is to ensure that there is a process for orderly development of the product as the technology is transferred into the marketplace. Another is to deal with any public concerns over safety in the use of this technology.

The coordinated framework articulated several points:

First, genetically engineered organisms are the same as any other organisms. DNA is DNA, and it has to function compatibly in any organism that it's in.

Second, the product rather than the process should be regulated. This has been kind of a mantra of U.S. policymakers, but fundamentally what is evaluated is the entire product including the organism. It doesn't mean we don't look at the process, but the process is only one of many, many attributes that we look at when we're evaluating product safety. We look at the end use of the product, whether it is an animal or a pharmaceutical or a new plant variety for pest resistance.

Third, the existing laws provide adequate authority for regulating these products. These existing laws were put in place, many of them a long time ago, to deal with risks that our society has agreed that we need to manage – risks from pesticides, pests and diseases of agricultural products, and risks to food safety.

All of these points still hold true in our minds.

The major agencies and departments involved in regulation in this area are the U.S. Department of Agriculture's Food Safety Inspection Service and the Animal and Plant Health Inspection Service ("APHIS"). Obviously, the Food and Drug Administration ("FDA") and the Environmental Protection Agency ("EPA") are also involved.

The statutory framework that these agencies regulate under are, for APHIS, the Plant Protection Act, passed in 2000, and the Virus-Serum-Toxin Act, passed in 1913. The Food Safety Inspection Service regulates under the Federal Meat Inspection Act and the Poultry Products Inspection Act. EPA regulates under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), the Toxic Substances Control Act ("TSCA"), and the Federal Food, Drug and Cosmetic Act ("FFDCA"). FDA also regulates under the FFDCA.

The U.S. system is very flexible because these major statutes or acts are already in place. To implement them we develop new regulations when new products or new contingencies arise. In this system, it is much quicker and easier to develop regulations. Regulations can be developed in one to three years, generally. A new statute can take up to 20 years to get through Congress in its various iterations.

APHIS was the first to put out regulations for the products of biotechnology in 1987. The Food and Drug Administration put out a policy in 1992. APHIS modified their procedures as products moved from developmental field testing to commercialization. The EPA put out a regulation for microbial products in 1997 and this year put out their first regulation for plants. They cover plant incorporated protectants or pesticides in plants. The FDA has also released this year draft guidance for voluntary labeling of products and a proposed rule on pre-market notification.

So to summarize the Federal system: APHIS regulates the development and field testing of genetically engineered products -- primarily plants; EPA looks at genetically engineered products that are classified as pesticides; and FDA ensures that food products are safe and wholesome.

The regulatory system is risk-based. It is based on safety. It is science-based. It is flexible. It is predictable in that companies and researchers are provided some idea of what is required and in what time frame that they can expect a decision. This is important for their planning.

The system is transparent. I think that for most people in this room the transparency that this country has is just a given. Any other country, any other place in the world, has no understanding of what transparency really is when what they have is compared to what exists in this country.

For instance -- and I am sure that others on this panel will say some things about the European Union ("EU") -- the EU will hold stakeholder meetings to discuss issues and regulation of genetic engineering, but they hand-pick those stakeholders. Here, everything is open. If you have a public meeting, anybody is welcome to come. And, we have many processes from the development of the statute to development of regulations to decisions on specific products where the public and any interested party has an opportunity to provide input.

The products that we look at are plants that have agronomic improvements and product quality improvements. Pharmaceutical plants are coming on line. Vaccines have been out there, like rabies vaccine, for several years. Animals are coming on line -- fish, livestock and insects.

Depending on the product, different agencies are involved in their regulation. For

instance, a viral resistance trait in a food crop will be looked at by all three agencies. Herbicide tolerance in a food crop will be looked at by USDA-APHIS and FDA, but EPA will look at the use of the herbicide. An ornamental crop engineered to be herbicide tolerant will be evaluated by just USDA, with EPA looking at the use of the herbicide. Modified oil content in a food crop will be looked at by USDA and FDA. A modified carnation will be looked at by just USDA-APHIS. So what agency regulates depends on the end use of the product as well as potential risks.

I just want to mention briefly that there are other kinds of regulation that USDA has. Those are marketing regulations. Our Agricultural Marketing Service implements the Federal Seed Act, and they also implement the Organic Standards Act. Our Grain Inspection Packers and Stockyards Administration (“GIPSA”) has been working with industry on testing certification. These are voluntary marketing processes. And these agencies are also working on identity preservation systems with industry.

In conclusion, with the regulatory system that we have, we want to continue to assure transparency in decision making. We want to continue to ensure consumer and public confidence. This includes international credibility. Let me give you an example of the credibility that the U.S. system has. I was at a Codex Alimentarius meeting in Japan a year and a half ago and they presented the results of a domestic survey of confidence, and the Japanese consumer has more confidence in our U.S. FDA than they do in their own Ministry of Health.

We plan to continue our science-based safety reviews and increase the scientific and public advice we get and also increase our coordination between the regulatory agencies, because the issues are changing rapidly and becoming more complex.

Thank you very much.  
(Applause.)

**MR. DELACOURT:** Thank you, Dr. McCammon.

Our next panelist is Dr. Robert T. Fraley, Executive Vice President and Chief Technology Officer of the Monsanto Company. Prior to his appointment to that position, Rob served in a variety of other capacities at Monsanto, including as Group Vice President and General Manager of the New Products Division and as Director of the Plant Science Research Group.

Rob is a Fellow of the American Association for the Advancement of Science and has served as a technical advisor to numerous government agencies, including the USDA and the National Science Foundation. In addition, he has authored more than 100 publications and patent applications relating to advancements in biotechnology.

Dr. Fraley.

**DR. FRALEY:** Thank you. Good morning. I appreciate the opportunity to be here today.

So my comments today are going to be on the regulation of ag biotech, regulation broadly covering both the regulatory process for the registration and maintenance of the products from a science and public safety perspective as well as some of the issues and regulation from an intellectual property perspective. I want to focus predominantly on agricultural biotech, but a lot of the comments I will make will have relevance, I think, both for food and pharmaceutical applications.

I am going to try to cover a lot of areas. I can't promise to be quite as concise as Sally was, but I am going to try to do this pretty quickly and just hit the top lines, but there are a number of things that I would like to point out and make some comments on.

First, I would like to present some general background on biotech, because biotech means a lot of things to a lot of people. In one sense, the domestication of grains and animals from 5,000 years ago is part of a continuous process by which man has evolved our food sources. People don't realize that the early corn that today we grow across the Midwest originally started in Mexico and was probably smaller than your little finger, and that domesticated livestock -- cows -- from Mesopotamia were the size of dogs 5,000 years ago. So it has been that continuous improvement through breeding that has given us the food security that we have today.

Arguably, the discovery of DNA in the late 1950s by Frances and Crick has brought that to a new level in terms of both power and precision, because once genes were discovered and the ability to isolate specific genes was made possible, that allowed for very, very precise introductions of

new properties into living organisms.

So rather than breeding randomly and combining thousands and thousands of genes, it is now possible in the laboratory to use techniques to isolate a single gene, move it, and express it.

Probably the best and most elegant examples even today were the first experiments done in the 1980s to take the human insulin gene and express it in an e-coli so that suddenly now, patients around the world who suffer from diabetes could actually use the human form of the protein and not be restricted to horse seed or bovine pancreas of sacrificed animals.

The human growth hormone was never available for burn victims or for people with problems in terms of growth rate because it had to be extracted from the pituitary gland of cadavers. Today that gene -- again expressed in simple laboratory bacteria -- can now be produced literally by the truckload and used to address these important needs.

That is the kind of potential that biotechnology has. In agriculture, we are now seeing for the first time the ability to add specific properties to plants to improve their potential in terms of resisting disease and insects and to help in weed control, as well as to change their composition from a diet and nutrition perspective.

The science is moving very, very quickly. The first DNA in genes were isolated in the late 1970s. The first work in crop plants led to the introduction in 1996. And already, we can see that this technology will drive fundamental changes across the life sciences and literally change the way we grow crops, the way we produce food, and the way we deliver health care.

If you talk particularly from an agriculture perspective, it comes at a very important time. If you step back and you take a look at the challenge we face today, it's always the problem of the common, but world population continues to grow. The most conservative demographics say we go from six billion to eight billion over the next 20 years. And more important than just the outright growth in population is the fact that dietary upgrading is occurring dramatically across Asia and the tropical countries, which is increasing demand further.

To put all that in perspective, most estimate that over the next 20 years, the amount of food produced on the planet needs to double, and that is a challenging increase in productivity that, frankly, has never been accomplished, and that is all occurring at a time when there is going to be less land used in farming because of a number of issues, mainly loss of land to urbanization and city growth as well as some of the restrictions we're seeing in terms of water loss and other challenges.

So this is why biotech is so important, because it's the one new tool. We are going to continue to need advances in plant breeding and the use of fertilizers and the judicious use of crop chemicals. But fundamentally, those advances have played out largely across the globe and the big opportunity is from using nature's own approaches to increase the inherent productivity and yield of a seed.

Now, this technology is starting to have its impact. The first biotech products -- and I was involved in the first product launch back in 1996 -- were introduced in the United States. Today, there are over 120 million acres -- and I just saw a report this morning that has been corrected; there are actually 125 million acres of biotech crops that are grown now around the world.

This growth rate has been phenomenal. This growth curve represents the fastest adoption of any new technology in the history of agriculture, and as you fly across the United States today, 70 percent of the soybean fields or the cotton fields, one out of every four corn fields, is based on biotechnology to reduce insect pressure, to help control weeds, and many more things are coming. So the technology has had a profound impact, not only in the U.S., but increasingly around the world. I will show you later the list of countries where technologies continue to move.

Now, the reason for the adoption and the benefits have been very significant. First, often misunderstood about the technology is that the technology actually, even in this first wave of better insect-controlling and better weed-controlled technologies, has the key consumer benefit of reducing pesticide use. The Bt cotton technologies reduced insecticide usage by over two million pounds. We have seen a big reduction in the use of herbicides where we have replaced multiple applications with a single product.

So the pesticide reduction has been phenomenal, and that can reach a significant portion of the total pesticide use as the technology is further adapted.

This is important, because, as you can see, when you actually poll consumer concerns around the world, the number one issue in the back of consumers' minds when they talk about food safety is pesticide contamination of foods and ground water, and this first wave of technology goes directly to reduce pesticide usage and can contribute significantly to food safety.

The other benefit clearly that has driven this has been the benefit that growers have seen, and this technology has driven economics and huge cost savings. You can see the estimates in terms of returns per hectare. Those dollars, when you consider the typical farmer is farming thousands of acres, are huge economic savers that have driven the technology.

Also, the convenience of the technology, not having to spray with an insecticide, having the ability to reduce your inputs and use new agricultural practices have had environmental and convenience advances that have driven the technology.

Clearly this technology has a lot of potential and has already started to have a lot of impact. One of probably the most significant impacts that every major study in biotechnology has demonstrated is that ultimately the greatest beneficiaries of biotechnology will be developing countries because of the fact that the technology is as scale neutral as any new technology that has ever been developed.

It doesn't take a new manufacturing facility. It doesn't take new factories to utilize biotechnology. It takes a gene and the seed, which is the traditional package that every farmer in the world knows how to deliver appropriately, and as a result of that, this technology is already starting to have an impact in a number of countries around the world.

Similar projects that are the best known are the work to create virus resistance in sweet potato and cassava, which are two of the staple carbohydrate-producing crops in much of the world; and then, of course, the golden rice and golden oil and golden corn projects. It is now possible to take the gene out of the daffodil and put it into these plants to produce the Vitamin A precursor that can correct both vision deficiencies and immunological deficiencies in a significant percentage of the population around the globe.

So tremendous technology with benefits both in the developing and developed world, and, of course, from the point of view of the long term, this is really just the beginning. The advances that are going on in the laboratories of companies like ours around the world today are stunning from a point of view of the long-term benefits for health and nutrition.

Monsanto and other companies are already working, for example, on how to increase the level of antioxidants in some of the base foods because antioxidants are known to be very potent preventers of cancer, and we can increase Vitamin E, we can increase other antioxidants and increase the healthful percentage of that dietary uptake in the population.

Another excellent example that is being worked on is in soybeans. Soybeans contain a natural compound that can reduce cholesterol levels. We have identified that compound and the biochemical pathway that produces it. We can elevate the production of this naturally-occurring cholesterol-lowering compound and introduce it into cooking oils at a low cost and a high benefit.

Another example is many of you are very familiar with the cardiovascular benefits of fish oils, the polyunsaturated fatty acids. No one likes fish oils, and all those stories about cod liver oil and holding your nose were quite true. But what we've been able to do is take the gene out of the algae that the fish feed on and actually introduce it into a soybean plant, so now it's possible for a land-based source of omega-3 fatty acids that have very proven clinical benefits in terms of cardiovascular health.

So it's this long-term impact in terms of nutrition and health that I think ultimately is quite exciting. There are many, many other dimensions that occur, including the ability to have plants make things that they don't today. Bioplastics is getting a lot of attention. We think that the prudent and appropriate focus of biotechnology is that bioethanol, biodiesel, can be sourced renewably from crops for addressing future energy issues.

Now, Sally talked a lot about the regulation of the technology and I am not going to be redundant with what she said; I am just going to highlight it maybe more from a user of her services perspective and frankly say that I believe, and we register products all around the world, that the U.S. regulatory system is clearly the model. It has set the standard on a global basis in a number of ways.

We believe that the coordinated framework that was put in place in 1986 and

involves the USDA for the agriculture side, FDA for the food safety, and EPA for the environmental side, is a great model because it focuses the expertise and capabilities to be world class in these key functional areas, and the coordinated framework allows the sharing of information and an appropriate amount of built-in redundancy.

We know that these agencies have pulled together a system as we survey the public, and as you take a look broadly, the Canadian and U.S. regulatory systems, which are modeled after each other, have the highest level of confidence of any regulatory agency in the world.

Certainly there have been challenges and there have been improvements that have been made, but this base has really been a key contributor to the confidence in the system, and it is based on a lot of testing and a lot of analysis.

Sometimes critics will say that these products are not thoroughly tested or that they've not been reviewed. I helped to develop the technology on Round-up Ready soybeans, which is on 60 percent of the acres today. That technology was developed in 1983. The product was launched in 1996. We did 13 years of testing and evaluation and safety studies to bring that product into the marketplace.

Even with as much controversy as we have had in Europe, you can see from the quote here that basically says from this extensive analysis that the EU has done on biotech crops, the use of this more precise technology and greater regulatory scrutiny probably make them even safer than the non-biotech conventional crops that are in use today.

There is a lot of regulation outside of the U.S., and this is one of our challenges. These products not only get approval by the U.S., but because grain trade is global, they're approved around the world. This is complex, it creates lots of room for mischief and non-tariff trade barriers and lots of costs, and one of the things we clearly need to do is streamline this process, because these products are moving very rapidly around the world and you can see the change since the first products were registered in 1995 to the vast number of countries that are utilizing, regulating or involved in it.

The exception has been Europe, which put a blockade on the technology. But even there, you can see from this quote from the Commission that Europe can't afford to miss out on the opportunities that these new sciences are providing, and they are now starting to re-look and re-think their regulatory process and make it more science-based. There are, nevertheless, opportunities to do that faster and clearly more effectively.

A key issue is there's lots of regulation. We now need these regulations to be harmonized. Without that, there are going to be international trade disputes. And these kinds of barriers can become non-tariff trade barriers. We are facing some of that today, and international bodies such as Codex and others I think can serve to help on that front.

Let me make a couple of quick comments on intellectual property and then I will close off for questions. I think you all know that innovation is critical, that intellectual property fosters innovation, that innovation drives economic growth.

Biotech is just starting, but by all accounts that we see, the opportunity that biotech has to basically change the agricultural industry, the food industry, the pharmaceutical industry and biofuels in the future, the effect on society and the economic impact and benefits are going to be profound for decades to come.

If you take a look at the U.S., you can already see billions and billions of dollars of sales being created through biotech, nearly a half a million jobs over the last decade in the U.S. as a result of the growth in biotech.

Importantly, the reason this growth occurred was because of intellectual property protection. If you go through this sequence, genes were considered to be composition of matter and were ruled to be appropriately patentable under U.S. patent law.

In 1980, the Supreme Court, in its Chakrabarti decision, held that man-made interventions in living organisms were also patentable. That led to the clarification in 1985 that plants were patentable.

Just recently, the EU has reaffirmed their own view that genes and living organisms are patentable as well. As you know, there is a case before the Supreme Court that was just recently heard. We certainly expect the Court to support and affirm the opinion that biotechnology products are patentable.

You can see since those key legal decisions the incredible growth in the filing of patents, and I will just point out, because of the encouragement of investment in the United States, over 60 percent of the global patents filed in any area of biotechnology are filed from U.S. sources, so an incredible impact.

Clearly the reason for this is because biotechnology is so information-intensive. It is the knowledge that is added that is the key intellectual property that has to be protected. It is not the infrastructure. It is not how you build a manufacturing facility. It is not a trade secret. It's that vital information that makes intellectual property protection so important in this area.

It is easy to copy. It is basically, with today's technology, it is as easy to copy a gene as it is for you to copy a CD or a piece of software. So having additional protection that benefits the protection of intellectual property is crucial, and it is key to maintaining this industry of companies that has developed in the U.S. and other places around the world.

From an IP perspective, there are three critical leave behinds here. First, leveling the playing field. It's clear that not all countries push for intellectual property protection as the U.S. has. Every opportunity, particularly from a Latin American and Asian perspective, to strengthen intellectual property will continue to strengthen and encourage innovation.

Second, we need to resist any effort to limit the legislation. It has been the broad scope of the U.S. patents that has encouraged this incredible investment in R&D. Anything that reduces that scope is going to reduce the incentive for R&D investment.

Third, there is also an opportunity to extend some of the same enforcement opportunities under patent laws we have for other copyright and trademark to further strengthen the IP system.

So just to close, biotechnology has created a very fundamental change in both how we grow crops, how we produce food, how we deliver health care, and it is affecting all parts of society and really all parts of the economic chain.

From a regulatory perspective, the U.S. has clearly set the model. That is a model to build on and it is a model to build on globally as we look for harmonization, and from an IP perspective, this has been key.

That is why this industry has gotten off the ground. That is why the U.S. has such a strong position, and we are poised to create literally hundreds and thousands of new products that will make farming more environmentally friendly, make foods with great benefits, and create drugs that address the human condition.

Thank you very much.  
(Applause.)

**MR. DELACOURT:** Thank you, Dr. Fraley.

While we are doing our computer switch here, let me take this opportunity to introduce the next speaker, Dr. Val Giddings.

Val is currently the Vice President for Food and Agriculture of BIO -- the Biotechnology Industry Organization. Prior to joining BIO, Val spent eight years with the Biotech Products Regulatory Division of APHIS.

During that period, Val served as the International Team Leader and Branch Chief for Science and Policy Coordination. His substantial international experience includes serving on the U.S. delegation to negotiate the biodiversity treaty as well as the delegation to the Air Summit in Rio. Val has also served as an expert consultant to the United Nations Environment Program and the World Bank.

Val, take it away.

**DR. GIDDINGS:** Thank you. It is a pleasure to be here. I feel that I have to point out after that introduction that in all those international venues where I am indicated as having been involved or been an advisor, I want to say that almost no one has ever taken my advice, and that is at least a partial explanation for some of the stuff I am about to tell you.

What I want to do this morning is to give you a little bit of an overview of what kind of international regulation there is of products of agricultural biotechnology. So I am going to talk about that a little bit -- very briefly -- and then I will address some of the criticisms of agricultural

biotechnology products that underlie some of the international efforts that I am going to mention. Normally this is more fun to do if I follow Dr. Mellon.

DR. MELLON: I am here.  
(Laughter.)

DR. GIDDINGS: But I will anticipate a couple of her remarks, I think, and will be delighted to have a little bit of back and forth as we usually do. We're good friends even though Mardi is just really wrong-headed about a lot of this.

DR. MELLON: Well said.

DR. GIDDINGS: You will get your turn.

On the international front, to put things into context, a couple of cartoons from one of my favorite cartoonists, Sidney Harris: "Well, well, this should create a nice little wave of panic and hysteria." And "Run for the hills -- the recombinant DNA has escaped."

The first subject that usually comes up in terms of international vehicles to regulate products of agricultural biotechnology is the biosafety protocol under the biodiversity convention.

This protocol was concluded after about eight years of negotiation, at 3:40 a.m. on the 20th of January in the year of 2000, and the beast continues to slouch toward Bethlehem in the process of implementation. Ongoing meetings continued as recently as two weeks ago in Nairobi.

There are a lot of details involved, but the principal focus of the protocol is supposed to be on transboundary movements of living modified organisms that may have adverse effects on the conservation of sustainable use of biodiversity.

This is on the face of it a little difficult to understand because agricultural products of agricultural biotechnology, you know, what are they? Well, basically they are new crop varieties.

My academic specialty is in the genetics of natural populations. I am profoundly interested in and concerned with threats to biodiversity. But the literature does not record an example of a wild species driven to extinction by the substitution of one agricultural variety for another. Agricultural biotechnology products are not among the threats to biodiversity. They don't even emerge from background noise. We know what the threats are. They are not addressed by this protocol. Nevertheless, the protocol we have with us.

One good thing about the protocol is there are a couple of caveats that are built into the language of it. They are largely being ignored in the implementation process, so it will be very entertaining to see how it all plays out. But the protocol was supposed to not duplicate other international agreements. There are a number of those which are relevant. There is also clearly expressed intent to be consistent with the World Trade Organization disciplines.

What does the WTO have to say? There are those who argue that the WTO is not relevant to international trade in the products of agricultural biotechnology for the simple reason that it mentions none of them explicitly. This misses a fundamental point about the WTO. The WTO, particularly the SPS Agreement -- the Agreement on Sanitary and Phytosanitary measures -- and the technical barriers to trade agreements, those deal with measures designed to address threats to agriculture.

Those threats that the measures are designed to address can come from any source. It doesn't matter. The TBT and the SPS are clearly applicable. We may see this reconfirmed in WTO cases if events in Europe do not correct themselves in the not-too-distant future. But the WTO is clearly applicable.

Also, measures taken to control threats identified must be proportional and minimally disruptive of trade. These rules are science-based and they have given us a very reliable mechanism for dealing with disputes that arise in international trade, where often there are stalking horses that are the real reason for the arising of the disputes, and this helps us sort through them and address them in a coherent way.

Codex Alimentarius is the WTO standard-setting body for labeling. It is science-based, and that is a great help because some of the measures that had been put forward or proposed in various quarters to mandate labeling for foods derived from crops improved through

biotechnology would want to put some sort of a label on there without recognition of the moral imperative to make sure that labels are accurate, informative, and not misleading as required under U.S. law.

Fortunately, labels proposed for the ostensible purposes of providing consumers with information without appropriate scientific grounding and assurances to make sure they do not, in fact, mislead the consumers have not found strong currency in the discussions on these topics in the Codex, but there are discussions that are going on and will be continuing. So it is something to keep an eye on.

The International Plant Protection Convention defines measures and procedures to protect agriculture. It is science-based. It is implemented by national phytosanitary bodies. What happens is according to rules that are laid out and set down under the IPPC. The national phytosanitary bodies must identify particular threats and measures to address them in accordance with agreed principles. This has been very effective and, again, it is applicable to products of biotechnology.

Criticisms of agricultural biotechnology -- I don't want to give Mardi's talk, so I will truncate this, but unproven benefits in agriculture, substantial risks, available alternatives -- "very creative, very imaginative logic, that's what's missing."

The global adoption rates for crops improved through biotechnology have been unprecedented in history. Those who argue that the benefits have not been forthcoming would have you believe that farmers everywhere around the world are absolute and utter fools, incapable of making rational decisions on the basis of cost and benefit. You don't see a dramatic curve like this in the absence of benefits. They are substantial, they are significant. Dr. Fraley referred to a number of them. I would be delighted to pursue it further.

I've got a bunch of quotes here that I will whip through very quickly.

"The experience with golden rice suggests that genetic engineering opponents do not so much care about the environment and consumers and hardly about the fight against hunger and malnutrition in the Third World. Rather, they seem to want a radical war against these new technologies for political reasons." That's not from an industry spokesperson. That's from Ingo Potrykus, who developed these new varieties of rice, and he is an independent academic researcher from Switzerland.

Patrick Moore, former Green Peace co-founder: "Let someone come forward and state that the possibility of saving 500,000 children from blindness is a zero benefit."

"Genetic engineering is mainly an interest of humans who do not have enough to eat."

"In the balance, it is clear that the real benefits of genetic modification far outweigh the hypothetical and sometimes contrived risks claimed by its detractors."

"The campaign of fear now being waged against genetic modification is based largely on fantasy and a complete lack of respect for science and logic."

"Genetically modified organisms are being assaulted by a sophisticated, well-resourced and coordinated campaign conducted by a small clique of highly networked, media savvy professional activists funded by foreign money."

"The campaign against biotechnology is not a spontaneous grassroots movement, but a carefully planned and orchestrated effort."

Some of these folks make me look diplomatic.

"Instead of rejecting the solutions offered by science, we should change policies to assure the solutions benefit the poor. Condemning biotechnology for its potential risks without considering the alternative risks of prolonging the human misery caused by hunger, malnutrition and child death is unwise and unethical."

Anybody that wants copies, send me an e-mail. I would be happy to share them with you. I could go on for hours, but out of deference to my colleague, whom I've just mortally injured, I will stop now and look forward to your comments, Mardi.

Thank you.

MR. DELACOURT: Well, those final remarks should certainly give us all something to chew on.

(Laughter.)

Our next panelist, showing up just in the nick of time, is Dr. Margaret Mellon. Mardi is currently the Food and Environment Program Director of the Union of Concerned Scientists. She is also the Co-Editor of "Food Web" -- a public voice on food, farming and the environment -- and the co-author of "Ecological Risks of Engineered Crops."

Mardi serves on the USDA's Advisory Committee on Agriculture Biotechnology and teaches a course on biotechnology at Vermont Law School. Mardi is a regular commentator on genetic engineering who has appeared on ABC's World News Tonight, CNN, NPR, and has been quoted in the Washington Post and the New York Times.

Dr. Mellon.

DR. MELLON: Thank you. I am indeed pleased to be here in the nick of time. I always hate to leave Val without anybody to counter his eloquence, but indeed I do think he does head off in the wrong directions in very important ways.

I am here to represent the Union of Concerned Scientists, which is a small non-profit that deals in a number of issues where society and technology overlap.

My focus is on genetic engineering, which is the molecular based technology that transfers genes -- and the traits that they code for -- from one organism to another without regard to natural boundaries.

I want to say at the outset that our organization, which is made up in large part, although not exclusively, of scientists, is not opposed to genetic engineering across the board. Some groups are, but we are not. Neither are we, however, bowled over by it. We don't think that it's necessarily the solution to all problems. Nor do we believe it's a kind of inevitable next step to which we should all simply acquiesce.

We are somewhere in the middle. We believe that it's a genuinely new technology, a powerful technology that is not all that well understood. We believe that its applications ought to be looked at carefully and critically.

We would like to see an approach to the technology that looks at the benefits, the risks, and the proposed alternatives. We think that a critical attitude and sound science are central to all three inquiries.

Roughly speaking, if you apply this kind of decisional rubric to the pharmaceutical industry, I think you come out somewhat as follows:

The benefits of drugs produced through genetic engineering are compelling. They save lives. There is no alternative, no other way to produce a lot of those drugs. They are based on biological molecules that can't be produced in a chemical laboratory. So there are very few alternatives.

Now, there are risks associated with producing drugs, but let me note two things about those risks. First, they are borne primarily by the people who would get the benefits, and second, they are worth it. The small risks identified with drugs from engineered bacteria -- and sometimes, because all drugs are very risky, they're not so small -- are worth running in exchange for better health. UCS supports this application of biotechnology.

A similar analysis of the use of genetic engineering to produce diagnostic products and methods -- another important application of the technology -- yields a similar result. Again, there are clear benefits. They outweigh the risks, and there just isn't another way to do what this genetic engineering can do. And we support this application.

But, turning to agriculture, if you apply this decisional rubric to agriculture, you just don't come out in the same place. There are not compelling benefits associated with genetic engineering as it is applied in agriculture. There are alternatives to engineered products that are being ignored. And there are risks -- risks that are not well understood.

Because many of the potential harms involve release of organisms into the environment, the risks associated with agricultural biotechnology are not likely to be remediable. These are mistakes we will only make once. Because once out in the environment, organisms are very difficult, in most cases impossible, to get back. So long as agricultural biotechnology has only modest benefits, plenty of alternatives, and poses ill-understood, but potentially irremediable risks, UCS will remain wary of the application of biotechnology to agriculture.

One feature of UCS' approach to biotechnology is that it's information-intensive. One has to look at every application of the technology and think hard about what the benefits are, what the risks are, and what the alternatives might be. And in each case, one can only go as far as the scientific and economic literature allows you to go.

So I can't go through a "risk-benefit-alternatives" analysis for all biotechnology products today. But I would just like to take a few minutes to discuss the analysis that accompanied the recent EPA's approval of Bt corn varieties, in particular to support my disappointment with the benefits of ag biotechnology.

Now, it might surprise folks to find that the EPA, which is quite a friend of the technology, didn't find that there were many benefits associated with Bt corn. According to the EPA analysis, Bt corn does not raise the intrinsic yield of corn -- the yield that you would get in the best circumstances. In addition, there were no overall increases in farmer profits. There was not even an overall benefit of pest reduction associated with the use of the technology. The lack of pest reduction benefits might seem surprising in a pest control product. But the target pest -- the European corn borer -- is not generally treated with pesticides, perhaps only on 5 percent of the corn acreage. And the pest only poses a problem every four or five years.

In the years, when the pest poses a problem, there might be some benefits in terms of farmer profits, but those are on the order of \$10 an acre. During most years -- that is, the four or five when the pest levels are too low to pose a problem -- the calculated benefits are so small that even the EPA says it's probably not in the economic interest of farmers to buy the product.

Farmers appear to adopt the product as an insurance policy against high pest years, which might be reasonable for them. But for the rest of us, avoiding pesticide use on 5% of corn acreage is a modest benefit, at best. On the other hand, you may also be surprised to find that there are risks associated with Bt corn. As was originally suggested by a scientist from Cornell, one of the varieties of Bt corn was definitely a threat to Monarch butterfly larva *in the field*, and it has been pulled off the market. But the Agency did not unearth the risk. It only became aware of it when monarchs hit the front page of newspapers. A thorough two-year analysis finally done by outside scientists showed that most of the Bt-varieties did not present a risk to Monarchs, but one variety did. We were all just lucky that the high-risk variety was not popular.

Although we do not have time to discuss all the products in the necessary detail, the bottom line is that the current applications of agricultural biotechnology do not offer tremendous benefits. And that failure to live up to inflated expectations is one reason, despite Val's eloquence, that agriculture biotechnology is in trouble. It's in trouble in the U.S. It's in trouble all around the world.

The biotechnology industry's current predicament is partially of its own making. Agricultural biotechnology has been arrogant and dismissive of critics and other people who have concerns -- I think legitimate concerns -- about this powerful new technology. The industry has also used its political power to produce a weak and less than confidence-inspiring regulatory system.

But the situation is not entirely the industry's fault. Many small issues entailed in the acceptance of biotech ride on the surface of much larger issues here and abroad. These include: the vulnerability of our food system; the vast over-production of commodity crops in the industrialized world and the subsidies that they elicit; the desires of consumers to regain control over and know what's in their food, and to have some say about how it's produced; and finally the growing resentment of American hegemony around the world.

Many people feel biotechnology is being forced on them by the U.S., and they don't have the option to say no. Many farmers are vulnerable to multinational corporations wielding patents.

There are also connections between the debate about genetic engineering in agriculture and its application in humans. If scientists can clone cows, it's that much easier to clone humans. Cloning humans poses important issues that many people want to work through. But the fast pace at which biotechnology is developing in agriculture seems to short-circuit that discussion by making the technology seem inevitable.

Finally, there is ongoing debate about the persistent, genuine needs of the billion people in the world who are chronically undernourished. Agricultural biotechnology has sought to cast itself as an essential part of the solution to complex problems of global food security. For those

who don't agree that biotechnology is the key to solving those problems, there is concern that the biotech debate is diverting attention from the real problems and their solutions.

To return to an earlier point, agricultural biotech is particularly vulnerable to the cross-currents of these bigger issues because it has no constituency outside of the companies and scientists who develop and sell the products. And because its benefits are unimpressive.

So my advice to the industry is to look for new products with more compelling benefits, to start taking seriously the concerns of consumers and critics, and to be willing to engage in a longer, deeper, more complicated public debate. This technology is worth it. And in the long-term, perhaps the public may be willing to accept a version of agricultural biotechnology that does not dominate our food system, but has found a few niches where it is genuinely needed.

**MR. DELACOURT:** Thank you, Dr. Mellon.

And last, but certainly not least is Peter Barton Hutt. Peter is currently a partner at Covington & Burling, where he specializes in food and drug law.

From 1971 to 1975, he served as Chief Counsel to the Food and Drug Administration. Peter has served on a number of scientific advisory committees, including the Advisory Committee to the Director of the National Institutes of Health and the NIH Advisory Committee to Review the Guidelines for Recombinant DNA Research.

He is the co-author, along with Professor Richard Merrill, of the leading food and drug law case book. Peter has also taught courses on food and drug law at a number of law schools, including the Harvard Law School, where I had the distinct pleasure of taking his course in the Winter Term of 1996.

And I would have said that last part even if Peter had not agreed to appear on this panel.

(Laughter.)

Peter.

**MR. HUTT:** Thank you, John.

I am going to focus, obviously, on the FDA regulatory aspects of food biotechnology.

A little bit of history will be helpful. Sally alluded to some of this. FDA has been regulating food safety since the Federal Food and Drugs Act of 1906. That law was superseded in 1938 by our present law, but basically the agency function of regulating food safety was unchanged.

From 1906 to 1958, there was no premarket approval of food ingredients or food products. In 1958, Congress divided the food world, if you will, up into two categories: ingredients that are generally recognized as safe. "GRAS" or, as we all call them, "GRAS ingredients" do not require premarket approval. Ingredients that are not GRAS require pre-market approval.

Most of our food supply fits into the GRAS category. Most of it has never been tested and never been approved by FDA or any other government agency. It has existed for years as generally recognized as safe, and new ingredients are also permitted under this statute without premarket approval if the manufacturer and interested scientists conclude that those ingredients are GRAS.

It is not, as many people misunderstand, a total premarket approval approach. I repeat: most of our food supply has never been tested or reviewed by the government.

With the advent of recombinant DNA, FDA decided to be quite conservative. They set up a completely voluntary consultation process, as they called it, under which anyone interested in bringing a new food ingredient or product to the market -- a new food variety or a modification of a traditional food, using either breeding techniques or recombinant DNA -- could come to FDA for a consultation. FDA reviews the data and FDA provides a letter saying that they do or do not object to marketing the food as GRAS, again, "generally recognized as safe."

In the past roughly ten years that this has been in place, more than 40 ingredients or products -- perhaps 50 by now -- have gone through this process. FDA has been satisfied with every one of them. More importantly, no product of recombinant DNA and related technology has come to the United States' food market without going through that process. In short, it's a voluntary process that has been used by industry 100 percent of the time.

Some foreign countries have raised question about the process because it is not

mandatory. The fact that it is de facto mandatory is not enough. Therefore, FDA last year, as Sally mentioned, put a proposal in the Federal Register to make the voluntary process mandatory.

The United States food industry has endorsed that proposal. The United States food industry has said they do not care whether the process of consultation is voluntary or mandatory. They will participate no matter which way it goes. And they continue to participate today.

My conclusion is that the system is working exactly as every one of us would want it to work. FDA is reviewing safety, the industry is acting responsibly, science is dictating the final conclusion of FDA, and the process actually is working far better than anyone could have dared hope.

Let me turn to food labeling, which has been probably more controversial than the food safety side. FDA has concluded from the beginning of recombinant DNA food that, absent some safety question, there was no reason to label any of these new foods as being the product of genetic engineering or recombinant DNA or biotechnology or anything else of that type.

Let me go back again and give a little lesson in history of the development of food labeling in our country. Under the original 1906 Food and Drugs Act, there was no mandatory labeling of any kind, believe it or not. You did not even have to put the name of the food on the label if you did not want to. (I think most people did.) It was not until 1913 that Congress enacted what was called the Gould Amendment to require net quantity of content labeling.

Then in 1938, when Congress enacted the current Federal Food, Drug, and Cosmetic Act, it determined that four things must appear on the label: the name of the food; the ingredients (and those ingredients are there for a safety reason, not just for a consumer right to know, so that people suffering from an allergy will be able to know what ingredients and what food products they should avoid); net contents; and the name and address of the manufacturer. In 1990, Congress enacted a new law making what FDA had previously done by regulations in the early 1970s -- namely, to require the familiar nutrition labeling you see on all your food -- a matter of statutory rather than administrative requirement.

That leaves an enormous number of constituents in food -- that we know are in the food -- that do not appear on the food label. I will name just ten of them to give you an idea of what we are talking about here:

1. Processing aids. These are chemicals used to process the food that are there in trace quantities in the final food but serve no functional purpose. They are not labeled.
2. Ingredients that migrate from food machinery. We know they are there, and we can quantify them. They are not labeled.
3. Ingredients that migrate from packaging. FDA, in fact, regulates these. We know they migrate. They are not on the label.
4. Pesticide residues.
5. Animal drug residues.
6. Flavoring substances.
7. Environmental contaminants, like dioxin and PCBs.
8. My favorite, what I named "unavoidable natural defects" -- namely, the number of fly wings in a pound of butter, the number of rodent pellets in a pint of wheat, and other unmentionables.
9. Nutrients other than the four that are listed in nutrition labeling.
10. Trace natural constituents.

All these things are in the food supply. They are not declared on the food label. Not a single one of them.

There are other characteristics of food other than the derivation from recombinant DNA that are not labeled. For example, interaction with drugs, the method of agricultural production, and methods of processing and manufacturing are not labeled.

If we were to put all this information on the food label, it would be a pamphlet or, indeed, a small book. FDA has determined we put things on the label that are of health and safety importance. The fact that something has been the subject of selective breeding -- which food has been, as Rob said, for years -- or the fact that it is made using recombinant DNA technology is not on the label. Two courts have now upheld FDA's position. One of those said it would be unconstitutional to require a manufacturer to put this kind of irrelevant information on the label.

So it appears to the courts, and it appears to the public except for a few people -- a

vocal minority -- that this is not health and safety related, not important, not relevant to consumer purchasing decisions, and should not clutter up our labeling.

In short, I think FDA is doing a fine job.

MR. DELACOURT: Thank you, Peter.

Well, that was quite a bit of material, so I think it would be best to move right to questions. I think there are going to be a lot of them.

Go ahead.

AUDIENCE PARTICIPANT: Yes. I have two questions, Dr. Mellon. The first question is, if we did not have bioengineered food, how would we feed the world? And secondly, what are the specific risks to humans from ingesting genetically engineered food such as Bt corn?

DR. MELLON: The first question is important and difficult to answer in short time because agriculture itself is so complicated. But let's try. To begin, the name of game in agriculture is surplus. We live in a world in which agriculture is enormously productive. U.S. agriculture produces more than we can either eat ourselves or sell to the people in the world who can afford buy it. The chronic surplus of commodities like corn, wheat and cotton drives prices down and leads to subsidies, depending on the year, of as much as \$20 to \$30 billion.

We just passed a bill in Congress -- which, by the way, did not mention feeding the world or caring at all about the needs of the world's hungry -- that envisions something like \$120 billion in subsidies -- am I right? -- over the next decade. The legislators project these subsidies at that level because economists believe that surplus conditions -- and low prices -- are going to last far into the future. So the question is, how did U.S. agriculture get to be so productive? Well it wasn't genetic engineering, which so far has no products that increase the intrinsic yield of crops. The answer is conventional breeding, an amazingly powerful, often neglected, technology.

The question should be, "how do we put the technology that made us so productive at the service of the nearly one billion people of the world who are really hungry?" Instead we are asking about agricultural biotechnology -- a very expensive new technology that requires premium prices (and patents) in order to pay for the underlying research. But there is no evidence right now that agricultural biotechnology can do anything fundamentally better than the conventional technology.

This notion that somehow conventional breeding has run the course, is exhausted, and that if we don't pass the baton to biotech, there is no way to feed the three billion additional people we expect over the next 30 years--has no scientific justification.

But food security is a complicated issue. And I think pursuing selected applications of biotechnology might make sense. But new biotechnology products would fall about number 15 on the list of important things to do to help the world's hungry and undernourished.

Higher on the list would be not subsidizing our corn and cotton. That would help keep prices up and developing country farmers on the land. Or we could invest in infrastructure -- roads, warehouses and machinery. We could assist international agricultural research establishments that are currently suffering from lack of funds.

As I said before, developing some biotech products may be on the list, but they are in no way essential, and nowhere near the top of the list. My fear is that by focusing all of our interest -- the little bit of interest that the U.S. actually pays to feeding the world's hungry -- on something that's so far down on the list of solutions, we undercut our ability to do something meaningful.

On the human health risks of corn, we know that the Starlink corn variety went through review by two different scientific advisory panels, neither of which gave it a clean bill of health. So the possibility remains that the Bt protein found in Starlink is an allergen. Although Starlink is off the market now, its story shows that developers do bring products to the market that could pose human health risks. I don't think that those health risks are going to be serious. I see no rationale for assuming *all* products of biotechnology are going to pose health risks.

But I do not have the level of confidence in these views I would like to have. I am concerned about the following fact: that in the peer review literature, there are only a handful of

studies that directly compare genetically engineered food to non-genetically engineered counterparts to see whether there is a difference. For the most part, we don't have strong body of scientific literature on which to base a conclusion that genetically engineered food is safe and we don't need to worry about it.

And I am really concerned about the voluntary nature of the approval process for biotech foods

MR. DELACOURT: Actually, I know that some of our other panelists will want to do a follow up on that, so I will ask them to briefly do so.

Do you want to start, Val? I saw you shaking your head.

DR. GIDDINGS: Well, there are some things that Dr. Mellon said that I agree with, particularly about the sorry state of public funding support for international agricultural research centers and things like that. But, you know, I filed that as an example of how someone can be half right and all wrong.

If Dr. Mellon were correct with her criticisms about the lack of value, the lack of benefit of agricultural biotechnology and all the complications and so forth that she cited, then, well, if I held those views, I wouldn't be investing my career in opposition to biotechnology. I would sit back and let market forces do their job, because they certainly would.

The graph that I showed you with the exponential upward curve is eloquent rebuttal in a way that is very difficult to overcome of the central thesis of her remarks, and I can go on for hours, but I will stop.

MR. DELACOURT: Do any of our other panelists have anything they would like to add?

DR. FRALEY: Just a couple of comments.

The agricultural industry in the U.S. is probably the least subsidized major industry in the world when compared to the subsidies that go into petrochemical, and subsidies that go into the health care system. It represents a huge component of our exports and our GDP. So the subsidization that occurs is trivial on the scale of that industry and I think very well justified.

Demand for these grains -- I must be looking at different charts, because the vast consumption that has occurred of the corn and soybean crop, the ending stocks are less than going into the year, the demand for grain on a world basis is quite high.

I think, though, the most important thing to focus on is the safety of the technology. There are thousands of pages of studies and tests, and not just reviewed by the U.S. system, but every major regulatory agency in the world including the European regulatory systems, which have approved the Bt corn technology and Roundup Ready soybeans. The Canadian regulatory system, Japan's system, and Singapore's have all found this technology to be absolutely safe and, as the European report mentioned, probably even safer than conventional foods because of the greater precision and greater scrutiny.

Here in the U.S. today, 70 percent of the soybeans, a quarter of the corn, 70 percent of the cotton is based on biotechnology, and the CDC reports not even a headache or an upset stomach. This technology has been proven safe in the laboratories, it has been proven safe in the fields, and it continues to be proven safe every day, and the benefits are significant. The rapid adoption, the potential for health care mediations I think are important.

The system continues to evolve. The oversight gaps that have been identified in terms of the pre-market notification, in terms of the labeling system are all being addressed and improved.

I think even the Starlink example that Mardi highlights is actually an example of the system working quite well. The Starlink corn that was misused by its originator last year was reported widely.

If you consider the impact and the consequences and what has occurred, less than a year later, that product has been taken out of the market. There are virtually no residues of that in the grain system. It has been very much reduced. Manufacturers have recalled product with any

detectable residues.

I don't think the underlying assumption that we have a choice as to whether the technology is going to be used or not is valid. Once a human society creates something, it then works on how we will develop it -- how we will use it. So it's not a question of are we going to say yes or no to the technology. It's how do we use it wisely and what are our choices in use of it.

From the perspective of safety, the technology is actually allowing us to have a rationale approach to determining safety on a variety of different levels. We now have the techniques to, let's say on the environmental level, go from the molecular biological level all the way to ecosystems, and this was a critical aspect of the knowledge we needed and still need to make assessments on a broad scale level.

On food safety, I think the technology is allowing us to actually delve into what it is that we need to know about safety.

So from my perspective, the question about the technology is not yes or no, do we use it or not. Obviously from the graphs and charts that were shown, it is being used. It's how do we use it wisely and how do we assure that those products that are out there are safe?

**MR. DELACOURT:** We will move on to the next question. Sir, yes.

**AUDIENCE PARTICIPANT:** Informational question. What's the status at FDA or elsewhere today with respect to cloned animals? Can beef or lamb from a cloned cow or sheep be sold for human consumption?

**MR. HUTT:** The answer is no.

**AUDIENCE PARTICIPANT:** Is that an FDA . . . .

**DR. MCCAMMON:** That's both FDA and USDA combined. I don't think you need to go through all the laws and regulations and controls, but the answer is a flat-out no.

**DR. MELLON:** They are scrambling. They were not prepared for it. They don't have a policy. They don't have regs. They just say "for the time being, don't do it."

**DR. GIDDINGS:** They have a policy and regs and a law and it has all been in place, and they're not scrambling.

**DR. MELLON:** No. Not on clones.

**AUDIENCE PARTICIPANT:** I would like to ask Dr. Fraley, is there promise in biotech to help us deal with what is on everybody's mind -- anthrax, smallpox and other plagues?

**DR. FRALEY:** Well, there are probably people here who are more qualified. I know Val has been part of BIO's effort to pull together all the efforts.

Part of the reason you're being able to see such quick analysis and detection is that the tools of recombinant DNA are allowing the identification of the strains and the stereotyping. People are starting to put into place technology for rapid sensing and monitoring of that technology.

Of course, I think it's important to just step back. Almost every new drug that comes out of the FDA today is based on biotechnology. It's either a recombinant protein itself, it has been identified because the gene product has been set up as a screen in a laboratory, or it is used in the manufacturing process. So many of today's modern antibiotics are based on a biotechnology origin.

I think we often overlook the pharmaceutical implications, but from both the diagnostic and treatment perspective, long-term immunizations, there is a lot that the industry is offering. Val, I know you've got a task force to pull all that together.

**MR. DELACOURT:** Does anybody else have a comment on that? You have a

question? Okay.

**AUDIENCE PARTICIPANT:** The law of unintended consequences comes into play with some of the bioengineered products -- for example, the pesticides. Foods are, obviously, different from pesticides, but is there any chance, with the law of unintended consequences, of producing a super product which would then not be controlled? I am just asking the question.

**DR. MELLON:** You should tell him about the mouse-pox.

**MR. DELACOURT:** Go ahead.

**DR. MELLON:** There are examples of scientists who have put together bacteria that were not expected to be pathogenic with new proteins that were not expected to be harmful and have come up with very virulent bacteria. In the case of the mouse-pox incident in Australia, scientists came up with a microorganism against which they could not produce an effective vaccine. They did this wholly by accident. No one was trying to produce a new weapon for bio-warfare. The research was intended for a beneficent end.

But there is no doubt that when you've got a powerful technology that allows you to cut and splice, put together bits and pieces of biological material that are not put together in nature and have never been put together before, that you do run the risks of creating novel, harmful organisms. It has happened and I think we need to accept it.

It doesn't happen very often.

**AUDIENCE PARTICIPANT:** What is the industry's side on this?

**DR. GIDDINGS:** If I may, the case that Dr. Mellon cites is true. It is also true that it was discovered before anything happened for reasons which I will get into in just a second. But the truth of that case is overshadowed by the extraordinary remarkability of that situation. It is the exception which, in fact, proves the rule, that those sorts of things just don't happen commonly.

A couple of the quotes I skimmed over very quickly. "Genetic engineering opponents resort to the precautionary principle in research. They demand that all risks be fully excluded." I do not think that this principle has been observed more strictly in any other technology right from the start.

Potrykus also said, "We can count ourselves lucky if all the other technologies we use daily without even thinking about them came close to genetic engineering in terms of safety."

It is true that you can use biotechnology to do something evil, but you know what? The real benefit, the real relevance of biotechnology here is that it enables us to do some things in response to the previous question. With bioterrorism, with anthrax, what do we really need? We need two things: one, the ability to detect rapidly so that, number two, you can treat affected individuals. Everyone recognizes what biotechnology can do on number two. Number one is the real crux of it. That's where our real Achilles heel is right now.

The DNA chips that have been developed to use in high throughput screening to look at hundreds of thousands and tens of millions of recombinants in different variations to find the ones of value, that technology can be in a relatively trivial sense adapted fairly quickly to produce diagnostic techniques to help us with exactly the societal challenge that we face today in bioterrorism. It is being done now and, though it won't be a silver bullet to solve the root problem, it will certainly be something that will enable us to manage it much more effectively in the not-too-distant future.

**MR. DELACOURT:** Okay. Unless -- do you have a comment?

**DR. MELLON:** That is one of the applications of the technology that we would wholeheartedly support.

**DR. McCAMMON:** I have just one additional, not quite so controversial point. One of the reasons why developers or researchers have to do so much field testing and evaluation is

because most organisms are damaged by manipulation, so they're less fit and they're less able to survive. They're less able to even reach the same standards of performance as their progenitors, or their parental lines if they're plants. Microorganisms, insects, other kinds of organisms actually have less ability to survive and it takes the long research process to even assure that your product is as fit as the parental organism.

MR. DELACOURT: Well, unfortunately I think we have run out of time. Actually, we've already run a bit over. So I would like to thank all the panelists. I think it has been a very productive discussion.

(Applause.)