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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

BIOTECHNOLOGY IN THE YEAR 2000 AND BEYOND
PUBLIC MEETING

Tuesday, November 30, 1999

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P R O C E E D I N G S

Welcome and Opening Remarks

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3 MR. LEVITT: Good morning. My name is Joseph A.
4 Levitt. I am Director of the Center for Food Safety and
5 Applied Nutrition here, at the Food and Drug Administration.
6 It is my pleasure both to be hosting and chairing this
7 meeting, and to be welcoming all of you here today.

8 This, as you all know, is the second of three
9 public meetings on foods produced by utilizing the tools of
10 modern biotechnology, sometimes called genetic engineering
11 or bioengineering.

12 As FDA Commissioner, Jane Henney, noted at the
13 Chicago meeting, we knew there would be keen interest in
14 this issue but, to be honest, we really did not anticipate
15 it quite at this level, which explains our need to obtain a
16 facility with a larger seating capacity. I apologize for
17 the inconvenience this change may have caused, but I think
18 if it means we can all be together in the same room it will
19 be well worth it. We tried diligently to contact everybody
20 directly that had signed up for the meeting, either by
21 telephone, by e-mail or by fax, and we hope that we were
22 able to reach everybody. We also have people posted at the
23 other people, if people do go to the wrong place, and we
24 will welcome them here later.

25 As I mentioned, today's meeting is the second of

1 three public meetings that FDA has planned on this topic.
2 The first public meeting was held a little more than a week
3 ago, on November 18th, in Chicago, Illinois. That meeting
4 included 11 panelists representing diverse viewpoints, 84
5 scheduled speakers and 96 press representatives. There is
6 clearly a lot of interest. More than 300 individuals also
7 observed the meeting at the overflow room and, happily, here
8 we have a larger room so we don't have the need for an
9 overflow room here. The third meeting will be held in
10 Oakland, California on December 13th.

11 By way of introduction, and to ensure consistency
12 between the three FDA public meetings, my opening remarks
13 will mirror those very closely that were provided by
14 Commissioner Henney in Chicago. As she did, I would like to
15 take a moment to stress that we, at the Food and Drug
16 Administration, are very pleased to have this opportunity to
17 share our experience with you and to listen to your views on
18 these very important subjects.

19 We recognize that there is not only a great deal
20 of interest in this topic, but also that there are widely
21 differing and, admittedly, very strongly held views on the
22 subject of biotechnology. While, at FDA, we wish to listen
23 to everyone, we also ask that we all listen to each other so
24 that the community at large can gain a better understanding
25 of the spectrum of use, and I know that actually in this

1 room I chaired a number of public meetings and have really
2 come to really see the value -- as I usually say at the
3 beginning, "I'll make a deal: I'll listen to each of you if
4 you all listen to each other" -- and I have found that that
5 really has helped a lot in terms of sometimes bridging the
6 views and gaining a better understanding across the board,
7 and I look forward to that pattern continuing today.

8 Now, FDA has a long history of public health
9 protection, as you all know. Our current law dates to the
10 early part of the century. Over the years, we have faced
11 many new developments that affect the food supply. For
12 example, in the 1950s the use of preservatives and other
13 chemicals in food led to concerns of our food safety. More
14 recently, FDA has been in the forefront of efforts, as part
15 of the President's Food Safety Initiative, to reduce food-
16 borne illness.

17 Throughout its history, the Food and Drug
18 Administration has based its regulatory decisions on sound
19 science with protection of the public health as our foremost
20 criterion. This is central to FDA's mission and tradition,
21 a tradition that continues with FDA's oversight of products
22 developed using modern biotechnology.

23 Now, let me briefly describe our efforts in the
24 area of biotechnology, and after I have finished Dr. Jim
25 Maryanski will speak much more extensively to this. In

1 1982, FDA approved a new insulin product, the first consumer
2 product developed using modern biotechnology. Since that
3 time the agency has had extensive experience in evaluating
4 the safety of products developed using this new technology.
5 The use of the tools of biotechnology in foods began in the
6 mid-1980s.

7 FDA completed its review of the safety of chymosin
8 or rennet preparation, the milk clotting enzyme used to make
9 cheese, in 1990. At that time, FDA received no public
10 comments about the safety of this ingredient. Recently,
11 however, the use of the tools of modern biotechnology to
12 produce new varieties of food crops has raised a number of
13 questions about the environmental effects of these crops and
14 about the safety and labeling of foods derived from them.

15 I should note that some questions, such as those
16 regarding human health and food safety and feed safety, as
17 well as food labeling, fall direction under FDA's authority.
18 However, others such as those regarding environmental safety
19 and the effects on the plants themselves, generally fall
20 under the authority of other agencies or departments of the
21 U.S. government, such as the Environmental Protection Agency
22 or the U.S. Department of Agriculture. Suffice it to say,
23 today we will be focusing on those issues that fall under
24 FDA's jurisdiction.

25 I would like to take this opportunity to briefly

1 explain how FDA oversees the safety of foods developed using
2 the tools of biotechnology, and to briefly share the
3 experience that we have had in evaluating the safety of
4 these foods over the past five years since the first such
5 whole food, the Flavr Savr tomato, entered the market.

6 FDA introduced our current policy for regulating
7 foods developed using the tools of biotechnology back in
8 1992, after an extensive scientific review. The policy was
9 discussed publicly during a joint meeting of FDA's Food
10 Advisory Committee and Veterinary Medicine Advisory
11 Committee in 1994. Since that time, firms have completed
12 food safety discussions with FDA involving over 40
13 consultations on new varieties of foods made using the tools
14 of biotechnology.

15 Now, as Dr. Henney articulated clearly at the
16 Chicago meeting, we believe that our policies and processes
17 in this area are well-grounded in science, and that we have
18 an excellent track record in applying our policy. We
19 believe that our oversight has been substantive, credible
20 and appropriate. We have now had five years of experience
21 with our consultation process. In a few minutes you will
22 hear more from FDA about the specifics of our experience,
23 the testing that has been performed by developers of new
24 varieties, the kinds of information that have been reviewed
25 by the agency, and the regulatory and scientific grounding

1 for our approach to oversight of these products.

2 It is our goal to have our review and regulatory
3 processes be as open and transparent as possible. We seek
4 each of your views about whether we need to consider making
5 adjustments to our current system in order to attain those
6 goals.

7 Now, because of the recent attention that has
8 arisen, we feel it is a very appropriate time to review our
9 experience and solicit views from a variety of interested
10 parties. We want to hear your suggestions on how we might
11 improve our approach to safety assessment as well as how
12 disclosure of information to the public would be best
13 achieved.

14 Now, let me take a moment to briefly explain the
15 format and logistics for today's meeting. This morning we
16 will focus on issues concerning the safety assessment of
17 these foods and FDA's regulatory oversight of them. There
18 will be a brief overview of our current approach to safety
19 assessment and the experience that FDA has had over the last
20 five years, and FDA representatives will provide that. We
21 will then ask our invited panelists to discuss issues
22 related to questions that we believe will help FDA evaluate
23 its current approach to safety assessment. So, we have both
24 a presentation of what we have been doing as well as views
25 from others on how we have been doing and ways we might

1 improve and strengthen the system.

2 This afternoon the focus will shift to issues
3 surrounding disclosure of information to the public. Again,
4 a brief presentation will be provided by FDA, followed by a
5 panel discussion. Finally, we have reserved nearly three
6 hours later this afternoon to hear the views of as many
7 members of the audience that signed up ahead of time as we
8 possibly can. However, due to certain time restraints we do
9 need to conclude our meeting promptly at seven o'clock p.m.
10 Because we want to ensure that everyone is able to present
11 his or her views, we are asking that all those presentations
12 be limited to two minutes. Again, we did this in Chicago
13 and actually the system really works.

14 When you checked in this morning, all of those
15 that are presenting this afternoon, you all should have
16 received a folder with a number on it. That number
17 indicates the order in which public presentations will be
18 made, and we will go through the logistics of that this
19 afternoon on exactly how to go about doing that.

20 Now, because we have limited time for public
21 comment at the microphone, I would like to remind everyone
22 here that we also welcome written comments. We have
23 established a public docket that will display all the
24 information that the agency has received from all its public
25 meetings. The FDA home page highlights these public

1 meetings and provides the latest registration information,
2 as well as easy access to reviewing pertinent information
3 and submitting comments directly through the Internet. As
4 many of you know, and hopefully all of you will know when
5 you leave today, the FDA home page is very simple:
6 www.FDA.gov. We are also transcribing the three public
7 meetings on this topic. The transcription of each meeting
8 will be made available in the docket and on the Internet as
9 quickly as possible, and our goal is to do that within 15
10 working days of each meeting. Information about how to
11 access the public docket and submit comments is in your
12 registration packet which you should have received on the
13 way in, if not, you can get one at the break, as well as on
14 the FDA Internet home page that I already referenced.

15 Finally, just before we begin, I would like to
16 extend a special thank you in advance to the members of both
17 our panels for agreeing to come and share their views with
18 us, with you and with each other. We have attempted to
19 assemble panels with members who represent the spectrum of
20 interested parties. Each, no doubt, has strongly held views
21 and useful information for all of us to consider. We have
22 relied in large part on umbrella organizations, including
23 consumer organizations, professional societies and trade
24 groups, to represent their members or to identify for us
25 panelists for this and future meetings, and for their

1 cooperation we thank them. We trust that the members of the
2 panels will express a diversity of views, explaining those
3 views and establishing a dialogue among the panelists to
4 ensure that the issues are fully disclosed.

5 I would also like to add my thanks, along with
6 those of Commissioner Henney, to all of the FDA staff who
7 have devoted a great deal of time and energy to making
8 today's meeting possible. That includes our staff at FDA
9 headquarters and, in particular, our employees in the Office
10 of Consumer Affairs, as well as our field staff, especially
11 those from the FDA Chicago district as well as the Baltimore
12 district offices. Their flexibility regarding the many
13 logistical challenges raised by today's meeting are
14 certainly greatly appreciated. Also, as I mentioned before,
15 I have held several meetings in this room and I can tell
16 you, it has never looked better.

17 FDA is primarily here, again, to listen and to
18 answer questions. Our goal is not to reach a conclusion by
19 the end of the day. We are engaged in the process of
20 listening, not pronouncing. Therefore, we will not engage
21 in debate on these issues primarily because we want to hear
22 the views of others.

23 I would also note that FDA is in litigation over
24 this policy, and we need to be respectful of the court
25 decision-making process as well.

1 Today's discussion and those that will follow will
2 no doubt stimulate our thinking. I welcome your individual
3 input and our collective working together. Again, thank you
4 very much for your attention during these introductory
5 remarks.

6 Let me now take a moment to introduce my
7 colleagues on the FDA panel. On my right is Mr. William
8 Hubbard, Senior Associate Commissioner for Policy, Planning
9 and Legislation in the Office of the Commissioner. To his
10 right is Dr. Stephen Sundlof, Director of our Center for
11 Veterinary Medicine. To his right is Miss Catherine Copp,
12 senior lawyer in our Office of Chief Counsel. At the far
13 end of the table is Dr. James Maryanski, the Biotechnology
14 Coordinator in my Center, the Center for Food Safety and
15 Applied Nutrition at the FDA. To my immediate left is Mr.
16 Robert Lake who is Director of the Office of Regulations and
17 Policy in that same center, the Center for Food Safety and
18 Applied Nutrition.

19 Now, since you have certainly heard more than
20 enough from me, I would like to turn to the substantive part
21 of the program and to Jim Maryanski who, as I said, is the
22 Biotechnology Coordinator in my center. Jim will provide,
23 as I mentioned, an overview of really what FDA's policy is
24 and how we have gone about applying that policy, the kind of
25 testing that companies are doing, and how we have gone

1 through the whole safety assessment process. It is my
2 pleasure to introduce Jim Maryanski.

3 **FDA Policy: 1994 to the Present**

4 **James Maryanski, Ph.D.**

5 DR. MARYANSKI: Thank you, Mr. Levitt. Good
6 morning, ladies and gentlemen.

7 This morning I will give you a very brief overview
8 of FDA's role in protecting public health and its role in
9 assuring the safety of foods produced through modern
10 biotechnology. I will give you a broad-brush picture of the
11 policy and approach that we have in place for assuring the
12 safety of these products, and give you a sense of the kind
13 of testing that is being done for food safety for these
14 products. I will also share with you some of the experience
15 that we have had in working with companies over the past
16 five years so that you have a sense of what we are doing
17 today, why we are doing it, and how we got to where we are
18 now.

19 [Slide]

20 The Food and Drug Administration, as many of you
21 know, is an agency in the U.S. government in the Department
22 of Health and Human Services. There are other public health
23 agencies that are part of this Department: The National
24 Institutes of Health, for example, and the Centers for
25 Disease Control and Prevention and FDA are all public health

1 agencies within this larger Department.

2 [Slide]

3 The Federal Food, Drug and Cosmetic Act is the
4 federal law in this country that gives FDA oversight over
5 most of our food supply. We have authority over all of the
6 food except for meat, poultry and egg products that are
7 regulated by the Department of Agriculture. So, it is this
8 Act that provides the legal tools for FDA to assure the
9 safety of all of the products under its authority, including
10 foods developed by modern biotechnology.

11 Our policies are always based on the best science
12 that is available, and that is a very important aspect in
13 our policy and we have spent a number of years studying the
14 science of modern biotechnology and its possible impact on
15 the food supply and food safety.

16 FDA is responsible for foods that are on the
17 market, in commerce, in the United States and foods that are
18 imported into the United States. So, both domestic and
19 imported foods fall under our authority. Of course, our
20 goal is public health protection. That is our mission. We
21 are here to ensure that the food supply is safe and
22 wholesome.

23 [Slide]

24 I would like to give you just a very brief
25 overview of how products produced by modern biotechnology

1 fit within the broader framework of the U.S. government
2 because there are several agencies that are involved in
3 looking at various issues that are related to the regulation
4 of these products. FDA, of course, is responsible for food
5 safety and labeling for foods that fall under our authority.
6 The Department of Agriculture, and particularly the Animal
7 Plant Health Inspection Service, APHIS, is responsible for
8 ensuring that plants either moved and grown in this country
9 or imported into the country do not pose problems for
10 agriculture. That department has regulations for permitting
11 field testing, as well as for the petitions that allow the
12 commercial growing of plants produced by modern
13 biotechnology.

14 [Slide]

15 The Environmental Protection Agency, EPA, also has
16 a very important role because they have responsibility for
17 ensuring the safety of pesticides. So, pesticides must be
18 registered by EPA.

19 To give you an example of a product and show you
20 how it fits within these three agencies and departments, the
21 BT corn, that is the corn that has its own built in
22 pesticide that you have undoubtedly heard about -- that corn
23 would fall under the Department of Agriculture for
24 consideration of whether it would pose any risk to
25 agriculture under the Plant Pest Act and the Plant

1 Quarantine Act. That product also would fall under EPA
2 because the BT is a pesticide. So, the BT would be
3 registered as a pesticide by EPA.

4 The food products and products for animal feeds,
5 such as high-fructose corn syrup that would be used in soft
6 drinks, for example, those products would fall under FDA.
7 So, that product is one for which the company would have to
8 go to all three government agencies to complete whatever
9 regulatory requirements are necessary for that product.

10 [Slide]

11 In the late 1980s, the Food and Drug
12 Administration began to receive a lot of questions about the
13 use of recombinant DNA techniques and the possible impact on
14 the food supply. At that time, we were already reviewing
15 petitions from companies for food processing enzymes such as
16 chymosin and alpha amylase, the enzyme that is used to make
17 corn sweeteners -- chymosin, of course, also is known by the
18 name rennet that is used for the milk clotting step in
19 making cheese. We were very familiar with food ingredients
20 produced by this technology.

21 But, at that time, we began to receive many
22 questions about whole foods -- soybeans, corn, potatoes,
23 tomatoes -- and how would those products be regulated; and
24 what kind of safety testing should be done to ensure the
25 safety of those products. So, we spent a number of years

1 with our scientists in FDA and working with scientists in
2 other agencies and other governments around the world to
3 work out a system, an approach by which foods could be
4 tested by the firms to establish that they were safe for
5 marketing.

6 In fact, when Calgene, which was the company that
7 developed the Flavr Savr tomato, approached FDA and asked us
8 to review all of their safety data for the product that they
9 were developing, which was the Flavr Savr tomato, that was
10 the first time really that FDA had been presented with the
11 question of how do we apply modern scientific methods to
12 show that a food, a whole food such as a tomato, is safe to
13 eat. So, we spent a good deal of time looking at that and
14 other questions related to the use of modern biotechnology
15 and its impact on the food supply.

16 And we published a policy in 1992, in the Federal
17 Register, which was a statement of policy. It was intended
18 to answer the questions that we were receiving at the time.
19 It was essentially a snapshot of the technology based on the
20 kinds of products that were being developed, and how we felt
21 those products could fit within the existing framework under
22 the Federal Food, Drug and Cosmetic Act. The policy that
23 was published applies to all methods of plant breeding.
24 That is, if foods are derived from plants that have been
25 developed by cross-hybridization, the traditional methods in

1 agriculture, or any of the other number of methods that
2 plant breeders use to introduce new traits into plants, or
3 by the new recombinant DNA or bioengineering techniques that
4 we refer to as modern biotechnology, we felt that all foods
5 should meet the same standards of safety under the Act and,
6 therefore, the policy applies to all foods. It applies to
7 both human foods and products that are used as animal feeds.
8 So, it covers fruits and vegetables and grains, as well as
9 the products that are derived from agricultural crops such
10 as vegetable oils or food starch.

11 [Slide]

12 The policy really explains how foods have always
13 been regulated, and how products that are derived by modern
14 biotechnology can fit within the framework by which foods
15 are regulated. FDA has two tools that it uses primarily to
16 assure the safety of foods under the Food, Drug and Cosmetic
17 Act. The Act places the legal responsibility for ensuring
18 the safety of food on the developer of the product and gives
19 FDA very broad authority to take action against the
20 developer or to remove the product from the market if it
21 does not comply with the law.

22 To give you an example, there was a potato
23 developed in the 1970s that had an excessive level of a
24 natural substance that occurs in potatoes. That product
25 could make people sick. Fortunately, it did not make any

1 consumers sick; it was discovered before. But FDA and USDA
2 worked together to remove that product from the market, and
3 that is what we call our postmarket authority.

4 We also have authority to assure the safety of
5 food additives. In fact, a food additive must be approved
6 by FDA before it can be used in food. There are a number of
7 exemptions under the law for substances that are added to
8 foods that are not food additives. For example, pesticides
9 are exempt from a definition of food additives because they
10 are regulated by EPA as pesticides.

11 Substances that are generally recognized as safe,
12 what we call the GRAS, GRAS food ingredients, are also
13 exempt on the basis that those substances are recognized by
14 experts familiar with food safety as being safe for use in
15 food -- salt, vinegar, spices, food-processing enzymes, a
16 number of things that have been commonly used in food are
17 considered to be GRAS.

18 We have applied this to the developments of modern
19 biotechnology, as well as other methods of introducing new
20 substances into food, in the context that if a gene is
21 introduced into a plant and the result of that gene is a new
22 protein that is present in the food, if that protein is not
23 generally recognized as safe it would be a food additive,
24 subject to premarket review by FDA. We have said that most
25 of the modifications that have occurred to date result in

1 new proteins in food that are either derived from other food
2 crops or are very similar to foods that are already safely
3 consumed in the food supply, and we have said that these
4 proteins will be presumed to be generally recognized as
5 safe.

6 What we have here is the legal tool though to
7 assure that if this technology, or any other technology, is
8 used to introduce a substance which is not generally
9 recognized as safe it would require premarket review and
10 approval by FDA before the food could be used in the market.

11 The most important part of the policy that we
12 published in 1992 was the guidance to industry. The
13 guidance to industry part of our policy provides information
14 about the kinds of issues related to food safety that
15 developers should take into account in bringing new foods to
16 market. It really provides a yardstick for the developer to
17 determine whether they are meeting the standards that FDA
18 expects them to meet under the Act. We consider this to be
19 a standard of care. When we published the policy in 1992,
20 this was really the first time that we had put down on paper
21 what the standards would be for agricultural crops in terms
22 of food production.

23 [Slide]

24 In 1992, when we published this policy, we did ask
25 for public comments, and one of the comment that we received

1 from many people was that there should be notification to
2 FDA about foods produced by modern biotechnology. As part
3 of the review of the Flavr Savr tomato, that review was
4 conducted over the period of time that we published the 1992
5 policy and, as part of our evaluation and determination of
6 whether that policy was an appropriate policy, we had a
7 meeting that was a public meeting of our Food Advisory
8 Committee where we presented our scientific approach to
9 looking at the safety of foods, to that committee, and we
10 used the Flavr Savr tomato as an example of a product
11 produced by modern biotechnology that had been tested by the
12 kinds of methods and approach that we felt were appropriate.

13 During that committee meeting -- our Food Advisory
14 Committee is a group of experts from outside of FDA that is
15 composed of academic representatives, industry
16 representatives and public interest representatives -- those
17 committee members had an opportunity to look at the approach
18 scientifically that we were recommending to companies, and
19 this product as an example of the kind of testing that would
20 be done under this approach.

21 The committee members felt that this was an
22 appropriate approach given the characteristics of the
23 product, and many members of the committee, including
24 consumer representatives, suggested to FDA that this product
25 really did not raise substantial food safety issues, and

1 that if there were to be similar products produced by this
2 technology, that FDA may need to have a more abbreviated way
3 to look at these products. We had spent about three years
4 of very intensive review, looking at all of the data
5 produced for that particular product. That was a very
6 useful review for the first product and it helped us in
7 establishing our policy.

8 But, we agreed with the committee members that
9 another approach would be needed for most products. So, we
10 established what we are now calling our consultation
11 procedures. These are procedures that are not legally
12 binding on companies but FDA strongly recommends that
13 companies follow them in bringing products to market.

14 We have discussed this approach through this
15 consultation procedure with our Food Advisory Committee and
16 our Committee for Veterinary Medicine, and we showed them
17 seven products that companies had consulted with FDA.
18 Again, they agreed with us that that seemed to be an
19 appropriate level of oversight at that time given the nature
20 of the products that were then coming to market.

21 [Slide]

22 There are several principles that I think are
23 important to keep in mind in thinking about how we approach
24 looking at the safety of foods. Today in the grocery store,
25 if you think about the grocery store, meat, poultry and egg

1 products, of course, are regulated by the Department of
2 Agriculture but if you visualize yourself walking up and
3 down the aisles, all of the other products fall under FDA
4 and those are the fruits and vegetables, the cereals, all
5 the packaged foods, all the additives that you see on the
6 label on the ingredient statement of the package. So, there
7 is a very broad number of foods that fall under our
8 authority, and it also means that our food supply is very
9 diverse. Think about the diversity of foods that we have in
10 our grocery stores today. So, our policy applies to all of
11 those products.

12 In asking whether a new product is safe, we ask
13 whether that product is comparable. Is it similar to its
14 conventional counterpart? Because the products of modern
15 biotechnology to date are all derived from common food crops
16 that have been used in agriculture for many years. So, it
17 is a process of comparing the new product with the
18 traditional product. How different is it? How similar is
19 it? And, are those differences, differences for which
20 additional testing would be needed?

21 The approach that we use at FDA for establishing
22 the safety of food additives is one that we realized would
23 not work as well for whole foods. Whole foods are complex
24 mixtures of chemicals. The paradigm that we have for food
25 additives relies on testing of single chemicals.

1 So, we had to come up with a different way to look
2 at the safety of foods, and that is a multi-disciplinary
3 approach where we look at many different kinds of scientific
4 information. One of the important pieces of information
5 that is rarely talked about are the considerations that
6 developers do all the time in bringing new varieties to
7 market, looking at their agronomic characteristics and their
8 quality characteristics, and those are very important in
9 determining whether a product can be successfully marketed.
10 Plant breeders have been very successful at avoiding
11 products that FDA would have to remove from the market on
12 the basis of public health.

13 We also have new tools for safety assessment that
14 are not available through other methods. The tools of
15 molecular biology that are the tools of modern biotechnology
16 also allow the scientist to determine the identity and the
17 function of the substances that are added to foods. This is
18 something that cannot be done by other methods of plant
19 breeding, and so we have a very powerful new tool in not
20 only developing new foods but being able to assess the
21 safety of those products. So, that information, taken along
22 with information that I will show you in a moment, of the
23 composition of the food and assuring that the food is what
24 we expect in terms of its vitamins, its nutrients and other
25 normal components of the food -- this kind of information is

1 information that we believe generally establishes that the
2 food is as safe as other foods on the market.

3 There could be circumstances where testing in
4 animals would be warranted but this is not routinely
5 recommended because feeding whole foods to animals can
6 produce very complicated results, and it is very important
7 to design the studies appropriately but generally scientists
8 around the world, including the World Health Organization
9 and the Food and Agriculture Organization, have agreed that
10 this approach is scientifically a sound approach for
11 assessing the safety of foods.

12 [Slide]

13 There could be circumstances where we would
14 require testing in addition to what I have just described.
15 For example, if the genetic modification of a crop leads to
16 an unusual protein or a new chemical in the food, or the
17 substance has some similarity to an allergen or a toxin,
18 then additional testing would be required. You may have
19 heard about a potato developed in Europe that contains
20 lectin. Certain lectins are known to be very toxic, and if
21 that potato were presented to FDA we would expect that there
22 would be considerable safety testing that would be required
23 to establish the safety of that product. So, testing is
24 really based on the characteristics of the product on a case
25 by case basis.

1 [Slide]

2 I would like to just give you a very broad-brush
3 picture of the kind of issues that breeders take into
4 account for food safety in looking at whether a food can be
5 marketed. This focuses on two aspects. First, of course,
6 there is an intended change in the plant or the food based
7 on the modification that has been made. So, it is important
8 to make sure that if there are new substances that will
9 actually be present in the food that those substances are
10 safe to consume. So, it is important to understand the
11 identity of the substance and its structure and function in
12 the food. That substance should also be assessed,
13 particularly if it is a protein, for whether it would be an
14 allergen. You will hear more about that later this morning.

15 Of course, it is important that the substance be
16 digestible like other substances in the diet. Dietary
17 exposure is something that is very important in food safety.
18 How much do we eat is the question. Is this something that
19 is a very trivial component of the food, or is it a major
20 component of a food?

21 Nutrition, of course, is a particularly important
22 issue. If the modification has been done to change the
23 nutritional properties of the food, then an evaluation would
24 have to be done in terms of how would that affect our
25 dietary intake of that nutritional component. Nutrition is

1 also important in animal feed. Many animals have diets that
2 are primarily one crop and, so, altering the nutrition of
3 that crop could alter the nutritional value for the animal.
4 So, that is an important consideration for the feed that is
5 fed to animals.

6 We also ask developers to look at whether there
7 have been any unintended or unexpected changes that would be
8 in the food as a result of the change that has been made.
9 All methods of plant breeding are known to result in
10 unintended changes in plants. Plant breeders routinely
11 evaluate a number of agronomic traits to determine whether
12 the plant is performing as it would normally perform.

13 But in addition to those ways of avoiding
14 unexpected effects, we have asked developers to take some
15 extra steps to minimize or reduce the likelihood that there
16 will be unintended effects that could affect public health.
17 That is done first by ensuring that the genetic material
18 that has been introduced in the plant is introduced in a way
19 that it is stable in the plant; it does not move around in
20 the plant's genome, and that reduces the likelihood of
21 additional unexpected changes.

22 We also ask developers to do extensive analysis of
23 the food for vitamins, minerals, nutrients and other
24 components of the food that are typical of that food to
25 assure that those components that are important to the food

1 are present at the levels that are expected. Those levels
2 are known to vary over many conditions of growth. The
3 genetic background of the plant, the environmental
4 conditions under which it is grown, whether it is a year of
5 a lot of rain or it is a year of drought will affect the
6 composition of the food. So, in analyzing these important
7 components in the food it is important to take into account
8 the range that is typical for plants that have been accepted
9 in the commercial market.

10 [Slide]

11 I would like to now very quickly give you some
12 examples of the kind of information, using soybean as an
13 example, to show you just a bit of the information that
14 companies are presenting to FDA as they look at these
15 products in terms of food safety.

16 I have mentioned that agronomic and quality
17 factors are important. Breeders evaluate plants over
18 several generations, in multiple field sites, in different
19 locations. That is to determine whether the plant performs
20 in a manner that is to be expected. I have shown just some
21 examples here. This is plant morphology, flower color, time
22 of flowering, resistance to disease, seed size and quality,
23 percentage composition of oil or protein. These are just a
24 few of the many characteristics that plant breeders
25 typically evaluate for soybeans and bringing a new variety

1 to market.

2 [Slide]

3 Products that have been produced by modern
4 biotechnology are also looked at in terms of the molecular
5 changes that have been made: What genetic material has been
6 introduced? What is new? What are its characteristics?
7 Are there any new proteins that are going to be produced in
8 the food or other substances such as fatty acids or
9 carbohydrates that will be new substances in the food as a
10 result of the change that has been made in the plant: And
11 are those substances safe for consumption? The components
12 of the food in terms of nutrients, anti-nutrients are
13 important in soybeans.

14 Soybeans also are a food to which some individuals
15 are allergic, and companies are looking at the native
16 allergens in soybeans to be sure that those have not been
17 increased through the genetic change that has been made.
18 Companies are also doing some animal feeding studies with
19 these foods for wholesomeness of the foods before they come
20 to market.

21 [Slide]

22 The analyses that are done for typical components
23 of the food are done comparing the new variety, which is
24 called transgenic here, with its parental strain or its
25 appropriate control. What is not shown here is that these

1 values then are also compared to the range that is typical
2 for that crop for these components. This is showing
3 carbohydrate, fat, protein, fiber analysis -- fiber is very
4 important in looking at whether a feed product is digestible
5 for animals.

6 [Slide]

7 Mineral analysis -- minerals are an important
8 component of foods.

9 [Slide]

10 Fatty acid analysis for the oils. I am showing
11 here only a few of the fatty acids that are typically
12 analyzed in soybeans. All the data that I am showing you
13 very quickly are composite data that we have derived from
14 the information that has been submitted to us.

15 [Slide]

16 The protein quality of the food is very important,
17 and the amino acid profile is an indicator of the quality of
18 that protein.

19 [Slide]

20 Soybean has a number of substances that are
21 considered to be anti-nutrients, and developers are also
22 analyzing those substances to be sure they are in the levels
23 that have been accepted as safe.

24 [Slide]

25 At this point in time, we have about a little over

1 40 crops for which developers have completed food safety
2 discussions with FDA. There are ten crops at this time for
3 which we have completed consultations. This is sugar beet,
4 canola, corn -- corn is the largest; there are 12 varieties,
5 cotton, potato, soybean, flax, raddichio, squash and tomato.
6 Those are the crops that have been modified by modern
7 biotechnology and companies have completed food safety
8 discussions with the agency at this point.

9 As you can see, at this time there is a relatively
10 limited number of food crops that have been developed by
11 this technology. There also is a limited number of traits
12 that have been introduced into these crops in terms of
13 improvements in the crops. These are for herbicide
14 tolerance, insect resistance, viral resistance that provides
15 resistance to common diseases in agriculture. There are
16 tomatoes that have improved ripening, and there are a number
17 of vegetable oils that have been developed. For example,
18 there are two vegetable oils that are different from their
19 traditional counterparts. There is a vegetable oil called
20 high oleic soybean oil, which is a soybean oil that is very
21 different from traditional soybean oil. It has a very
22 elevated level of a fatty acid called oleic acid, and that
23 oil can be used as a high temperature frying oil, whereas
24 soybean oil cannot typically be used as a high temperature
25 frying oil without prior processing of the oil.

1 [Slide]

2 I would also like to give you a sense of the time
3 that developers work with the agency before these products
4 come to market. On your left, it says pre-submission. This
5 is the time that companies discuss the kinds of testing that
6 they will do on foods developed from plants through modern
7 biotechnology. This is 15 to 20 months. These are also
8 just examples. I have selected seven consultations at
9 random just to give you a sense of what is typical. It is
10 about a year to two years that companies discuss with FDA
11 the kinds of tests that they will do, and the results of
12 those tests.

13 This side is post-submission. Post-submission is
14 the time when developers submit to us a summary of the
15 safety and nutritional data that they have developed. That
16 is when they are really saying to FDA, "we feel we have done
17 all the testing that is appropriate and necessary to meet
18 all the provisions of the Food, Drug and Cosmetic Act." FDA
19 then looks at this information to determine whether there is
20 any reason why we would take action against this product if
21 it went to market. In other words, does it contain an
22 unapproved food additive? Will it be mislabeled? Is its
23 nutrient profile something that would not be acceptable in
24 the food? Is there a new allergen in the food? These are
25 the kinds of questions that we are looking at. On the

1 average, it takes about five months for us to complete that
2 process.

3 You can see in the yellow boxes that there are
4 some that are very short. There are a number of products
5 which may be the second or third generation of a product
6 where both FDA and the company are very familiar with the
7 kinds of testing that would be needed for that product, and
8 so the consultation process is also very much more
9 abbreviated.

10 But, I think what is important is that companies
11 do come in a considerable period of time ahead of when they
12 want to market the product. That is very important. Our
13 policy has always been that our door is open, and we
14 encourage companies to come early and often, particularly
15 when a product is a new product that we are not familiar
16 with.

17 [Slide]

18 I would just like to close by reminding you of the
19 standard of food safety. Foods developed through the
20 methods of modern biotechnology must be as safe as other
21 foods on the market. That means that the food must not only
22 be safe and wholesome; any substances that are added to the
23 food must either be food additives that have been approved
24 by FDA and regulated by FDA, or they must be generally
25 recognized as safe. There may be pesticides that are

1 regulated and approved by EPA. But this is the standard
2 that we hold these foods to. We will not accept a lower
3 standard for any new food.

4 Thank you for your attention.

5 [Applause]

6 MR. LEVITT: Thank you very much. We will be
7 making copies of those slides you have seen up there
8 publicly available on the web page and you can be looking
9 for those also.

10 Let me now take the opportunity to welcome to the
11 stage -- and maybe somebody is going to show you the easiest
12 way to get here -- our first panel. I will introduce you
13 after you are up here as you move to our first panel
14 discussion. It is a little tight up here but we will get to
15 know each other very well today.

16 **Scientific, Safety, and Regulatory Issues**

17 **Introduction**

18 MR. LEVITT: Thank you. It is now time to begin
19 the discussion of our first panel on the scientific, safety,
20 and regulatory issues. In terms of logistics, I will ask
21 each panel member to give brief opening remarks, about five
22 minutes worth. These remarks will be followed by discussion
23 among the panel members and questions from the FDA panel.

24 Let me first review the three questions that we
25 have asked our panelists to address to help us evaluate our

sgg

1 current policy. These were printed in the Federal Register
2 and are in your packets.

3 The first question reads, has FDA's consultation
4 process Dr. Maryanski described achieved its intended
5 purpose? Based on experience to date, should this
6 regulatory approach "sunset," should it continue in its
7 current state, should it be made mandatory, or otherwise be
8 revised? So, how should we deal with the consultation
9 process?

10 Number two says, what newly-emerging scientific
11 information related to the safety of foods derived from
12 bioengineered plants is there, if any? Are there specific
13 tests which, if conducted on such foods, would provide
14 increased assurance of safety for man or animals consuming
15 these foods? So, that is really focused on the kind of
16 testing that is done.

17 Three, what types of food products derived from
18 bioengineered plants are planned for the future? Will these
19 foods raise food safety issues that would require different
20 approaches to safety testing and agency oversight? If so,
21 what are those approaches? So, for that we ask you to look
22 into your crystal balls and tell us what is coming down the
23 pike.

24 I am pleased to introduce the members of the first
25 panel. You have in your packets additional biographical

1 information. If I mispronounce anybody's name, please
2 correct me. You ought to have your name spoken correctly.
3 First is Dr. Peter Day. He is the Director for Agricultural
4 Molecular Biology at Rutgers University.

5 Next to him is Miss Carol Tucker Foreman. She is
6 a Distinguished Fellow and Director of Food Policy Institute
7 at the Consumer Federation of America.

8 Next is Dr. Rebecca Goldberg. She is a Senior
9 Scientist and Manger of the Biotechnology Program at the
10 Environmental Defense Fund.

11 Next is Mr. Steven Druker, who is the founder and
12 Executive Director of the Alliance for Bio-Integrity.

13 Next to him is Dr. Samuel Lehrer, who is Research
14 Professor of Medicine, Adjunct Professor of Microbiology and
15 Immunology, and Adjunct Professor of Environmental Medicine
16 with Tulane University Medical.

17 Finally, we have Dr. Terry Etherton, who is
18 Department Head and Distinguished Professor of Animal
19 Nutrition, College of Agricultural Sciences, Department of
20 Dairy and Animal Sciences at Penn. State University.

21 We will go straight to the first panelist, and
22 again ask if you could try to keep your remarks to about
23 five minutes, and then we will come back for follow-up
24 questions. Let's just start then with Dr. Day.

25

Panel Discussion

1 DR. DAY: Thank you, Mr. Chairman. First of all,
2 I would like to congratulate Dr. Maryanski on an elegant and
3 complete introduction. While he was talking I almost
4 thought he was a plant breeder.

5 Let me just make a few comments about the science.
6 I will try to address the FDA's questions in the course of
7 my comments. First of all, my own position is that the
8 revolution that we are experiencing in the development of
9 new varieties of crop plants is a continuation of a process
10 that began hundreds or thousands of years ago.

11 We have established a tradition, I think, since
12 Asilomar in 1976, of being concerned about we are seen to be
13 doing in our laboratory and experimental fields. The NIH
14 guidelines were established. The NIH established a risk
15 assessment research program and, as a result of these
16 activities, we became more and more at ease with what were
17 perceived as risks, sincere risks, 20 to 25 years ago.

18 The process that the FDA has established, together
19 with the other federal agencies, I think is working very
20 well. I believe that the regulatory approach that is in
21 position works satisfactorily. While I think it could
22 continue in its current state, I think that it needs to be
23 flexible to take account of new situations as they arise.

24 Now, as I see it, the scientific risks fall into
25 two categories. First of all, the risks to food and the

1 question of food safety arises, and the FDA, like the other
2 federal agencies, has chosen to focus on the product rather
3 than the process by which it is produced. I think this is
4 sound, and I know of no information that suggests that the
5 process itself is dangerous. The product is what we should
6 focus on. I think because the technology enables us to do
7 things that are new and different we need to continue to
8 focus on the product and to ensure that it is safe.

9 The second area of concern, which is attracting a
10 lot of attention, is the potential impact of biotechnology
11 on the environment. Now, agriculture has a profound effect
12 on the environment. I don't think any of us would dispute
13 that. I see that biotechnology will have a much less severe
14 effect than agriculture itself. No doubt, during the course
15 of the morning we will be discussing specific instances but
16 let me give you one instance, and that is BT corn -- well,
17 two, I would also like to refer to the herbicide resistant
18 soybeans.

19 In BT corn one has relieved the farmer of applying
20 conventional pesticides and the untargeted effects that they
21 have. The BT corn also has the advantage of reducing the
22 incidence of mycotoxins in damaged ears fed to animals.

23 The herbicide resistant soybean has replaced, by
24 using one herbicide, five or six different herbicides that
25 are conventionally used to control weeds in soybean crops.

1 We can't go back to hoeing. While there are cultural
2 methods that will limit weed development, herbicides are a
3 cheap and effective method of weed control that also have
4 other benefits as far as the soil structure and the question
5 of the number of tillage operations that are applied to
6 fields -- we can economize in fuel.

7 Are there new things that are ahead? Yes. There
8 is some concern over the horizontal spread of introduced
9 genes and their impact on natural populations of plants.
10 That horizontal spread has been a feature of conventional
11 agriculture, of course. Many weeds in agricultural areas
12 are associated with crops. For example, in Europe the
13 introduction of canola and the spread of the seeds alongside
14 roads has meant that canola has become quite a common weed.

15 Now, one interesting new technology is the
16 introduction of transgenes into chloroplasts. Chloroplasts
17 are not transmitted in pollen, and some colleagues of mine
18 at Rutgers have developed a method of introducing transgenes
19 into chloroplasts, thereby limiting the spread of transgenes
20 through pollen.

21 The third FDA question asks what types of food
22 products derived from bioengineered plants are planned for
23 the future. I think what we have seen at the moment has
24 had, unfortunately, rather little impact on the consumer
25 since herbicide resistance and insect resistance don't

1 really affect the product in the market in terms of its
2 appeal to the consumer. There are a number of new things
3 that are being developed that are more difficult to manage
4 and that I think will be very impressive.

5 We must also remember that biotechnology doesn't
6 just contribute through the introduction of new genes.
7 There are other technologies that involve, for example,
8 marker-assisted selection and technologies that are based on
9 the growing understanding of the construction of plant and
10 animal genomes that enable plant and animal breeders to work
11 with even greater precision than they do now.

12 But perhaps what is most important is the
13 potential that biotechnology has for the developing world,
14 and I am thinking of examples like golden rice which has an
15 increased content of vitamin A and an increased iron
16 content, and crops like wheat which has been engineered to
17 grow on aluminum toxic soils which limit production in many
18 parts of the developing world.

19 I don't think we can afford to ignore and to set
20 aside the potential of this tool to do some remarkably
21 important things to safeguard the world's food supply.

22 Thank you, Chairman.

23 MR. LEVITT: Thank you very much. We will just
24 proceed right down the row. Carol Tucker Foreman?

25 MS. FOREMAN: Thank you very much for conducting

1 these public hearings on foods derived from bioengineered
2 plants, and for the opportunity to appear on this panel.

3 Consumer Federation of America is a non-profit
4 association of 260 pro-consumer groups which seeks to
5 advance consumer interests through advocacy and education.
6 Our members include state and local consumer organizations,
7 senior citizens groups, consumer cooperatives and trade
8 unions.

9 In the past few months, Americans have become
10 increasingly aware of, and increasingly concerned about
11 genetically engineered foods. The concern seems to be
12 driven by a number of factors -- a sudden realization that
13 by next year almost half of the corn, soybeans and cotton
14 planted in the U.S. are likely to be transgenic crops; the
15 vociferous rejection of these products by European
16 consumers; the ongoing debate over the potential for
17 environmental damage and economic concentration resulting
18 from the rapid growth of genetically engineered foods; the
19 utter absence of any direct consumer benefit in any of the
20 products now on the market or anywhere close to being on the
21 market; and, most importantly, the potential for some human
22 health risk arising from the consumption of genetically
23 engineered foods.

24 The concern about genetically engineered food is
25 in marked contrast to the public's acceptance of genetically

1 engineered drugs. When faced with serious illness, most of
2 us are willing to take some risks to combat the disease but
3 food is different. Food is special. We eat to sustain life
4 and health. Since food is so basic to us both physically
5 and emotionally, it is really not surprising that consumers
6 are extremely averse to any food-related risk, especially if
7 that risk is perceived as imposed by someone else beyond our
8 individual control and without any countervailing benefit.
9 In short, we eat because it is good for us, not because it
10 benefits those who grow, process or sell food.

11 Industry and, to a certain extent, the government
12 argue that decisions about the approvals of genetically
13 engineered foods should be based solely on what is described
14 as sound science. Industry and government insist that sound
15 science says GE foods are safe and for many that is
16 dispositive. Consumers aren't so sure. Good data and sound
17 science are vital elements of good public policy but they
18 aren't the only consideration. In science there aren't any
19 final answers. Data are never complete; they are always
20 evolving. The soul of the scientific process is challenge
21 and revision as new data become available. Three years ago
22 sound science told the Food and Drug Administration that it
23 should approve the diet drug fen-fen, and last year's sound
24 science told the Food and Drug Administration that it was
25 best to withdraw that drug from the market.

1 Food safety policy should be based on the best
2 data and the best science but, in the end, the policy
3 represents a choice among competing interests and values.
4 Policy makers must balance industry's desire to bring new
5 products to market and the farmer's desire to increase yield
6 against the public's concern about safety.

7 Public confidence in genetically engineered foods
8 has been eroded by the sense that government has been too
9 sensitive to the needs of industry. We all have to live
10 with the impact of the circumstances governing the original
11 policy on genetically engineered foods. On May 27, 1992 The
12 New York Times reported that Vice President Quayle announced
13 details of a new government policy for streamlining
14 regulation of these foods. Mr. Quayle, according to The
15 Times, told a briefing of industry executives that the
16 policy was part of the Bush administration's regulatory
17 relief program, and said the U.S. was the world leader in
18 biotechnology and we want to keep it that way.

19 It is really very difficult to persuade the
20 public, after an introduction like that, that the
21 government's primary interest is food safety. During Food
22 and Drug Administration's consideration of an appropriate
23 regulatory structure for GE foods, officials of the agency
24 were extremely aware of the fact that if they required a
25 prior approval of all of these new products it would suck up

1 every bit of the agency's resources and there would be very
2 little to apply to others. FDA now asks the public for its
3 views on the process, and the answer is the process began
4 under a cloud of political influence and managerial bean
5 counting, and FDA has not dispelled that cloud.

6 I believe that food biotechnology has enormous
7 potential benefits to the world. They are benefits I would
8 like to see realized, but there are none of those benefits
9 to civil society at this point. FDA's present challenge is
10 to develop a regulatory process that will assure public
11 confidence.

12 I have some suggestions for it. The government,
13 beginning with the President, should make a clear statement
14 that human safety is the first, second and third most
15 important point in determining whether to approve GE foods,
16 and that the government will assign sufficient resources to
17 do the work required.

18 Second, FDA should require submission for review
19 and formal approval of all genetically engineered products
20 prior to marketing. Last week, Dr. Michael Jacobson, of the
21 Center for Science and the Public Interest, laid out
22 examples of how the agency might require varying amounts of
23 information depending on the specifics of the products.

24 Third, consumers must have, and will have, a role
25 in this debate. I propose that the agency create a special

1 advisory committee on biotech engineered foods. The
2 committee could help the agency shape the necessary
3 questions and policy. I am a member of the Department of
4 Agriculture's Meat and Poultry Inspection Advisory Committee
5 which has worked exceptionally well over the past several
6 years to help that agency shape policy and keep it
7 transparent.

8 In a field as new as this one, it may be useful to
9 establish an independent quasi-governmental research
10 institution that could raise key regulatory issues and
11 sponsor research into them. The Health Effects Institute,
12 which deals with clean air issues and is funded by
13 government and industry, I think is an excellent model to
14 look at.

15 I have gone over my time so I want to just briefly
16 address labeling. The agency has asked another panel to
17 discuss that. Two quick points, labeling is not a
18 substitute for assurance of safety. No food should be
19 approved unless it is safe. The strong mandatory pre-
20 approval process that I have suggested should eliminate the
21 concerns of industry that people would assume a labeled
22 product is less safe than its traditional counterpart. But
23 for consumers, access to adequate information to make a
24 rational decision in the marketplace is absolutely
25 essential, and I am confident that the public will be more

1 comfortable with this technology and more prepared to see it
2 move forward if it has the assurance of some premarket
3 review and approval and if the products are labeled. Thank
4 you.

5 MR. LEVITT: Thank you. Next is Dr. Rebecca
6 Goldberg, Environmental Defense Fund.

7 DR. GOLDBURG: I would like to begin by thanking
8 the FDA for inviting me to speak today, and before I begin
9 my remarks concerning FDA policy, I want to note that it is
10 unfortunate that the FDA has scheduled this public hearing
11 during the World Trade Ministerial meeting, in Seattle,
12 because as a result a number of public interest
13 representatives who might otherwise be at this hearing are
14 now in Seattle.

15 Well, to move on, in my brief remarks today I will
16 first comment on food safety and then on FDA regulation of
17 foods derived from genetically engineered crop plants, which
18 I will refer to as genetically engineered foods.

19 To most consumers, genetically engineered foods
20 are essentially foods with added substances, usually
21 proteins. As Jim Maryanski explained, this is because genes
22 code for proteins. In most cases, these added proteins will
23 likely prove safe for human consumption. Nevertheless, just
24 as with conventional food additives, substances added to
25 foods by genetic engineering may in some instances prove

1 hazardous.

2 One concern about adding proteins to foods via
3 genetic engineering is that they may cause susceptible
4 individuals to become allergic to foods that they previously
5 could safely consume. Food allergies are a serious public
6 health concern, affecting roughly two and a half to five
7 million Americans. Allergic reactions cause discomfort and
8 in some cases can cause life-threatening anaphylactic shock.
9 Since known food allergens are proteins, foods with new
10 proteins added via genetic engineering could sometimes
11 become newly allergenic. This concern is real. One company
12 has already dropped plans to commercialize soybeans with a
13 Brazil nut gene after testing revealed the soybeans were
14 likely to cause allergic reactions in Brazil nut allergic
15 individuals.

16 Unfortunately, there is currently no predictive
17 methodology for testing the allergenicity of most proteins
18 introduced to foods via genetic engineering. Testing is
19 only possible for proteins from commonly allergenic foods,
20 such as nuts. Proteins from commonly allergenic foods can
21 be screened for so-called antibody-antigen reactions using
22 blood serum available from individuals with common food
23 allergies. However, for most proteins, including those from
24 foods that are not commonly allergenic and those from non-
25 food sources such as bacteria, no such testing is possible.

1 In other words, most proteins added to foods via genetic
2 engineering cannot be tested for allergenicity. Instead,
3 industry scientists simply screen the biochemical
4 characteristics of proteins to see if they are consistent
5 with the characteristics associated with allergens. It
6 remains to be seen how effective such screening will be in
7 protecting the public health.

8 Extremely troubling to me, FDA regulators have
9 failed to assume a leadership role in addressing the
10 potentially serious food safety risks from allergens added
11 to foods via genetic engineering. Consider the following
12 three points:

13 First, although FDA co-sponsored a scientific
14 meeting on food allergy in 1994, the agency has not used its
15 scientific resources to develop and publish guidance to
16 industry on how to assess the allergenic potential of
17 proteins. FDA should develop such guidance. Given the
18 existing uncertainties about assessment of potential
19 allergens, guidance would both be helpful to industry and
20 reassuring to consumers.

21 Second, FDA's current policy concerning labeling
22 of genetically engineered foods may not adequately protect
23 public health. FDA at the moment does not generally require
24 labeling of genetically engineered foods, although the
25 agency will require labeling if there is evidence that a

1 substance added to a food is allergenic. However, should an
2 allergen added to a genetically engineered food not be
3 detected by industry's current screening procedures,
4 allergic consumers will likely not be able to avoid foods
5 containing the allergen.

6 EDF urges that FDA reconsider its policy for
7 labeling of genetically engineered foods, not only as a
8 matter of public information, the topic of the next panel,
9 but also potentially to help some consumers avoid exposure.

10 The third point is that FDA does not appear to be
11 taking significant steps to sufficiently improve the
12 scientific understanding of food allergens to develop
13 predictive tests for allergenicity. FDA should assume a
14 leadership role in funding and advocating support for
15 scientific research that may result in the development of
16 predictive testing methodology for food allergens.

17 I would now like to turn to FDA's policy for
18 regulation of genetically engineered foods, which appears to
19 do more to protect the biotechnology industry than to
20 protect consumers. As I stated earlier, most genetically
21 engineered foods are essentially foods with added
22 substances, at this point usually proteins. FDA's policy
23 gives manufacturers who use genetic engineering to add
24 substances to food considerably more discretion than
25 manufacturers who use other technologies to add substances

1 to food.

2 Under the Federal Food, Drug and Cosmetic Act and
3 FDA's current regulations, a food is adulterated if it
4 contains an added substance unless either, (a) FDA has
5 approved the safety of the substance by issuing a food
6 additive regulation or, (b) the substance is what is called
7 generally recognized as safe.

8 The upshot is that FDA requires that manufacturers
9 have scientific evidence to support the safety of substances
10 traditionally added to foods or in food processing, for
11 example, sweeteners or thickeners.

12 In contrast, under FDA's 1992 policy, the agency
13 will only require food additive petitions for substances
14 added to foods via genetic engineering, and I quote, in
15 cases where questions exist sufficient to warrant formal
16 premarket review. In other words, FDA will only require
17 data substantiating the safety of genetically engineered
18 foods when there is already reason to believe that the foods
19 might be hazardous.

20 Thus, FDA's 1992 policy appears to significantly
21 weaken the long-standing requirement under food safety law
22 that food manufacturers must establish scientifically the
23 safety of new substances added to food before selling them
24 to the public, regardless of whether the manufacturers think
25 they are safe. In other words, FDA's policy strongly favors

1 food manufacturers at the expense of consumer protection.

2 In response to the considerable public outcry that
3 followed the publication of FDA's policy in 1992, the agency
4 now recommends that manufacturers voluntarily consult with
5 the agency before bringing genetically engineered foods to
6 market. However, because these consultations are outside
7 the regulatory system, they are not subject to public
8 scrutiny and are not a satisfactory substitute for a
9 regulatory program.

10 The Environmental Defense Fund urges that FDA
11 revise its 1992 policy to be more protective of consumers.
12 In particular, we urge that FDA draft a new policy that
13 would do the following two things:

14 First, subject substances added to food via
15 genetic engineering to the same regulatory requirements as
16 substances added to foods via more traditional means. FDA
17 should squarely place the burden on industry to substantiate
18 scientifically the safety of substances added to foods via
19 genetic engineering.

20 Second, FDA should require manufacturers to
21 consult with FDA before bringing genetically engineered
22 foods to market. FDA does not now require such mandatory
23 consultations for foods altered by more traditional means.
24 However, at least for the near future, while genetically
25 engineered foods are new and their potential hazards are not

1 fully understood, it behooves FDA to require such
2 consultations. Thank you very much.

3 MR. LEVITT: Thank you. Next we have Mr. Steven
4 Druker, Alliance for Bio-Integrity.

5 MR. DRUKER: Thank you. I am very pleased to be
6 here today, and I commend Commissioner Henney and Mr. Levitt
7 for holding these meetings. I must say that I am still
8 somewhat surprised to be here because I am one of the
9 strongest critics of the FDA's current policy on
10 bioengineered foods, and I have coordinated a major lawsuit
11 to change it, a lawsuit which is currently pending in U.S.
12 District Court. The fact that I am here suggests that the
13 agency truly is open to hearing from all sides and,
14 hopefully, it suggests that the agency is also open to
15 change and that is very good because current FDA policy does
16 require changing.

17 Although it claims to be science based, numerous
18 experts criticize it as scientifically flawed, and nine of
19 these experts are so concerned that the policy is
20 scientifically unsound and morally irresponsible that they
21 have taken the unprecedented step of joining as plaintiffs
22 in the lawsuit that my organization is spearheading to
23 compel the FDA to institute mandatory rigorous safety
24 testing of all genetically engineered foods.

25 These scientist-plaintiffs are eminent, and their

1 concerns deserve close attention. They include a professor
2 of molecular and cell biology at the University of
3 California, Berkeley, a respected molecular biologist at the
4 State University of New York, and the associate director of
5 targeted mutagenics at Northwestern University Medical
6 School. This latter scientist routinely employs genetic
7 engineering in the medical field, but he is deeply troubled
8 at the extent to which it is being used in food production
9 without adequate safeguards. Also included in our plaintiff
10 group is Prof. Philip Regal, an internationally renowned
11 plant biologist at the University of Minnesota. Dr. Regal
12 has state, in a sworn declaration to the court, quote, there
13 are scientifically justified concerns about the safety of
14 genetically engineered foods and some of them could be quite
15 dangerous, unquote.

16 Why do these nine plaintiffs and so many other
17 scientists regard FDA policy as unsound? They think the
18 agency is disregarding the well-recognized potential for
19 recombinant DNA techniques to produce unexpected toxins and
20 carcinogens in a different manner and to a different degree
21 than do conventional methods.

22 Unfortunately, the FDA's official position ignores
23 this heightened potential for the unknown, for unpredictable
24 negative side effects. Instead, the agency focuses almost
25 exclusively on the factors that are known and are

1 predictable -- the transferred genetic material and the
2 substances it is known to produce. In effect, it is
3 evaluating each transgenic substance as if it were an
4 ingredient mixed into a preexisting food rather than as a
5 factor that can cause unpredictable deleterious changes in
6 the developmental process of a food organism. As one of our
7 plaintiffs, the respected molecular biologist Prof. Liebe
8 Cavalieri has stated, such an approach is "simplistic if not
9 simple minded."

10 Although the FDA's official statements ignore
11 these unpredictable kinds of negative effects of genetic
12 engineering, its own scientists are well aware of them.
13 This came to light when the FDA had to give us copies of its
14 files during the course of the lawsuit. You know, the
15 agency is asking us to bring forth to them any newly
16 emerging scientific evidence. Well, this evidence that I am
17 about to share with you is not new, but it is newly emerging
18 and it is unfortunate it took a lawsuit to pry it out of the
19 government's own files.

20 I will only be able to give you a brief summary, a
21 brief taste of some of the memoranda that are from the FDA's
22 own scientists, in their own files. FDA microbiologist, for
23 instance, Dr. Louis Pribyl stated: "There is a profound
24 difference between the types of unexpected effects from
25 traditional breeding and genetic engineering." He added

1 that several aspects of gene splicing "may be more
2 hazardous."

3 Similarly, Dr. E.J. Matthews of the FDA's
4 Toxicology Group warned "genetically modified plants could
5 ... contain unexpected high concentrations of plant
6 toxicants," and he cautioned that some of these toxicants
7 could be unexpected and could "be uniquely different
8 chemicals that are usually expressed in unrelated plants."

9 Also, the head of the FDA's Center for Veterinary
10 Medicine wrote in a memorandum to Dr. Maryanski, "CVM" --
11 that is the Center for Veterinary Medicine -- "believes that
12 animal feeds derived from genetically modified plants
13 present unique animal and food safety concerns."

14 Also, Mitchell J. Smith, who was head of
15 Biological and Organic Chemistry Section at the Center for
16 Disease Control and the Center for Science and Nutritional
17 Safety at FDA, wrote in a letter to Dr. Maryanski that the
18 agency's proposed policy on genetic engineering turns FDA's
19 prior practice on its head.

20 The numerous in-house critiques of the agency's
21 proposed policy are best summed up by Dr. Linda Kahl, an FDA
22 compliance officer, who protested that the agency was
23 "trying to fit a square peg into a round hole by trying to
24 force an ultimate conclusion that there is no difference
25 between foods modified by genetic engineering and foods

1 modified by traditional breeding practices." She declared,
2 "the processes of genetic engineering and traditional
3 breeding are different and, according to the technical
4 experts in the agency, they lead to different risks."

5 It is important to note that was not Dr. Kahl
6 expressing her own opinion. She was carefully summarizing
7 the many memoranda from the technical experts that are in
8 the file, and that is a fair summary.

9 In light of the unique risks, FDA scientists
10 advised that genetically engineered foods should undergo
11 special testing. The Division of Food Chemistry and
12 Technology cautioned, "some undesirable effects such as
13 appearance of new, not previously identified toxicants may
14 escape breeders' attention unless genetically engineered
15 plants are evaluated specifically for these changes. This
16 Division, as well as many other FDA experts, recommended
17 that such tests had to include rigorous toxicological
18 testing.

19 Not only was the agency aware of uncertainties
20 within its own ranks, it also knew there was considerable
21 disagreement about the safety of genetically engineered
22 foods in the scientific community at large. For instance,
23 FDA biotechnology coordinator, Dr. James Maryanski,
24 acknowledged in a letter to a Canadian health official, on
25 October 23, 1991, that there was not a scientific consensus

1 about safety. He also admitted, "I think the question of
2 the potential for some substances to cause allergenic
3 reactions is particularly difficult to predict."

4 Nonetheless, the FDA not only disregarded the
5 warnings of many of its own scientists about the unique
6 risks of gene-spliced foods, it covered them up and it has
7 taken a public position that is quite opposite. It's
8 official policy statement declares: "The agency is not aware
9 of any information showing that foods derived by these new
10 methods differ from other foods in any meaningful or uniform
11 way."

12 Now, I invite the members of this audience to
13 consider the sampling of statements from FDA's own
14 scientists I just shared with you and then to consult our
15 web site, www.biointegrity.org, where we have posted the
16 original versions of these documents, photocopies, along
17 with many other such memoranda, and you consider in your own
18 minds whether you can accept the FDA's claim that it has no
19 information about meaningful differences -- if you can
20 accept that as a good faith attempt to represent reality or
21 whether, instead, it appears to you as a ploy calculated to
22 deceive the public and evade the law.

23 So, a strong case can be made that FDA policy
24 violates sound science and, therefore, a strong case can be
25 made that it does violate the law, the U.S. Food, Drug and

1 Cosmetic Act. In this statute, Congress instituted the
2 precautionary principle and definitively decreed that no new
3 substance shall be added to our food unless that substance
4 has been demonstrated to be safe through standard scientific
5 testing.

6 While the FDA agrees that the foreign genes that
7 get inserted into a plant, along with the substances it
8 produces, are in principle food additives, it maintains they
9 are exempt from regulation because they fall into the
10 exception for substances that are generally recognized as
11 safe, or GRAS. However, as already noted, FDA records
12 indicate such manipulations are not even recognized as safe
13 among the agency's own scientists, let alone by a consensus
14 in the scientific community.

15 Second, the law is explicit that any recognition
16 of safety must be based on "scientific procedures," and both
17 the FDA and the courts have heretofore consistently
18 interpreted "scientific procedures" as referring to studies
19 published in peer-reviewed literature. Moreover, the FDA's
20 own regulations emphasize that the tests supporting a
21 general recognition of safety "require the same quantity and
22 quality of scientific evidence as is required to obtain
23 approval of the substance as a food additive." This means,
24 in the FDA's own words, that the tests must demonstrate "a
25 reasonable certainty that the substance is not harmful under

1 its intended conditions of use." Yet, neither the FDA's
2 records nor the scientific literature indicate that such a
3 test exists for even one genetically engineered food.

4 In fact, the main test that attempted to
5 demonstrate the safety of a bioengineered food through
6 standard toxicology tests failed to do so. That food was
7 the Flav'r Savr tomato, the first genetically engineered
8 organism that the FDA reviewed. In commenting on those
9 tests, Dr. Robert J. Scheuplein, director of the FDA's
10 Office of Special Research Skills, stated that the tests
11 raised by failed to resolve a safety issue. He wrote, "the
12 data fall short of a demonstration of safety or of a
13 demonstration of reasonable certainty of no harm which is
14 the standard we typically apply to food additives. To do
15 that we would need, in my opinion, a study that resolves the
16 safety questions raised by the current data." Yet, the FDA
17 approved that product anyway on the grounds it was generally
18 recognized as safe, even though the law requires such
19 recognition to be based on precisely the kind of test that
20 had failed to demonstrate safety. Interestingly, FDA
21 officials claimed that the Flav'r Savr passed muster so well
22 that the rigor of its testing will not have to be repeated
23 for other bioengineered foods.

24 So, although the generally recognized as safe
25 exemption was intended to permit marketing of substances

1 whose safety has already been demonstrated through sound
2 testing, the FDA is now using it to circumvent testing and
3 to approve substances based on inferences drawn from less
4 rigorous forms of analysis -- inferences that are dubious in
5 the eyes of several of its own as well as many other
6 experts.

7 Moreover, it is very important to make clear that
8 although government officials repeatedly boast that no
9 genetically engineered food has ever caused any harm to
10 human beings, once such food did kill dozens of Americans
11 and permanently disabled over 1500 others. That was a
12 genetically engineered food supplement of the amino acid L-
13 tryptophan. It caused those deaths in the late 1980s. By
14 the way, only that batch of genetically engineered L-
15 tryptophan caused that problem. It was later found that
16 those batches contained some very highly toxic contaminants
17 at very low levels. They escaped standard pharmacological
18 testing. The pharmacologic analytic tests showed those
19 supplements to be pure but they killed people and they
20 permanently destroyed the lives of over 1500 others.

21 On July 18, 1991, Douglas L. Archer, then the
22 Deputy Director of FDA's Center for Food Safety and Applied
23 Nutrition, was invited to testify before Congress on this
24 tragedy. In his written remarks he did not once mention the
25 word genetic engineering or indicate that the L-tryptophan

1 supplement in question had been genetically engineered.
2 Rather, he blamed the problem on food supplements in
3 general.

4 Yet, just a few months after his testimony, on
5 September 27, 1991, Dr. James Maryanski, responding to
6 questions from the Government Accounting Office doing an
7 independent study of that tragedy, admitted his own memo in
8 the record, "I said that we have no new information, that we
9 do not yet know the cause of EMS" -- that was the specific
10 ailment that killed the people -- "nor can we rule out the
11 engineering of the organism." It couldn't be ruled out
12 then. The process of genetic engineering was questionable
13 and dubious then and it remains dubious, and many eminent
14 scientists believe that genetic engineering itself is still
15 the most probable cause for those deaths and disabilities.

16 MR. LEVITT: Excuse me, Mr. Druker, in fairness to
17 the other panelists, if we could try to wrap up --

18 MR. DRUKER: Okay, I will wrap up --

19 MR. LEVITT: -- and we will have additional time
20 for questions.

21 MR. DRUKER: I am sorry, but this information is
22 very important and has not been brought to light, and it
23 should have been by now. I am sorry, I will wrap up.

24 The FDA says it is now in a listening mode. If
25 its ears are truly opened, then its conscience should have

1 been touched. You know, we are not involved in some
2 abstract academic debate. What is at stake is the safety of
3 the nation's and ultimately the world's food supply. All
4 relevant evidence has to be considered, and the FDA claims
5 that its processes are transparent and clear and, yet, all
6 of this evidence I have just brought forth has been
7 obfuscated, at best, by the agency.

8 Mr. Levitt and Commissioner Henney, when you hear
9 my remarks I really implore you to consider very carefully
10 whether the agency's current policy is scientifically sound;
11 whether it is in line with the precautionary principles
12 mandated by U.S. law; whether it really serves the public
13 or, as Dr. Goldberg and others have said, better serves the
14 interests of the biotechnology industry.

15 If, God forbid -- if genetically engineered foods
16 do kill and cripple again, those that continue to make
17 statements that are dubious will have it on their own
18 conscience. It is time for change. Thank you very much.

19 [Applause]

20 MR. LEVITT: Thank you, Mr. Druker. Again, as
21 with any of the speakers today, if people have additional
22 written information they would like to submit to the docket
23 to be sure it gets in the record, we, by all means, are
24 happy to accept that and, again, we will have additional
25 time for questioning after all the speakers are done.

1 Next, we have Dr. Samuel Lehrer of Tulane
2 University Medical Center.

3 DR. LEHRER: Thank you very much.

4 [Slide]

5 My task this morning is to address the issue of
6 genetically modified foods with regard to allergenicity. In
7 particular, I would like to consider the safety assessment
8 of these foods in a very short period of time so that you
9 understand what the process is and address the issues of are
10 we doing enough; is there more that we can do?

11 [Slide]

12 First we just need to consider food allergy.
13 Allergies occur in about one to two percent of the adult
14 population and four to six percent of the pediatric
15 population. Almost all food allergies are due to eight
16 foods or food groups.

17 Symptoms of food allergy can be highly variable,
18 and most food allergies are IgE-mediated immunological
19 reactions, and this is very important because this
20 distinguishes true food allergies from other food
21 intolerances which have a metabolic or toxic basis.

22 [Slide]

23 Food allergens generally are proteins, but it is
24 important to remember that not all proteins are food
25 allergens. Generally, plants contain tens of thousands of

1 proteins, yet, very few of these proteins are allergenic.
2 Most allergens are stable for digestion and processing, and
3 major allergens tend to be abundant proteins within a food.
4 They are in a food in high concentrations. Many food
5 allergens have been cloned and characterized.

6 [Slide]

7 Now, when we consider biotechnology's use in terms
8 of improving food supply, as Dr. Day indicated, this has
9 been around literally for thousands of years. But what
10 distinguishes the old biotechnology from the new
11 biotechnology is genetic engineering, and genetic
12 engineering, as some have already said, is a method that
13 facilitates the identification and selection and transfer of
14 genes in coding of a specific protein into the genome of
15 another organism. This method precisely determines which
16 proteins are introduced into the organism and where they are
17 expressed.

18 Now, most proteins that are introduced into crops
19 are not stable to digestion or processing, and most
20 applications require only minute amounts of new protein or
21 even no protein at all to have the desired effect. So,
22 these last two points, if you remember what I said in the
23 previous slide about allergens, suggest that the likelihood
24 of these proteins being allergenic is minimal.

25 Interestingly, biotechnology is even being used to

1 reduce the allergenicity of some foods. For example, a
2 group in Japan is producing hypoallergenic rice, and I
3 believe that several groups are attempting to do this with
4 other crops in the United States.

5 [Slide]

6 When we consider the concerns about genetically
7 modified crops we first need to identify the risks. What
8 are they? How can these risks be assessed, and how can they
9 be minimized? This assessment must be based on accepted
10 scientific principles. This is very important and this is
11 something the other panelists have said already. Also, the
12 criteria should be the same as that used for other foods.
13 Finally, we need to consider how these risks relate to the
14 benefits provided by the genetically modified food.

15 [Slide]

16 To address these issues, as Dr. Goldberg
17 mentioned, the FDA, EPA and USDA sponsored a conference in
18 1994 on the scientific issues related to the potential
19 allergenicity of transgenic food crops, and this was one of
20 the first meetings to address this issue and discuss some of
21 the concerns involved.

22 In 1995, there was a series of meetings on the
23 allergenicity of genetically modified foods sponsored by the
24 Allergy and Immunology Institute and the International Food
25 Biotechnology Council, in Washington, D.C. These meetings

1 resulted in the publication of a monologue and critical
2 reviews in Food Science and Nutrition, in 1996. This
3 monologue addressed allergenicity in general of foods and,
4 in particular, genetically modified foods, and proposed a
5 decision process in which we can address these issues.

6 This decision tree was based on utilizing
7 immunochemical procedures for testing for allergens, as well
8 as comparing the physical chemical properties of the
9 introduced proteins to known allergens, and this is
10 utilizing the most current technology available. Actually,
11 in response to some of the issues that Dr. Goldberg raised,
12 I might mention that most of the foods that we eat today
13 could not pass this process.

14 [Slide]

15 I just would like to review briefly application of
16 this decision process. Dr. Goldberg already mentioned the
17 Brazil nut protein that was expressed in soybean during and
18 it was later shown that this was actually a major Brazil nut
19 allergen. Contrary to what she was saying, to me, this is
20 an example of how the system works because we were able to
21 identify the product; development was stopped and the
22 product was never marketed, in spite of the fact that it was
23 being developed as an animal feed.

24 [Slide]

25 So, in conclusion, I believe that the probability

1 of an introduced protein, that it will be allergenic, is
2 extremely low. There are definitive methods to detect the
3 transfer of known allergens and measure changes in native
4 autologous allergens.

5 Through the combination of genetic and physical
6 chemical criteria, I believe that it provides assurance that
7 proteins from sources with no allergenic history will not
8 pose significant concerns about allergenicity.

9 Now, I also want to add, as Dr. Goldberg
10 mentioned, that although we are basing all of these
11 assessments on the available technology, technology can be
12 improved and I think that we should be directing more
13 efforts in terms of developing better models in which we can
14 better assess the allergenicity of new foods being developed
15 by these new technologies. But, based on the current
16 technology, I believe that we are doing everything possible
17 to identify the allergenicity. Thank you.

18 MR. LEVITT: Thank you very much, and our final
19 presentation will be from Dr. Terry Etherton.

20 DR. ETHERTON: Thank you, Mr. Levitt. Mr. Levitt,
21 members of the Food and Drug Administration and listening
22 panel, thank you for giving the Federation of Animal
23 Sciences Societies the opportunity to provide comments today
24 on the scientific and safety issues of livestock feeds
25 derived from plants developed using biotechnology

1 techniques.

2 As background, I have conducted research in the
3 areas of endocrine regulation of nutrient metabolism and the
4 development of novel biotechnology products for application
5 in animal agriculture. I am an expert in the use of
6 numerous feeds by livestock, including digestion and
7 absorption of nutrients for milk production and growth.

8 The Federation of Animal Sciences Societies, or
9 FASS, is a professional organization made up of
10 approximately 10,000 scientists in academia, government and
11 industry which exists to serve society through the
12 improvement of all aspects of food animal product. FASS
13 represents the combined membership of the American Dairy
14 Science Association, the American Society of Animal Science
15 and the Poultry Science Association.

16 As requested, Mr. Levitt, we will comment on newly
17 emerging scientific information related to the safety of
18 feeds derived from genetically modified crops. It has been
19 estimated that the supply of food required to adequately
20 meet human nutritional needs over the next 40 years in the
21 global village is quantitatively equal to the amount of food
22 previously produced throughout the entire history of
23 humankind. This poses a daunting challenge to the global
24 village for several reasons. First, virtually all land
25 suitable for farming worldwide is being farmed. Secondly,

1 destruction of tropical rain forest or wildlife habitat is
2 not a viable option for environmental considerations.

3 Thus, the only feasible solution is to develop new
4 technologies that enhance food product efficiency. Genetic
5 modification of crops for our livestock has been conducted
6 for many years. Plants to supply feeds for livestock have
7 been improved over the years because new plant varieties
8 were developed using conventional techniques of plant
9 breeding and genetic selection.

10 Crops to supply feed for livestock produce through
11 modern methods of biotechnology are emerging from research
12 and development to the marketplace. Crops developed using
13 modern methods of biotechnology are referred to as
14 genetically modified crops as opposed to crops using
15 conventional plant breeding. Both conventional and
16 biotechnology techniques have benefited agriculture.

17 Corn grain, whole plant chopped corn and soybeans
18 from the currently genetically modified crops have been fed
19 to livestock and compared with conventional feeds to
20 determine the effects on feed consumption, digestibility and
21 animal responses. Chickens, sheep, beef cattle and dairy
22 cattle have been used in this research.

23 These data indicate that the chemical composition
24 of the genetically modified and conventional feeds are
25 substantially equivalent, and are well within the normal

1 range of values reported in the scientific literature.
2 These data indicate that feed consumed, digestibility of
3 feeds, nutrient absorption, growth, milk production, milk
4 composition and health of livestock fed genetically modified
5 and conventional feeds were equivalent.

6 The digestive process in all livestock breaks down
7 the nutritional components in feeds, including protein and
8 amino acids and DNA and nucleic acids. Because the
9 nutrients in these feeds are broken into smaller components,
10 the plant proteins have not been detected in milk and the
11 plant proteins would not be expected in meat and eggs.
12 These data, and our understanding of nutrient digestion,
13 absorption and metabolism indicate that these genetically
14 modified feeds are safe for livestock to consume. In
15 addition, the food products of livestock consuming these
16 feeds are safe for human consumption, and will be of benefit
17 to the nutrition and well being of the world's population,
18 especially children in developing countries.

19 In conclusion, FASS strongly recommends that
20 science be the basis for acceptance of genetically modified
21 feeds for livestock. FASS endorses the use of biotechnology
22 techniques to improve agricultural plants and animal
23 products. FASS also believes that agricultural
24 biotechnology has the capability to improve the supply of
25 livestock feeds and healthful animal and plant food products

1 and, thereby, help to meet the nutritional needs of the
2 growing world's population.

3 In closing, Mr. Levitt, I thank you for the
4 opportunity to provide this testimony. FASS is highly
5 supportive of the existing FDA consultation process, and I
6 would like to leave you with the perspective that we now
7 live in an era where the greatest proportion of people in
8 recorded history have the luxury of dying of old age
9 diseases, and we have the safest food supply that humankind
10 has ever seen. Thank you.

11 **Panel Answers FDA Questions**

12 MR. LEVITT: Thank you. Let me thank all the
13 panelists, and the audience for being so attentive during
14 all of these presentations.

15 We will now proceed to a little more of a Q&A
16 format. What we will do, so everyone knows what to expect,
17 is I will start with a question and I will just ask
18 everybody down the line to provide an answer to it, and we
19 will just kind of go right in order. We will then go right
20 down the line and, hopefully, magically that will occur
21 about the time we are supposed to take our lunch break. If
22 not, you know, we will watch the time as it goes along.

23 I will start with something you have already been
24 prepared to answer, as a way of kind of easing into this,
25 and a number of you have answered it directly or indirectly

1 but I think it would be nice to just kind of get together
2 the views, if you will, together in the proceedings. That
3 really is the first question the FDA asked in the Federal
4 Register with regard to the current consultation process on
5 how it ought to be modified, if at all.

6 I will read you the question again which says, has
7 FDA's consultation process achieved its indented purpose?
8 Based on experience to date, should this regulatory approach
9 "sunset," should it continue in its current state, should it
10 be made mandatory, or would it be otherwise revised? So, I
11 think you have all the potential possibilities there. We
12 will start with Dr. Day.

13 DR. DAY: My view is that it isn't broken and it
14 doesn't need to be fixed. I think that if the FDA is
15 flexible and reactive to new problems as they arise, then
16 they will continue to safeguard our interests in the way
17 they have so far.

18 I don't accept the hypotheses as scientific facts.
19 Some of the statements that Mr. Druker made are
20 hypothetical; they have not been shown to occur. So, that
21 is my comment, Mr. Chairman.

22 MR. LEVITT: Thank you. Miss Foreman?

23 MS. FOREMAN: Yes, thank you. I think I made it
24 perfectly clear in my prepared statement that I think this
25 system was born under a cloud and that cloud has deterred

1 public confidence in the system. I don't think you can
2 magically determine that these products are safe any more
3 than we are magically going to finish in time for lunch --

4 [Laughter]

5 -- and I am hungry! A mandatory approval system
6 doesn't cost the agency anything except resources, and the
7 public ought to be prepared to make those resources
8 available. It will cost the industry something but not very
9 much, if one believes Dr. Maryanski about the consultative
10 process. It rewards the industry by increasing public
11 confidence in that process, and all you have to do is look
12 around the country today and see what is happening out
13 there, and you realize people are not confident with the
14 process as it exists right now. And, you know, it just
15 doesn't work to try to insult people into purchasing your
16 products. It doesn't work to sit there and say, "Jane, you
17 ignorant slut, if you don't believe this is safe it's
18 because you're stupid." You have to persuade the public
19 that the government has a process that protects the public's
20 interest.

21 MR. LEVITT: Thank you. Dr. Goldberg?

22 DR. GOLDBURG: Well, as I made clear in my
23 statement, I think there is good reason to improve FDA's
24 policy so that it is more protective of consumers. As Carol
25 pointed out, I don't think that will come at a terrible cost

1 to industry, and maybe some benefit because consumers might
2 feel more secure about the safety of the food supply. As it
3 now stands, I think that a voluntary system is in the future
4 highly susceptible to problems should companies choose not
5 to go along with crossing t's and dotting i's for the Food
6 and Drug Administration. For example, Dr. Lehrer noted the
7 example of the Brazil nut gene in the soybeans as an example
8 of how the system worked; that the problem with the Brazil
9 nut allergen was detected before the product ever reached
10 market. I would like to point out that that example was
11 entirely independent of the regulatory system. The company
12 that created the soybeans, Pioneer Hi-Bred, behaved very
13 responsibly and hired a good scientist to do the analyses,
14 and when the analyses came back chose voluntarily to
15 withdraw the product. There is no guarantee to consumers,
16 however, that in the future all the companies will behave so
17 well, and that is why I think many of us would like a system
18 that more squarely places the burden of proof on industry to
19 demonstrate the safety of the foods it is producing.

20 MR. LEVITT: Thank you. Mr. Druker?

21 MR. DRUKER: Mr. Levitt, you asked us to address
22 specifically whether the purpose of the current consulting
23 system has been achieved. It depends on what its purpose
24 is. If its purpose is to give the illusion that the Food,
25 Drug and Cosmetic Act is being followed and that these foods

1 have really been established safe before they are marketed,
2 then it is serving its purpose because that is the illusion
3 that is being given.

4 But if you really want to follow the law and make
5 sure that no genetically engineered food product reaches the
6 market, reaches American dinner tables without having been
7 demonstrated to a conclusive level that it is safe, then
8 there needs to be a change because, as I mentioned, and I
9 would invite Dr. Day or anyone else here to cite one example
10 of a single genetically engineered food that has been
11 established safe through scientific testing, published in
12 the peer-reviewed literature, to the standard required by
13 law.

14 We have many of our scientific plaintiffs who have
15 signed sworn declarations submitted to the court saying they
16 are not aware of a single such study. As I already
17 mentioned, the FDA's own scientists say that the studies on
18 the Flavr Savr tomato were inconclusive and raised a safety
19 issue that was not resolved.

20 So, if you want to be in compliance with sound
21 science, as you claim; if you want to be servants of the
22 law, then change the policy. Require mandatory safety
23 testing, and require that every genetically engineered food
24 be established safe to reasonable certainty of no harm
25 before it appears on American dinner tables.

1 MR. LEVITT: Thank you. Dr. Lehrer?

2 DR. LEHRER: Yes, I believe that the system is
3 effective now. Can it be improved? Yes. I think that as
4 technology improves, we probably can make better decisions
5 addressing some of these questions. I might be actually
6 overlapping with point two but, in general, I think the
7 system is functioning well.

8 DR. ETHERTON: Mr. Levitt, as I said in my
9 comments, and would like to emphasize that they reflect
10 those of the FASS membership, we believe that the
11 consultation process has achieved its goal and are
12 supportive of it continuing in its current state. Thank
13 you.

14 MR. LEVITT: Thank you very much. I will next
15 turn to Mr. Hubbard.

16 MR. HUBBARD: Dr. Day, it has been well stated
17 that consumer anxiety in Europe is much higher on this issue
18 than in this country, although I think Ms. Foreman mentioned
19 that it is increasing. Can you give us some of your
20 perceptions of why it is higher in Europe? Is it consumer
21 enlightenment? Can you tell us more about that?

22 DR. DAY: Well, I think there are several reasons.
23 One is that the public's confidence in government science in
24 Britain was severely shaken by the mad cow disease epidemic,
25 particularly the risk of contracting Creutzfeldt-Jakob

1 syndrome from the prion that is responsible for that
2 disease.

3 I think too that the consultative process that we
4 have in this country is better than it is in Britain. I
5 don't know of an agency in Britain that would hold a hearing
6 of this kind, and I think that this kind of meeting is
7 extremely important in allowing people to express their
8 concern so that we can have the kind of discussion that we
9 are having here this morning. That happens to a much less
10 well-developed extent in the U.K.

11 MR. LEVITT: I think I would like to give the
12 other panelists an opportunity to respond to that question,
13 if you would like, in terms of why consumer concerns appear
14 to be greater in Europe than they are here.

15 MS. FOREMAN: I agree with Dr. Day in terms of the
16 history of government regulation and the utter failure of
17 the government in Great Britain to deal with mad cow disease
18 responsibly. More recently you had the utter failure of the
19 government in Belgium to deal with the dioxin and, in fact,
20 to mislead the public. That has not been the case here,
21 and the agency is to be applauded for beginning this process
22 of consultation.

23 But I think the real difference is that this has
24 simply been an issue for a longer period of time in the
25 European countries than it has been here, and maybe on

1 January 1 we will all wake in concern and genetically
2 engineered foods will have disappeared in the United States
3 -- don't bet on it. I have a feeling that we are in for a
4 long and painful process here that could be cut off if you
5 will decide to take some steps that are reassuring to the
6 public, that is, a mandatory review and approval and, as
7 Becky and I keep saying, doesn't cost the industry an awful
8 lot and may reward them as well.

9 MR. LEVITT: Thank you. Dr. Goldberg?

10 DR. GOLDBURG: Well, I think there is a myriad of
11 reasons for the differences, some of which have already been
12 elaborated on and I can't go into completely. I must say
13 though that I have been involved in issues concerning the
14 use of genetic engineering in agriculture for 13 years now
15 at the Environmental Defense Fund, and was involved in the
16 early stages of the development of federal regulations for
17 biotechnology, and at the time those regulations were
18 established biotech products were all in the R&D stage. So,
19 to the extent that what was going on received media
20 attention, the concerns to consumers were all hypothetical.
21 They were in the future. These foods were prospective.

22 I think the debate in Europe has unfolded in a
23 different way. When regulatory systems started being
24 developed, when consumers started to think about these
25 issues the foods were real -- they were on their table.

1 Therefore, I think there is a lot more concern.

2 Agreeing with Carol, I don't think we have seen
3 the last of the issue here. Although the U.S. public to
4 date has not expressed the same kind of concerns we have
5 seen in Europe, I think people are growing in their
6 awareness that many genetically engineered foods are now on
7 their tables, and want some assurance, some independent
8 oversight of the safety of these foods.

9 Finally, I would like to point out one other
10 difference in biotechnology perception in Europe and the
11 U.S., and I think that has to do with how at least some
12 individuals in the scientific community receive the
13 technology. I think it is important to consider that
14 biotechnology is the baby of the U.S. scientific community
15 and, as such, people in this country -- scientists in this
16 country have all sorts of interests in its development, and
17 that is less true in Europe.

18 For example, in Europe we saw a very critical
19 report on genetically engineered foods come out of the
20 British Medical Association. I don't think we would see
21 that here. I think there are important cultural differences
22 not only among the public but also in the scientific
23 community.

24 MR. LEVITT: Thank you. Mr. Druker?

25 MR. DRUKER: Yes, there are several reasons. One,

1 as has been mentioned, the FDA has in many respects, over
2 the last 30-some years, performed very well and admirably,
3 and gained the respect of the American public. I can think
4 of the thalidomide drug which many European governments
5 unwisely approved. The FDA took a precautionary approach
6 and saved a lot of agony. Tobacco quite recently -- the FDA
7 has become a great champion of public health when it comes
8 to wanting to regulate tobacco. So, you have gained some
9 laurels and I think that transfers to your stance on
10 genetically engineered food.

11 Also, of course, there is a difference of media
12 coverage though within Europe and the U.S. The American
13 media has tended, by and large, to just report the
14 promotional statements of the industry spin doctors and of
15 the government spokespeople who continue to say that there
16 is really no risk and these foods have been guaranteed safe.
17 U.S. Secretary of Agriculture, Dan Glickman, has been saying
18 for years these foods have been proven safe. So, people
19 believe it. They aren't aware that they are only assumed to
20 be safe on the basis of hypotheses, which is not adequate.

21 Also, of course, the mad cow disease incident in
22 Great Britain really has I think heightened concern in Great
23 Britain and in Europe. Relevant to that, I think it is
24 important to note that the scientist, the main scientist in
25 Great Britain who predicted that there would be a mad cow

1 disease type of problem well before it happened, Dr. Richard
2 Lacey, who has an M.D. and also has a Ph.D. in genetics, and
3 is professor of medical microbiology at the University of
4 Leeds in the United Kingdom, predicted that and the British
5 government ignored him for a long time. Then, lo and
6 behold, he was right.

7 Now, Richard Lacey cannot be a plaintiff in our
8 lawsuit because he is not a U.S. citizen but he has
9 submitted a sworn declaration to the court, and he has said
10 that he believes, along with the rest of our plaintiffs,
11 that the same potential for widespread problems from
12 genetically engineered foods exists as it did several years
13 ago in the mad cow disease episode before the problem became
14 completely manifest. He reminded the judge that mad cow
15 disease has about a 12-17 year latency. So, the fact that
16 we haven't seen people dropping dead in droves yet from
17 genetically engineered food should not give us great
18 confidence because things can be building up. And, he is
19 not a scare monger; he is an eminent scientist. But, he has
20 said that the claims about the safety of genetically
21 engineered food rests far more on wishful thinking than on
22 solid scientific evidence, and he has told the court that
23 these foods should not be on the market unless they can be
24 demonstrated safe through rigorous testing, testing which is
25 currently absent.

1 DR. LEHRER: I agree with much of what has been
2 said by my fellow panelists, with probably one major
3 exception. First, I think mad cow disease is an important
4 reason why Europeans are somewhat distrustful of what is
5 told to them about their food supply, or are more concerned
6 about their food supply because of their experience with
7 this disease.

8 In addition, I have several Europeans in my
9 laboratory and we have had extensive discussions on this
10 very topic, and I think there are cultural differences
11 between Europe and the United States with regard to food. I
12 think the Europeans have a very intimate relationship with
13 their foods. Americans do to a degree, but also Americans
14 eat very quickly. Fast food started in the United States.
15 Americans don't necessarily have the same cultural
16 relationship with food that Europeans do and this may
17 contribute to the process.

18 Another possibility has been raised in terms of
19 biotechnology being developed in the United States, and a
20 lot of these products that are being developed are being
21 developed by large American corporations that want to market
22 them in Europe, and I think there may be some concerns about
23 that in terms of large American companies marketing these
24 products there. That may have contributed to it.

25 I do disagree with the issue of media coverage.

1 Maybe we are reading different articles, but my experience
2 has been that I find the media tends to sensationalize
3 topics. Particularly with genetically engineered foods,
4 many of the articles that I have read, for example, with the
5 Brazil nut expressed in soybean, have titles which suggest
6 problems in the food supply rather than that this has been
7 identified and it is not being marketed. So, at least my
8 experience has been that the media does not downplay this in
9 the United States.

10 MR. LEVITT: For the record, that was Dr. Samuel
11 Lehrer. Finally, Dr. Etherton?

12 DR. ETHERTON: My observation reflects several
13 points that Dr. Lehrer shared and Dr. Day. What I would say
14 is that early on scientists, like myself, that were engaged
15 in discovery research in plant and animal biotechnology
16 discovered that an important element of developing products
17 was to become engaged as an advocate to talk about the need
18 for new technologies, their evaluation as far as safety to
19 the consumer. The rate-limiting step in developing these
20 technologies and their implementation is not the discovery
21 or a new technique or the idea, it is eventually to talk to
22 the American public about the need for and safety, and it is
23 very difficult to talk about these because they are complex
24 biologies. A high proportion of people in the United States
25 haven't had a lot of science education. And, historically I

1 think American scientists became more engaged earlier --
2 scientific organizations did, and I think that is built on
3 the fact that there is a cultural difference. I think the
4 people who got on a boat and came to North American three or
5 four hundred years were a different gene pool than those
6 that stayed behind.

7 [Laughter]

8 MR. LEVITT: Thank you. Next we will turn to Dr.
9 Stephen Sundlof, Director of our Center for Veterinary
10 Medicine.

11 DR. SUNDLOF: Thank you, Joe. First of all, I
12 would like to compliment the panel on a very stimulating
13 discussion. I learned a lot.

14 I heard two things and, although they are not
15 mutually exclusive, I would just like to explore them a
16 little bit. On the one hand, I heard that using modern
17 biotechnology you can more precisely transfer specific
18 characteristics, specific traits to these genetically
19 modified crops as opposed to through traditional plant
20 breeding where you may get a number of gene expression
21 products. So, that is one comment.

22 The other comment that I heard also was that there
23 is a potential for unknown expression products to occur.
24 So, the question that I would like the panel to address is,
25 first of all, I would like to get some kind of a sense of

1 the magnitude of the risk. How likely is that occur? The
2 example that was given was the L-tryptophan supplement,
3 dietary supplement. As a follow-up to that, has the
4 technology improved that would make such an expression
5 product less likely to occur now than it did back when that
6 incident occurred?

7 DR. DAY: I must admit that I have not seen a
8 complete account of the tryptophane story. The most recent
9 one that I read, however, indicated to me that the
10 contaminant problem arose because the company making the
11 tryptophane from a genetically engineered microbe omitted a
12 purification step. I have not seen any evidence confirming
13 that the contaminant was a problem of the genetically
14 engineered organism per se. The genetically engineered
15 organism produced more tryptophane and the company making
16 the product could make a short cut by eliminating the
17 purification step which caused the problem. I am open to be
18 corrected on that by other panelists who may have more up to
19 date information.

20 We regard to the question of unpredictable effects
21 from introducing transgenes, first of all, the transgene and
22 the associated DNA that carries it into the recipient
23 organism can be characterized, and it is characterized; the
24 DNA sequence is known. There is the possibility, by having
25 flanking sequences of DNA that are homologous to those

1 already in the organism, of some control over where it is
2 located.

3 Now, yes, one has to admit that there is the
4 potential that it might have an unpredictable effect. But,
5 when you are comparing that operation with what is quite
6 frequently done in conventional plant breeding of taking
7 plants that have been isolated from each other maybe for
8 hundreds or thousands of years, and they are brought
9 together by plant collectors in gene pools and term plasm
10 banks, and they are inter-crossed, sometimes with great
11 difficulty because there are sexual sterility barriers, and
12 the genetic differences between those individuals are very
13 considerable, much more so than the precisely characterized
14 DNA that is in an insert, then I think you have a much, much
15 greater probability of unpredictable effects.

16 Jim Maryanski referred to one instance, the
17 product of an unusually high level of solanine in a potato
18 variety called Lenape that was introduced. It was a hybrid,
19 or derived from hybridization of the cultivated potato with
20 a wild Mexican species, and that variety had to be
21 withdrawn. He used it as an example of post-release
22 regulation.

23 None of our food is one hundred percent safe. It
24 may be contaminated with microorganisms, spoilage organisms.
25 This is the most important problem that we face in our food

1 supply. As a biologist, I can't give the critics one
2 hundred percent assurance of anything biologically because
3 of the nature of the materials that we work with. All I can
4 say is that in my opinion, and of many other scientists, the
5 comparative risk is much smaller.

6 MS. FOREMAN: Well, I was going to pass on this
7 and leave it to the scientists, but since I spend a great
8 deal of my time dealing with microorganisms and their
9 contamination of food products, I just want to say, Dr. Day,
10 that in that case the public has some warning about the
11 presence of danger, and the capacity by handling food
12 products carefully to avoid that danger. That may not be
13 the case when you are dealing with these genetically
14 modified organisms. So, now back to the scientists.

15 DR. GOLDBURG: I would like to briefly first
16 comment on L-tryptophan. At one point a number of years
17 ago, I spent some time looking at the L-tryptophan problem
18 and came to the conclusion really that no one knows or is
19 likely to ever resolve what caused the problem with L-
20 tryptophan. The manufacturer of the L-tryptophan, a company
21 called Show Denko, changed two steps in the production
22 process for L-tryptophan, both changing a purification step
23 and the genetic engineering of the organism. So, whether
24 the problem was caused by one or both of these process
25 changes is unclear. A researcher at the National Institute

1 of Health, names Esther Sternberg, invested considerable
2 time trying to isolate contaminants in problematic L-
3 tryptophan that might have caused the disease and was left
4 with a myriad of confusing research results. So, while I
5 think it would be wrong to say that genetic engineering
6 caused the L-tryptophan problem, it would also be wrong to
7 rule it out as a potential cause.

8 On to the predictability of genetic engineering,
9 as Dr. Day said, it is absolutely true that the genetic
10 sequences that are introduced to a food via genetic
11 engineering, or to a crop plant, are well known or can be
12 very well known. However, there are some very serious
13 limits to how precisely genetic sequences can be put into
14 the chromosomes of plants. It is generally not known or not
15 controllable where inserted gene sequences land in plant
16 chromosomes, and there is some potential there for gene
17 interactions that could have so-called pleiotropic effects.
18 Certainly, there has been a lot of study of these effects
19 with genetically engineered flowers, looking at flower
20 color, and many unexpected effects have been documented.

21 Whether or not there is more variability in
22 selective breeding or genetically engineering I don't think
23 we know yet. Genetic engineering is still new and I think
24 we are still finding out to what extent unexpected effects
25 pose serious health concerns.

1 I must say, as someone who works to represent
2 environmental and consumer interests, my biggest concerns
3 about genetically engineered foods come from the really
4 unlimited universe of gene products that can be introduced
5 to foods via genetic engineering, and that is what makes
6 them really different than traditionally bred crop plants.

7 MR. DRUKER: Just to say one more point about the
8 L-tryptophan, or maybe a couple of points, the reason, by
9 the way, that we cannot conclusively rule out genetic
10 engineering or conclusively show it was some lax behavior on
11 the part of Showa Denko in their testing procedure is that
12 all of the relevant evidence was destroyed before the
13 international team of experts could come to the lab and
14 actually make the determination. So, it will remain a
15 mystery.

16 But the fact is, as Dr. Maryanski admitted to the
17 GAO, genetic engineering as a process cannot be ruled out.
18 It could not be ruled out in 1991 when he made that
19 statement. It still can't be ruled out. And, the law
20 requires a reasonable certainty of no harm. There is
21 reasonable doubt about the process of genetically
22 engineering itself -- and those strange toxins that were
23 produced are the kinds of unexpected toxins that the FDA
24 scientists were warning about in the statements I read
25 earlier and that many of the scientific experts who are

1 plaintiffs in our lawsuit warn about.

2 What is troubling is that the government tries to
3 deny that any genetically engineered food has caused harm.
4 Did then, and recent statements continue to boast that no
5 genetically engineered food is even caused as much as a
6 sniffle or a sneeze. It is just running away from reality.

7 Now, on the question of whether gene-splicing
8 techniques are more precise, again as has been acknowledged,
9 they are precise to the extent that you know exactly what
10 genetic material you are putting in. They are far less
11 precise in terms of being able to gauge adequately what the
12 ultimate effects are going to be and that, of course, is
13 what most directly relates to the issue of food safety.

14 I think it is very important just to give a
15 perspective on what is going on from what we already know
16 about information science. Genomes, DNA is an informational
17 code. We already know a lot about informational codes from
18 our own man-made computer software. And what we have
19 learned is that those codes, when they get to a certain
20 level of size and complexity -- we can no longer control
21 what happens when we do input. Even when software engineers
22 make a very well calculated change to a system that they
23 have completely designed and they have the whole
24 understanding of how that system is supposed to interact as
25 a whole, we have learned -- we, meaning the human race --

1 that we cannot control the unintended effects. In fact, it
2 is to the extent that the standard textbooks on software
3 engineering will say if you find an error in a program, the
4 best procedure is to leave it alone because, by trying to
5 fix that error, the likelihood of creating some unintended
6 effect somewhere else in the system is great enough that it
7 is better to live with an error than you know about than fix
8 it and create one that you don't yet know about.

9 Now, compared to even the most complex man-made
10 computer software program the genome of a living organism is
11 far greater and far less understood by the human brain. We
12 know very little about it. We know it is far more
13 unpredictable and, yet, we are intervening and making
14 changes that we should know could make deleterious negative
15 side effects that we cannot predict.

16 It is very interesting, and then I will end, but I
17 think it is sobering and I would like the FDA officials to
18 consider -- the FDA currently regulates medical devices, and
19 in that capacity it regulates software that runs those
20 devices. If a pacemaker or an x-ray machine -- these are
21 run by software -- if a company wants to make a change in
22 the software code that already is known to be safe, if they
23 make a change the FDA requires them to go through rigorous
24 regression testing to put that system through almost every
25 possible permutation and combination to make sure that no

1 unintended consequences came out. Why? Because that is the
2 industry standard. We know that that can happen when we
3 change informational systems. Yet, when it comes to food
4 safety, the biotech companies are making semi-random
5 insertions into the most complex informational systems in
6 the universe and the agency says we assume that is the same
7 thing as doing what has been happening in a very holistic,
8 natural way for hundreds of thousands, millions of years.
9 Go right ahead. You don't need to do any testing. I think
10 that that dichotomy is so gross that it deserves further
11 consideration.

12 MR. LEVITT: Dr. Lehrer?

13 DR. LEHRER: I am going to restrict my remarks to
14 allergenicity with regard to unintended or unpredicted
15 effects. In my opinion, with the current assessment methods
16 in place, I think it is highly unlikely that we would have
17 unanticipated allergen being expressed. Certainly, when we
18 are dealing with the transfer of proteins from known food
19 allergens or altering known foods which contain allergens,
20 this is, I would say, almost absolute.

21 With sources of proteins or genes from foods in
22 which we have no information about the allergenicity, I
23 believe based on the levels of expression, the digestibility
24 of these proteins, and the comparison of properties with
25 known allergens, that it is highly unlikely that there would

1 be an unanticipated allergen being expressed. Nevertheless,
2 we base this on current technology and, as Dr. Goldberg
3 mentioned, I think we can improve our risk assessment and
4 decision-making process as technology improves, and I think
5 that we need to devote efforts toward that so that we can
6 even minimize an already low or minimal risk.

7 MR. LEVITT: Thank you. Dr. Etherton?

8 DR. ETHERTON: Thank you. I would like to share
9 that the probability of their being an unpredictable or
10 unlikely side effect is very, very small. It is important
11 to appreciate, and you heard this morning that there is a
12 very, very extensive regulatory and oversight process that
13 FDA plays out. This is really the flagship organization in
14 the world, and there is a lot of stuff that they require
15 scientists to provide that work for companies. There is
16 oversight by advisory panels and, as you have heard, there
17 are some emerging technologies. We are now standing at the
18 gate where, when a genome is sequenced -- in other words,
19 when we have all of the information for the entire sequence
20 of a plant or animal and know all the genes, we will then be
21 able to evaluate what are called array techniques, that is,
22 a way to look at expression of all these genes to see which
23 are turned on or off.

24 My point is that when you engineer a plant or
25 animal using very precise techniques, I might add, so we can

1 target them out to precise locations, then we can look at
2 that effect on all other genes in the animal, whether they
3 are turned on, off or are unaffected. That will be a
4 powerful step forward.

5 We also know a lot about structure of proteins and
6 function and, as information technologies evolve, we in fact
7 now have very powerful ways to predict function. Then, the
8 obvious point is that you evaluate this in an experimental
9 setting and provide those data to the appropriate regulatory
10 agency to assure that these are as safe as know using
11 existing technologies, which are really very powerful.

12 Thank you.

13 MR. DRUKER: If I could just add something to that
14 because on the question specifically you asked about the
15 magnitude of risks. In that memorandum from Dr. Linda Kahl,
16 of the FDA, she mentioned that there is no data that
17 addresses the relative magnitude of the risks. Then she
18 says, are we asking the scientific experts to generate the
19 basis for this policy statement in the absence of any data?
20 It is no wonder that there are so many different opinions.
21 It is an exercise in hypotheses forced on individuals whose
22 jobs and training ordinarily deal with facts.

23 So, there isn't solid evidence, and I think what
24 you were just speaking about is a hypothetical possibility
25 in the future but, according to all of the scientists who