

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

BIOTECHNOLOGY IN THE YEAR 2000 AND BEYOND
PUBLIC MEETING

Thursday, November 18, 1999

9:00 a.m.

Metcalfe Federal Building,
77 West Jackson Boulevard - Room 331
Chicago, Illinois

1 We, at the Food and Drug Administration, are very
2 pleased to have this opportunity to share our experience and
3 listen to your views on this very important topic. We
4 recognize that there is not only a great deal of interest in
5 this topic, but also that there are widely differing and
6 very strongly held views on this subject, and while we wish
7 to listen to everyone, we will also ask that we all listen
8 to each other so that the community at large can gain a
9 better understanding of the spectrum of view points and the
10 range of concerns about this field.

11 FDA has a long history of public health
12 protection. Our current laws date back to the early part of
13 the century and over these years, we have faced many new
14 developments that effect the food supply. For example, in
15 the 1950's the use of preservatives and other chemicals in
16 food led to concerns about food safety. More recently, FDA
17 has been in the forefront of efforts as part of the
18 President's food safety initiative to reduce food borne
19 illness.

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

1 Let me briefly describe our overall efforts in
2 this area of biotechnology, which includes products in both
3 the medical or pharmaceutical area, as well as products that
4 have been developed in the food arena. In 1982, FDA
5 approved a new insulin product; the first consumer product
6 developed using modern biotechnology. Since that time, the
7 Agency has had extensive experience evaluating the safety of
8 products developed using these techniques. A number of
9 these products are now on the market and available to health
10 professionals and their patients.

11 The use of tools of biotechnology in foods began
12 in the mid-eighties as well. FDA completed its review of
13 the safety Chymosin or Rennet preparation, the milk clotting
14 enzyme used to make cheese in 1990. At that time, FDA
15 receive no public comments about the safety of this
16 ingredient. Recently, however, the use of tools of modern
17 biotechnology to produce new varieties of food crops has
18 raised a number of questions about environmental effects of
19 these crops and about safety and labeling of foods derived
20 from them.

21 I should note that some questions, such as those
22 regarding human health and food, and feed safety, as well as
23 food labeling, fall under FDA's authority. However, others,
24 such as those regarding environmental safety and the affects
25 on the plants themselves, generally fall under the authority

1 of other agencies or departments of the U.S. Government;
2 such as the Environmental Protection Agency or the U.S.
3 Department of Agriculture.

4 I would like to take this opportunity to briefly
5 describe how FDA oversees the safety of foods developed
6 using these techniques and to briefly share the experience
7 that we have had in evaluating the safety of these foods
8 over the past five years, since the first such whole food,
9 the flavr savr tomato entered the market.

10 FDA introduced our current policy for regulating
11 foods developed using these techniques in 1992, after an
12 extensive scientific review. The policy was discussed
13 publically during a joint meeting of the FDA's Food Advisory
14 Committee and our Veterinary Medicine Advisory Committee in
15 1994. Since that time, firms have completed food safety
16 discussions with FDA in over forty consultations on new
17 varieties of foods made using the tools of biotechnology.

18 We believe our policies and processes in this area
19 are well grounded in science and that we have an excellent
20 track record in apply our policy. We believe that our
21 oversight has be substantive, credible and appropriate. We
22 have now had five years of experience with this consultation
23 process.

24 In a few minutes, you will hear from Dr. Maryanski
25 about the specifics of our experience. The testing that has

1 been performed by a variety of developers that have
2 developed a variety of new products and the kind of
3 information that has been reviewed by the Agency and the
4 regulatory and scientific grounding for our approach to
5 oversight of these products.

6 It is our goal to have our review and regulatory
7 processes be as open and transparent as possible. We seek
8 each of your views about whether we need to consider making
9 adjustments to our current system. Because of the more
10 recent attention and controversy that has arisen, we fell
11 that it is an appropriate time to review our experience and
12 solicit views from interested parties. Specifically, we
13 want to hear your suggestions on our approach to safety
14 assessment and, if it is adequate, or needs strengthening
15 and how disclosure of information to the public on foods
16 that have been developed using these techniques would be
17 best achieved.

18 Let me take a moment to just briefly describe the
19 format and the logistics for today's meeting. This morning
20 we will focus on issues concerning the safety assessment of
21 these foods and FDA's regulatory oversight. There will be a
22 brief overview of our current approach to safety assessment
23 and the experience that FDA has had over the past five
24 years. We will then ask our invited panelists to discuss
25 issues related to questions that we believe will help FDA

1 evaluate its current approach to safety assessment. We will
2 then break for lunch and I should note that there's a food
3 court that is one level below us downstairs. Or, if you
4 desire to go out, we do have a list of restaurants for
5 you, but I would caution that we plan to start again
6 promptly at 1:00.

7 This afternoon, the focus will be on the issues
8 surrounding disclosure of information to the public. Again,
9 a brief discussion will be had by Robert Lake, from the FDA
10 staff. This will be followed by a panel discussion with the
11 format that will be used this morning as well. And, after
12 this second panel concludes, we've reserved two and a half
13 hours to hear the views of as many members of the audience
14 as we possibly can.

15 We will need to conclude the meeting promptly at
16 6:00 and because we want to insure that everyone is able to
17 present his or her views, we are asking that all
18 presentations by members of the public be limited to two
19 minutes.

20 When you checked in this morning, you should have
21 received a folder with a number on it and that number
22 indicates the order in which the public presentations will
23 be made. Because we do have a limited time for open
24 comments this afternoon, I'd like to remind you that we
25 welcome your written comments and have established a public

1 docket that will display all of the information that the
2 Agency has received from all of its public meetings and we
3 will also be posting this on our website.

4 We have also requested that today's meeting be
5 transcribed and the meeting transcript will be made
6 available in the docket as quickly as possible; we expect
7 within ten working days. Information about how to access
8 the public docket and submit your comments are also included
9 in your registration packet.

10 But, before we begin, I would like to extend a
11 very special thank you in advance to the members of our
12 panels for agreeing to come and share their views with us;
13 with you and with each other. We've attempted to assemble
14 panels with members who represent the spectrum of interested
15 parties. Each, no doubt, has very strong has very strongly
16 held views and very useful information for all of to
17 consider. We have relied, in part, on umbrella
18 organizations including consumer organizations, professional
19 societies and trade groups to represent their members and to
20 identify for us panelists for this and future meetings and
21 for their cooperation, we extend a very hardy thank you.

22 We trust that the members of the panel will
23 express a diversity of views, explaining those views and
24 establishing a dialog among the panelists to ensure that
25 issues are fully discussed. I would also like to add my

1 thanks, as Commissioner, to all of the FDA staff who have
2 devoted a great deal of time and energy to make today's
3 meeting possible. It includes not only our staff at the FDA
4 Headquarters in Washington, but particularly our employees
5 here in the Chicago District Office. Their flexibility
6 regarding the many logistical challenges raised by today's
7 meeting are greatly appreciated.

8 Again, let me underscore, FDA is here to listen
9 and to ask question or provide clarification about our
10 current policy. Our goal is not to reach a conclusion by
11 the end of the day. We are beginning the process of
12 listening, not pronouncing. We will not engage in debate on
13 these issues, primarily because we want to hear the views of
14 others.

15 Today's discussion and those that will follow will
16 no doubt stimulate our thinking. I welcome your individual
17 input and our collective work together.

18 Thank you, very much and let me now introduce the
19 members of the FDA panel to you. Really, the senior
20 leadership of the Agency, Sharon Smith-Holston, who is the
21 Deputy Commissioner for International and Constituent
22 Relations; Stephen Sundlof, who is the Director for our
23 Center on Veterinary Medicine; Margaret Porter, who is the
24 Chief Counsel at the Agency; Robert Lake, who is the
25 Director of the Office of Regulations and Policy and our

1 Center for Food Safety and Applied Nutrition; and James
2 Maryanski, who is our Biotechnology Coordinator in the
3 Center for Food Safety and Applied Nutrition.

4 I would now like to ask Dr. Maryanski to make his
5 presentation and then we will proceed to the panel.

6 DR. MARYANSKI: Thank you very much, Dr. Henney.
7 Good morning ladies and gentlemen. I have the honor of
8 describing our policy for overseeing the safety of foods
9 developed by modern biotechnology to you this morning.

10 I am going to explain to you very, very briefly
11 the legal authority that FDA has for assuring the safety of
12 foods, the process by which we are working to oversee these
13 products and I would like to take an opportunity to tell you
14 a little bit about the kind of testing that is done on foods
15 developed by modern biotechnology and to share with you some
16 of the experience that we have had over the past five years
17 in which firms have been consulting with the Agency on these
18 products.

19 May I have the first slide, please?

20 I'd just like to give you a little orientation.
21 The Food and Drug Administration is an agency within the
22 Department of Health and Human Services. You are
23 undoubtedly familiar with the Centers for Disease Control
24 Prevention, CDC, and the National Institutes of Health, NIH.
25 FDA and these agencies are health agencies within this

1 department.

2 FDA's Food Biotechnology Policy, as is all the
3 other regulations that FDA carries out, are grounded in the
4 Federal Food, Drug and Cosmetic Act. This is the law that
5 has been in place in the United States, essentially in the
6 same form in terms of the safety of food, since 1938 and we
7 have had a number of new technologies come forward in that
8 time. Maybe a little bit of light would be helpful.

9 [Laughter.]

10 Our mission is public health protection. That is
11 our mission. That is our goal. We carry that mission out
12 using sound science based policies. That is essential to
13 our policy for biotechnology, as well as to other products
14 that we regulate.

15 FDA has authority over foods that are in commerce
16 in the United States and foods that are imported and this
17 includes both foods that are used for human food and feeds
18 that are derived from crops that are used as animal feed.
19 We, of course, are here to ensure that the food supply is
20 safe and wholesome for the public. That is our primary
21 mission.

22 I would like to give you a little sense of how
23 products developed by biotechnology are regulated within the
24 framework of the broader U.S. Government. There are three
25 agencies primarily involved in overseeing various aspects of

1 these products as they come to market. FDA has authority
2 over the foods and animal feeds both for safety and for the
3 labeling of these products to the extent that these products
4 are derived from crops.

5 The Department of Agriculture has authority to
6 protect the country and protect agriculture from plant pests
7 under the Plant Pests Act and the Plant Quarantine Act.
8 Many of the environmental issues that are discussed with
9 respect to products developed by modern biotechnology are
10 assessed in the process that has been established by the
11 Department of Agriculture.

12 The Environmental Protection Agency, EPA, has
13 authority over the safety of pesticides. Pesticides are
14 registered by EPA. FDA actually monitors any tolerances
15 that are established for pesticides in foods, but it is EPA
16 that has the authority to establish the safety of pesticides
17 in and on foods. So, to give you an example, a product that
18 is developed where a plant is modified to produce its own
19 pesticide, such as what is commonly called BT corn, for
20 example.

21 That product is one in which a company would
22 discuss and go through the process at USDA for field testing
23 for the examination of the characteristics for plant pests.
24 Because that substance, BT, that is introduced into the corn
25 is a pesticide, the BT is registered by EPA and their

1 registration takes into account both environmental
2 considerations and food safety considerations. So, it is
3 EPA that has authority for pesticide traits that are
4 introduced into plants. FDA has authority over all of the
5 traits that are not pesticide in nature.

6 May I have the next slide, please?

7 In the late 1980's, FDA was receiving a number of
8 questions about the use of recombinant use of DNA
9 techniques, or what we have called modern biotechnology, in
10 producing food crops. At that time, we had had some
11 experience already in foods with the use of these modern
12 biotechnology techniques to produce food ingredients; food
13 processing enzymes. Companies were already discussing food
14 ingredients with the Agency and we were well along reviewing
15 these milk clotting enzyme, Rennet or Chymosin, that is used
16 to produce cheese.

17 As you have heard earlier, we also had
18 considerable experience from the pharmaceutical side with
19 the use of these modern techniques of biotechnology in
20 producing various drugs and vaccines. In addition, the
21 National Institutes of Health had had a recombinant DNA
22 Advisory Committee in place for number of years looking at
23 considerations of the use of these new technology in
24 research. And, so we had a great deal of experience that we
25 were able to draw on when the questions about modern

1 biotechnology and its application to foods began to be posed
2 to FDA.

3 Nevertheless, we convened a group of scientists
4 within FDA and we spent several years looking at the
5 possible impacts of that science on the food supply, trying
6 to make sure that we could understand all potential aspects,
7 given the kind of products that were coming to market at the
8 time. And, our goal then was to answer the questions that
9 were being posed to us by the industry to assure that
10 companies would have the advice of FDA in terms of safety
11 testing before those products reached consumers. We did not
12 try to envision the kind of products that would come down
13 the road five to ten years later. We looked at the kinds of
14 products that were then under development and we based our
15 approach to regulation and safety on the characteristics of
16 those products.

17 In 1992, we published a statement of policy in the
18 Federal Register. That statement explained, first of all,
19 how we regulate foods under the Food, Drug and Cosmetic Act.
20 It also explained how the products developed by modern
21 biotechnology would fit within that regulatory framework.
22 That policy applies to foods that are derived from crops
23 developed by all methods of plant breeding; hybridization,
24 other methods of conventional plant breeding and the newer
25 techniques of recombinant DNA or genetic engineering, what

1 we call the tools of modern biotechnology.

2 Our assessment was that foods should all meet the
3 same standards under the Food, Drug and Cosmetic Act. And,
4 therefore, regardless of method by which the food is
5 developed, the food should meet one standard so that our
6 policy applies to foods derived from crops. That means
7 foods such as fruits, vegetables, cereals. It also includes
8 products that are derived from crops; such as food starch or
9 vegetable oils.

10 The policy applies to human foods. It also
11 applies to animal feeds that are used in agriculture. The
12 policy explained the legal framework, and I'm going to do
13 that very briefly for you. But, the most important part of
14 the policy, at least from my prospective, was that we put
15 down on paper the standard of care, in terms of safety
16 testing, that developers should follow in bringing new crop
17 varieties to market in terms of food and feed. And, we
18 established a process to make sure that companies could talk
19 to the Agency when they have questions and we have strongly
20 encouraged the companies to talk to use before they go to
21 market with products that are developed by new technology.
22 We consider that to be prudent practice.

23 May I have the next slide?

24 We have had a public process in place over a
25 number of years developing our policy. Since the '92 policy

1 was published in 1992 and we did request public comments on
2 that policy, we have been taking steps since that time to
3 address a number of the issues that were raised by the
4 public in the comments to that policy; comments such as the
5 public felt that FDA should know about these products and so
6 we have established the consultation procedures. There were
7 many comments about labeling that we will address this
8 afternoon and in 1993 we published a notice requesting
9 additional information from the public on that topic.

10 And, there were scientific issues that we have
11 addressed since 1992, allergenicity and the use of the
12 selectable marker genes, the antibiotic resistant marker
13 genes, where we have consulted with expert scientists to
14 ensure that the guidance that we provide to industry is
15 based on the best science that's available.

16 This has been an open process. There were
17 approximately ten times, between 1984 and 1994, which was
18 the year that FDA made the decision on the flavr savr
19 tomato, when we either held a public meeting or had an
20 opportunity for the public to comment on various issues that
21 were before us. In that process, we have explained our
22 policy and our approach to safety assessment to our Food
23 Advisory Committee and our Committee for Veterinary
24 Medicine.

25 We explained the policy, the safety assessment

1 approach that I will describe to you in a few minutes and we
2 used the flavr savr tomato and other products as examples to
3 give the committee members a sense of the kind of products
4 that FDA was seeing at that time. FDA had conducted a full,
5 comprehensive, scientific review at the company's request of
6 the flavr savr tomato and that review and evaluation was
7 discussed with our committee members and the committee felt
8 that that was a very useful exercise for both the industry
9 and the Agency; given the fact that there was a new
10 technology and given that there were many questions. But,
11 they also recognized that that product did not raise
12 substantial safety issues.

13 Members suggested to the Agency that if there were
14 going to be more products of a similar nature developed by
15 this technology, that we might want to consider a process
16 that would not be so resource intensive, but would still
17 allow the Agency to exercise appropriate oversight in
18 assuring the product's safety before they reached the
19 consumers. And, we also felt, based on the experience that
20 we had had in discussing the characteristics of products
21 developed by modern biotechnology with the companies, that
22 was also our assessment. We felt that the procedures for
23 consultation would allow FDA to interact with the company in
24 a way that we would be able to identify any safety issues
25 that were not resolved before these products come to market.

1 In looking at the application of modern
2 biotechnology, we have felt that it is very important to
3 understand how foods are developed by conventional means.
4 We have many foods in the grocery store. We only have to
5 think about walking up and down the aisles of the grocery
6 store, of the tremendous variety of fruits, vegetables,
7 cereals, as well as all the processed foods that are
8 available to realize that we have a very diverse food
9 supply.

10 We believe that that food supply should be
11 standard by which any new product is evaluated. We would
12 not accept a product of lower standard in terms of safety,
13 but what should occur is that any new product should be
14 compared with its traditional counterpart, because, in fact,
15 the foods that we are seeing developed by modern
16 biotechnology are derived from food crops that have been
17 part of our agricultural system for many years. They are
18 not new, completely different entities that we have not seen
19 before. Rather, they are foods derived from crops in which
20 one or a few well characterized genes have been introduced
21 to provide new traits to the crop; sometimes for effects
22 that benefit the farmer, such as disease prevention, or
23 resistance to pests. Other times, for modifications to the
24 finished product for the consumer; such as modified
25 vegetable oils.

1 Nevertheless, these crops are developed using
2 techniques that allow the scientist to understand the genes
3 that are being introduced and, therefore, the traits that
4 are being conferred on the foods. They avoid a number of
5 the difficulties of conventional plant breeding in that
6 breeders typically must spend as many as ten years crossing
7 plants to remove undesired traits, because during
8 conventional hybridization, many genes are introduced and
9 those genes often encode substances that produce undesirable
10 traits.

11 So, one of the primary advantages of the newer
12 techniques is that they do give the developer much more
13 precision in developing these products. These techniques
14 also allow the developer a wider range of potentially useful
15 traits in that genes derived from essentially any organism
16 can be introduced into a crop and that, of course, has
17 raised questions by many individuals about the safety of
18 transferring genes across boundaries and that is something,
19 I hope, maybe we will have a chance to discuss a little bit
20 later today.

21 We realized when we started thinking about the
22 questions companies were posing to us, that we could not
23 rely on the standard methods of testing food additives that
24 are traditionally done. Food additives are essentially
25 single chemicals and we have established methods of

1 toxicological testing that are subjected to establishing the
2 safety of food additives.

3 But, foods are much different. They're very
4 complex substances. They consist of many chemicals and so,
5 therefore, it is well established in science that testing of
6 whole foods in animals is not as easily amenable as the
7 testing of single chemicals. So, we had to had to have a
8 different approach to establishing the safety of a food
9 derived from a crop.

10 We have spent a number of years working both
11 within FDA and with other international bodies; such as the
12 World Health Organization, and the Food and Agricultural
13 Organization, to establish general principles for the
14 testing of foods that are derived from crops. The approach
15 that is being used is one that I would characterized as a
16 multi-disciplinary approach that relies, first and foremost,
17 on the steps that plant breeders take bringing products to
18 market. There are a number of considerations that plant
19 breeders evaluate for a new crop and those have been very
20 successful in sorting out the products that should come to
21 market from those that should not. There are very few
22 occasions where a new variety has raised a public health
23 issue.

24 The molecular techniques are also a powerful new
25 tool, not only to develop new crops, but to help us better

1 understand the changes that are made in those crops. These
2 tools allow us to understand what substance is introduced
3 into the food, what its function is, how it will work in the
4 food, and that is something that we don't have with other
5 methods of plant breeding.

6 We are also recommending to companies that they
7 take additional steps in assuring the safety of these
8 products by doing analysis that I will show you examples of
9 in a few minutes, of the important nutrients, minerals,
10 vitamins and other components of the food that are known to
11 be important, so that we can be sure that those things that
12 are important about the food have not been changed in a way
13 that was not intended.

14 These foods derived from crops are not routinely
15 subjected to animal feeding studies, though as you will see
16 in a moment, companies do do certain kinds of wholesomeness
17 studies in animals. But, there may be circumstances where
18 additional testing would be required and we believe it would
19 appropriate if the information that is accumulated does not
20 answer a particular question, to design a study very
21 carefully so that it would answer any question that was not
22 resolved. And I will give you a couple of examples.

23 To date, we have not seen any products in which
24 new substances introduced into the food are unusual. To
25 date, the genes that have been introduced into foods produce

1 primarily enzymes; that is those substances that fall under
2 FDA's authority are primarily enzymes and those substances
3 have been shown to be readily digestible, not be similar to
4 any toxins or allergens. They are present at very low
5 levels in food.

6 On the other hand, we could see examples in the
7 future where additional testing would be needed. For
8 example, if a protein were introduced into a food by these
9 tools of modern biotechnology, just as would be the case if
10 it were introduced in manufacturing or through any other
11 method, if that protein has a function that is very unusual
12 compared to proteins that we normally consume safely in
13 food, we would expect to have additional testing for that
14 protein. That would also be true, of course, of a new
15 chemical that would be added to food.

16 We would also expect to have additional testing if
17 a substance added to food showed similarities to known
18 toxins or allergens. And, to give you an example of one
19 that has been in the news, if a potato was modified to
20 produce a lectin, a lectin is a substance that is known to
21 have toxic properties, one would expect to have additional
22 information to establish the safety of that product. So,
23 that we would design the safety testing for a food that is
24 designed by modern biotechnology, just as we would for foods
25 developed by other methods, based on the characteristics of

1 the food and what kind of food safety issues they present.

2 I would like to just give you a very brief
3 overview of some of the kinds of information that FDA
4 recommends that companies develop in evaluating food safety
5 for new varieties. We consider both the intended change
6 that is made in the food and we also consider unintended
7 changes in the food. In terms of intended changes, I have
8 just talked about new substances such as proteins. We can
9 understand a great deal about toxicity of proteins by
10 understanding their structure and function. Proteins are
11 very common in foods, and at this stage of the technology,
12 the new substances that result in food, as a result of
13 modern biotechnology, our proteins or fatty acids or
14 starches, they are not complex chemicals of another nature
15 at this point of the technology.

16 We, of course, want to assure that these
17 substances can be consumed, that they're not toxins or
18 allergens. How much is in the diet is an important food
19 safety question for these products as well as for other
20 products. We also, would examine whether there were
21 nutritional changes in the food. This is an important
22 criteria often the case of animal feed. Because, in the
23 case of animals, an animal is often feed a diet that is
24 primarily one crop and, therefore, nutritional modifications
25 of that crop can have an impact on the animal's nutrition.

1 And, so it is a very important consideration for animal
2 feeds.

3 One of the questions that is often raised is the
4 question about unintended or unexpected effects that might
5 occur. In plant breeding, it is common practice to have
6 unexpected effects by all methods of plant breeding and
7 breeders take a number of steps to evaluate new varieties to
8 ensure that they don't have any unexpected, adverse effects.

9 In addition to those steps, we have recommended to
10 companies that there are some steps that can be taken to
11 further minimize the likelihood of unexpected effects. One
12 of those ways is by ensuring that any genetic information
13 that is inserted by modern biotechnology is inserted in a
14 way that is stable so that it does not move around in the
15 organisms chromosomes and that reduces the likelihood of
16 additional unexpected effects.

17 We also ask developers to evaluate the key
18 nutrients in toxicants as I've described to ensure that
19 those elements have not been changed in any way that would
20 adversely effect health. And, it is taking into account the
21 agronomic, the characteristics of the plant, the stability
22 of the genetic insertion and the analysis of the important
23 key components of the plant that we feel provides adequate
24 assurance that the plant has not been modified in ways that
25 would be adverse to health.

1 I am going to give you some examples of the kind
2 of information that is developed for foods derived by modern
3 biotechnology using soybean as an example because it is a
4 major crop. There are number of characteristics that are
5 evaluated by the breeders for crops developed by all methods
6 of plant breeding and these include how the plant looks, its
7 morphology, how it flowers, how it sets seeds. These are
8 just a few of the characteristics that are evaluated. There
9 are many others that would be too numerous to put on the
10 slide. But, these traits are evaluated over a number of
11 years in different growing sites because the developer has
12 to determine whether that plant is stable in terms of its
13 characteristics, whether it resists diseases in the
14 community where it will be grown and this is an important
15 part of evaluating a plant for commercial production.

16 I'd like to show some of the kinds of information
17 that have been developed on soybeans. First of all, as I
18 have said, the molecular techniques of modern biotechnology
19 allow the scientist to better characterize the changes that
20 are made and the safety of any new proteins or other
21 substances can also be addressed directly. Information is
22 also developed on nutrients, trace minerals, anti-nutrients,
23 things like the trypsin inhibitor. But, there are a number
24 of substances that are very typical of soybeans. Each crop
25 has different substances that are typical of that crop and

1 those substances are being analyzed to be sure that they
2 occur at the levels that are typical for that crop.

3 There are individuals who are allergic to
4 soybeans. So, there are substances in soybeans that are
5 allergens and companies have taken the steps to assure that
6 those substances are not increased above the native levels
7 in the crop. There are also feeding studies that are
8 conducted on these products in various kinds of animals to
9 assure the wholesomeness of the product.

10 I'm going to show you some data that I won't fully
11 expect you to try to fully understand. I really want to
12 show you an example of the kind of information that is being
13 provided to FDA on these products. We have taken
14 information out of a large volume of information that is
15 part of our consultation process. This slide is showing
16 some of the characteristics for carbohydrates, for fats, for
17 proteins, for fiber. Fiber is an indicator of the
18 digestibility of the product, particularly for use in animal
19 feeds.

20 The companies control, excuse me, the companies
21 assess the values for the modified plant, the new plant,
22 that is what is called here the transgenic plant, in
23 relationship to a conventional control. What is not shown
24 here, is that we also examine whether these values fit
25 within the range of values that is typical for the

1 particular component that is being analyzed for crops that
2 have been accepted as commercially acceptable varieties.

3 As you might imagine, growing crops under
4 different conditions of weather and different genetic traits
5 can lead to variations in the substances in the crop and
6 that is typical and we see that quite often. So, it's
7 important to understand how the values that are generated
8 compare with the range that has been typically found to be
9 acceptable.

10 And I will just quickly go through several slides
11 here. This is mineral analysis looking at calcium,
12 phosphorus, potassium, again, comparing the new variety with
13 its control and as not shown here, looking at the range that
14 is typical for these components in soybeans.

15 Amino acid analysis is very important,
16 particularly for the protein that is derived from soybean
17 and this only shows five of the amino acids the companies
18 analyze for a complete amino acid profile and that gives an
19 indication of the quality of the protein that will be
20 derived from this product and how it compares with other
21 varieties of soybean.

22 Oil is also obtained. Soybean oil is obtained
23 from soybeans and so it is important to analyze the fatty
24 acid content, the composition of the food oil and this is
25 showing some examples of various fatty acids that have been

1 analyzed for soybean derived by modern biotechnology
2 compared to its conventional counterpart.

3 There are substances that are called
4 anti-nutrients in soybean. All of these substances are
5 typical, they're native to the plant and they are substances
6 such as phytic acid that binds phosphorus, which is an
7 important nutrient and very important in animal feed. So,
8 it's important to assure that the phytic acid level is not
9 greatly elevated.

10 I would like to give you a sense of where we are
11 at this point of this new technology. To date, there are
12 over forty products, as you have heard, that companies have
13 completed food safety and feed safety discussions with FDA.
14 These come from a relatively limited number of crops at this
15 point. There are ten crops shown here and because they may
16 be hard to read, I will read them for you. It's sugar beet,
17 canola, corn, corn, cotton, potato, soybean, flax,
18 radicchio, squash and tomato. These are the crops for which
19 companies have completed at least one or more consultations
20 with FDA.

21 There also are a limited number of traits that
22 have been introduced into these crops at this point and this
23 gives an idea, gives you a sense of the kinds of
24 modifications and the proportion of crops. The herbicide
25 tolerance is by far and away the largest number at this

1 point. There are some modifications that are more directed
2 toward the consumer and I will give you an example. There
3 is a product that is called hyleac soybean oil. Hyleac
4 soybean oil is very different from conventional soybean oil.
5 It is a product that has been developed by modern
6 biotechnology to increase the content of a normal fatty acid
7 in soybean oil, oleic acid. Oleic acid occurs at about
8 twenty-three percent in oil, but the new variety contains
9 eighty percent or as much as eighty percent. That oil is a
10 very different oil than soybean oil. It is an oil that will
11 withstand high temperatures for frying of foods and does not
12 have to be processed in order to be used as a high frying
13 temperature. And so, it is an oil that avoids the problem
14 of food processing of oils with the introduction of
15 trans fatty acids.

16 So, this is one of the products that is a very
17 different product from its conventional counterpart and, as
18 you will hear this afternoon, also has a different name,
19 hyleac soybean oil, to distinguish it from the conventional
20 product.

21 You often hear that companies consult with FDA and
22 that that process is voluntary and there often are questions
23 about whether that process is adequate. So, I would like to
24 give you just a little bit of sense of how this process
25 works. The consultation process is voluntary. It is not

1 legally required that a company come to FDA to talk to us
2 about a food. However, the Food, Drug and Cosmetic Act is
3 not voluntary. Companies must meet the safety standards of
4 the Act and, therefore, it is important, both to FDA and the
5 companies, that any product coming to market meets those
6 standards.

7 The consultations have been established so that
8 companies have an opportunity to make sure that they are
9 meeting all of the safety provisions and labeling
10 requirements of the Act before the product goes to market.
11 And, this also gives the FDA an opportunity to make sure
12 that the safety testing has been appropriate and has
13 answered all of the questions related to safety.

14 It is typical for companies with new products to
15 come to FDA early and our advice to companies is come early
16 and often. And, what is shown on this slide on the left is
17 the time for several consultations. These are just selected
18 examples to show that the time in which companies consult
19 with FDA before coming in with the actual information that
20 is developed for going to market. This time includes
21 discussions with our scientists about appropriate tests for
22 safety and also discussions about some of the results as
23 they're obtained during that time.

24 They may also discuss specific protocols for tests
25 such as allergenicity or changes in nutrition. So, this is

1 a time when there is an opportunity for FDA scientists and
2 the company scientists to discuss the nature of these
3 products and the kinds of tests. And, as you can see, it's
4 typical for a company to spend as much as one or two years,
5 before going to market, with FDA discussing the appropriate
6 tests.

7 We strongly recommend that when companies have
8 completed the testing for these products that they provide
9 us with information about the kinds of tests that they have
10 done and that shows us the results they have found and how
11 those results compare with other varieties for foods derived
12 from a particular crop. That is shown on the right in terms
13 of the time that occurs when FDA receives a submission from
14 the company, until we provide them a letter telling them
15 that we have no further questions at this time based on the
16 information that has been presented to us.

17 So, this is a process that in many cases occurs
18 over two or three years. Sometimes, there are products, as
19 you can see by the yellow boxes, that are fairly short
20 because they're products that we're well familiar with and
21 the company is familiar with the kind of information that we
22 would expect to be developed. And so, it does not take a
23 long time, but usually this process is much more
24 protractive.

25 The goal, of course, is that to ensure that any

1 new foods that are developed are as safe as the foods that
2 we have in the market today and that is a process, that is a
3 goal that we think is appropriate in terms of evaluating new
4 varieties with conventional varieties. We must ensure that,
5 in fact, these foods are as safe as other foods. If the
6 food contains a new substance, that is not present in the
7 conventional food, but has been added by genetic
8 modification, that substance would be a good additive unless
9 it is generally recognized as safe.

10 Food additives require pre-market review by FDA
11 and so that if there is a substance that is not generally
12 recognized as safe, it would have to be approved by the
13 Agency.

14 To date, all of the substances that have been
15 introduced into foods, as I have told you, are enzymes that
16 are very similar to enzymes currently found in food. They
17 are not similar to toxins or allergens. They are present at
18 very low levels in the food and those substances have been
19 presumed to be generally recognized as safe. But, we could
20 very well, in the future, see new substances, different
21 substances, and if that is the case, those substances would
22 require pre-market approval by FDA. That is the legal tool
23 that we have to assure that if there is a new substance
24 introduced into food by any method, that substance must be
25 approved by the Agency before the food may be sold in

1 commerce.

2 We also, of course, have very broad authority if a
3 food is not as safe as another food, if a food presents a
4 problem or illness or health to the public, the Agency has
5 broad authority to remove that food from the market. It is
6 that enforcement authority that has protected consumers
7 since 1938, so that we have this authority. We have this
8 authority. We would, of course, exercise it if needed and
9 that is the authority that has been used to assure the
10 safety of most foods in the grocery store. So, it is
11 through the Food, Drug and Cosmetic Act and the provisions
12 that allow FDA to take a food off the market if it presents
13 a health problem or to assure that any new substance that is
14 introduced into the food is either regulated and approved as
15 a food additive or generally recognized as safe before those
16 foods may go to market.

17 That is the standard. Companies bear a legal duty
18 in ensuring their products meet all of the standard of the
19 Act and that is a serious responsibility. We have
20 established procedures to make sure that companies have an
21 opportunity to ensure that they are meeting all of the
22 provisions of the Food, Drug and Cosmetic Act before these
23 products go to market.

24 Thank you very much.

25 DR. HENNEY: Thank you, Dr. Maryanski, twofold.

1 One for giving us a very nice overview that was, I think,
2 comprehensive and complete about our experience to date in
3 this area and introducing us to the legal framework under
4 which we act in this regard.

5 The twofold part is for keeping us not only on
6 time, but ahead of time. We are scheduled for a break at
7 10:15 before we hear from the first panel. Why don't we
8 take that break now, reassemble at 10:15 and then we will
9 start hearing from the panel.

10 [Whereupon a break was taken.]

11 DR. HENNEY: It's now time to begin our discussion
12 from the first panel on the scientific, safety, and
13 regulatory issues. I'm going to ask each panel member to
14 give brief opening remarks and these remarks will be
15 followed by a discussion among the panel members and
16 questions from the FDA panel. Let me review the questions
17 that we have asked our panelists to address in order to help
18 us evaluate our current policy. First, has FDA's
19 consultation process, which has just been described to you,
20 achieved its intended purpose? Based on experience to date,
21 should this regulatory approach a sunset continuance with
22 its current state, be made mandatory, or otherwise be
23 revised?

24 Secondly, what newly emerging scientific
25 information related to the safety of foods derived from

1 bioengineered plants is there, if any? And are there
2 specific tests which, if conducted on such foods, would
3 provide increased assurance of safety for man or animals
4 consuming these foods?

5 Third, what types of food products derived from
6 these plants are planned for the future, and will these
7 foods raise food safety issues that would require different
8 approaches to safety testing and Agency oversight? If so,
9 what are your suggested approaches?

10 I'm pleased to introduce the members of this panel
11 to you. There's much more biographical information in your
12 information packet about each and every one of these
13 panelists. But, first will be Dr. Ralph Hardy. He has been
14 President of the National Agricultural Biotechnology Council
15 and represents the Boyce Thompson Institute for Plan
16 Research.

17 Next is Dr. Val Giddings. He is the Vice
18 President for Food and Agriculture for the Biotechnology
19 Industry Organization. Dr. Michael Jacobson is Executive
20 Director of the Center for Science in the Public Interest,
21 and a card-carrying microbiologist.

22 Mr. Charles Margulis represents the Greenpeace
23 Genetic Engineering Campaign. Dr. Steven Taylor is
24 Professor of the Department of Food Science and Technology
25 of the University of Nebraska. And Dr. Barbara Glenn is

1 representing the Federation of Animal Science Societies.

2 I'd like to invite Dr. Hardy to make his opening
3 remarks and then we'll just have each panel member follow in
4 sequence, and then our question and answer period.

5 DR. RALPH HARDY: Good morning. Can you hear me
6 okay? I'm a scientist by training, a part-time farmer and,
7 of course, I'm a consumer. Pleased to be a member of this
8 panel. Being a scientist, I want to make a couple comments
9 in the science area before I begin. I believe, as a
10 science-based person, that science provides the most
11 reliable input for policy decision making on issues of
12 environmental and human health risk and safety.

13 Furthermore, the most reliable science has a
14 rigorous quality that is reproducible and is supported by
15 expert peer evaluation. I've been asked to provide some
16 background overview of the area of genetic modification,
17 including what Dr. Maryanski's referred to as modern
18 biotechnology or I will refer to as molecular biotechnology.

19 Agriculture has used genetic improvement of
20 modification over decades, centuries and even millennia, to
21 help meet the food, feed and fiber needs of a world
22 population that has grown from 300 million to 6 billion over
23 the current millennia. Essentially all foods from a
24 domesticated source come from genetically modified or
25 improved plants and animals, even prior to molecular

1 biotechnology.

2 Genetic modifications by humans is not new, and
3 dates back to the origin of agriculture, about 10,000 B.C.
4 The tools of genetic modification have become more powerful
5 as they have progressed from selection, the earliest days,
6 to hybridization, to mendelian genetics, to quantitative
7 genetics, to induced mutation, to fusion, somafloal
8 [phonetic] variation, anthroculture, to name several, not
9 all, to molecular genetics.

10 Molecular methods are the basis of modern
11 biotechnology and the genetically improved organisms are
12 variously referred to as genetically engineered organisms,
13 GEO's, genetically modified organisms. Although, that's
14 confusing since we've been modifying organisms, as I
15 indicated, for centuries, etcetera, or GMO's or transgenics.

16 Highly domesticated organisms, bacteria, plant,
17 animal, are genetically modified for improved use as a food,
18 feed or fiber crop, as a microbe for fermentative production
19 or a processed food - example, beer, wine, bread, or
20 industrial product - example, fuel ethanol, or as an
21 improved dairy animal or an egg or a meat producer.

22 These genetically modified organisms are more fit
23 for our domesticated use. In general, they're less fit out
24 there in the unprotected world. Our quality of life is
25 highly dependent on genetically modified organisms. If

1 potatoes and tomatoes had not been genetically modified,
2 they would be too toxic for humans to eat.

3 Our ability to provide food for twenty times as
4 many people in 2000 A.D. as 1000 A.D., is increasingly
5 supported by genetic modification. The above is a product
6 of genetic modification at what I call the organismal level,
7 in contrast to the molecular level. Now the molecular tools
8 enable more rational and directed genetic modifications.

9 Only a few genes are involved in molecular plant
10 genetic modification versus the estimated 30,000 or more
11 different genes of a higher plant in the traditional or
12 organismal process. The genetic roulette, if you will, and
13 I think there's been a recent advertisement where that word
14 has been used. The genetic roulette is much less with a few
15 genes with known function than with the 30,000 or genes in
16 organismal genetic modification, with a huge number.

17 At this stage, there's probably more than 50
18 percent of the genes in a plant that we don't know the
19 function of. The involvement of only a few genes of known
20 function in the molecular process helps focus risk
21 assessment in contrast to the involvement of this large
22 number of genes in the organismal process.

23 What do we know about environmental and human
24 health risks from genetically modified organisms? Most
25 importantly, risk of a product is inherent in the product,

1 not the process by which it is made. If identical products
2 were made by either molecular or organismal genetic
3 modification, they would have identical risks.

4 We have substantial experience with organisms
5 modified at the organismal level. All of our domesticated
6 crops and animals. The products have been of low risk. In
7 fact, the major real food safety risk is microbial
8 contamination, which has no relationship to genetic
9 modification, although the analytical tools of molecular
10 biotechnology may help to reduce this problem.

11 Plants do have toxins, but on our domesticated
12 crops developers are sensitive to this risk. There are
13 examples in the past where, during development, for example
14 of potatoes, where solanines exist where developers have
15 found that there were excess solanines there. And the
16 development of those and the commercialization aborted.

17 The major experience base, as Dr. Maryanski has
18 indicated, is applicable. The major experience base from
19 organismal modification is applicable to molecular genetic
20 improvement. Our experience base with foods from molecular
21 genetic modification is ten years. I think the premiere
22 product fermentatively produced, chymosyn, that was
23 mentioned earlier today, was approved by FDA for cheese
24 making in 1990.

25 Transgenetic bacteria or transgenetic yeast

1 produce FPC, fermentatively produced chymosyn, under highly
2 controlled conditions and provide a 98+ percent pure
3 chymosyn for cheese making. This year, 80 to 90 percent of
4 cheese in the U.S. and Canada is made by FPC.

5 Personally, I hope the cheese that I ate for
6 breakfast this morning was made with highly pure FPC rather
7 than traditional rennet, which is only two percent pure and
8 obtained from slaughtered calf stomachs. If you ate cheese
9 with any regularly during the last ten years, you've been
10 eating a transgenetic food product.

11 In my view, the review process of FDA for the
12 molecularly improved crop plants, which you've heard about
13 this morning, is appropriate. It is much more demanding
14 than crops improved by organismal genetic modification but,
15 of course, we have less experience with these than we do the
16 organismal thing.

17 To my knowledge, no substantiated example of a
18 significant risk to the environment or human health,
19 relative to the products being replaced, has been documented
20 by rigorous scientific replication. Of course, we must
21 continue to be watchful for negative effects in order to
22 assure improved product safety.

23 Our major focus should be, and I think this is the
24 most important point, on what is rather than the nebulous
25 and never-ending what if.

1 Some have suggested the need for a greater role of
2 the public sector in assessing food safety. If this is the
3 wish of society, certainly that could occur, but if the
4 public sector was to perform that function, there would need
5 to be substantial public sector funding.

6 The tools of molecular genetic improvement
7 continue to advance and will farther diminish concerns about
8 antibiotic resistance as marker genes, as was mentioned
9 earlier, or the possibility of gene escape where wild and
10 weedy relatives would exist.

11 Let me make a brief comment about labeling,
12 although I realize that's this afternoon it will be
13 discussed. It's clearly a contentious issue. The right to
14 know, as we've discussed in the National Ag Biotech Council,
15 is a very important right. Substantive changes in
16 compositions, etcetera, as we've heard would be labeled.
17 Does it serve the consumer to label something where there is
18 no demonstrated nutritional negative health or positive
19 health benefit.

20 I appreciate the opportunity to make this
21 presentation. The National Ag Biotech Council will be,
22 within the next two weeks, releasing a document of which the
23 cover page is here. It will read NABC Statement 2000 on
24 Agricultural Biotechnology, Promise, Process, Regulation and
25 Dialog. And regulation and dialog, in our judgment, is key

1 to trust and trust is what holds this whole system together.

2 Thank you.

3 DR. JANE HENNEY: Thank you. Now, the next
4 speaker is Dr. Val Giddings.

5 DR. VAL GIDDINGS: Thank you, Commissioner.
6 Dr. Henney, with your permission, I'd like to submit my
7 written remarks for the record and briefly summarize them.
8 The first thing I'd like to do is thank the Food and Drug
9 Administration for holding this and the subsequent hearings.
10 The central requirement for a credible regulatory system and
11 process is openness and accountability.

12 And this hearing is one of a long series of
13 similar efforts that the FDA and the other regulatory
14 agencies in the United States have conducted. And it's a
15 brilliant example that illustrates why our consumers can
16 have confidence in the work of your agency and your fellow
17 agencies and have reliance that the products that they are
18 consuming are rigorously evaluated for safety.
19 So, thank you very much for holding these hearings.

20 I'm speaking here today on behalf of the
21 Biotechnology Industry Organization which is a trade
22 association representing companies and research institutions
23 in the United States and worldwide that use biotechnology to
24 produce new products for the benefit of farmers, consumers,
25 all of us in our daily lives.

1 We have over 850 members, as I mentioned, and are pleased to
2 be invited to be here to testify this morning.

3 My own background, like Dr. Hardy's, is that of a
4 scientist. I'm a geneticist with expertise in natural
5 populations and the use of particular molecular techniques
6 to understand them. So, that's the point of view from which
7 a lot of my remarks will be coming.

8 In our written testimony this morning, we took a
9 direct approach to answering the questions that were posed
10 in the Federal Register Notice that announced these
11 hearings. So, I'd like to briefly answer those and then
12 reserve the rest of the time for discussions.

13 The first question has the consultation process
14 achieved it's intended purpose? Based on experience to
15 date, should this approach be sunset or continued in its
16 current state or be made mandatory or otherwise revised? We
17 think that the process, as it's been carried out to date,
18 has done a highly praiseworthy job of ensuring that the
19 products of foods that derived from crops improved through
20 modern biotechnology are at least as safe as, if not safer
21 than, those that we have hitherto consumed, which have given
22 us the safest, most abundant, nutritious and cheapest food
23 supply in history.

24 We see no evidence based on science, no evidence
25 based on experience for any requirement to change this

1 process. It seems to work very well. If it's not broken,
2 there certainly doesn't seem to be any compelling, much less
3 a persuasive argument for fixing it.

4 What newly emerging scientific information related
5 to the safety of foods derived from bioengineered plants is
6 there, if any? Are there specific tests, which if conducted
7 on such foods, would provide increased assurance of safety
8 for man or animals consuming those foods?

9 A variety of organizations, international
10 authoritative scientific bodies, have looked at these
11 issues. The Food and Agriculture Organization of the United
12 Nations, the World Health Organization of the U.N., the
13 Organization for Economic Cooperation and Development,
14 International Life Sciences Institute, and more, and they've
15 all concluded that risk and safety concerns associated with
16 foods derived from crops improved through biotechnology are
17 not unique to the processes of biotechnology, as we have
18 heard earlier.

19 And that whatever risk issues there are are of the
20 same nature as those associated foods derived through
21 conventional breeding. We are not aware of any emerging or
22 new scientific information that would challenge this. If
23 any such information does come forward, we think the issue
24 should be revisited, but we are unaware of any at this
25 point.

1 What type of food products derived from
2 bioengineered plants are planned for the future? Will these
3 foods raise food safety issues that would require different
4 approaches testing and oversight and, if so, what are those
5 approaches?

6 Well, the first products, most of the first
7 products that we've seen have focused on agronomic or output
8 traits which have brought benefits first, and most
9 immediately, to farmers in terms of helping improve their
10 choices for different techniques for overcoming constraints
11 on production and the daily challenges they face in
12 production.

13 But, they've also resulted in a variety of
14 improvements to the quality of the foods produced and, so
15 forth, that have been beneficial directly to consumers. As
16 the technology continues to develop, we expect to find food
17 products produced that will have characteristics relating to
18 nutrition and health assurance that would improve their
19 safety profiles and nutritional impacts.

20 We believe that the current mechanism, the
21 decision trees laid out in the 1992 policy statement,
22 provide a robust means for asking the sorts of questions
23 that must be answered in order to ensure that the
24 appropriate safety assurances can be provided. And, to the
25 extent that any new questions come up with particular

1 products, we think FDA has, under the Food, Drug and
2 Cosmetic Act, ample authority to as those sorts of
3 questions.

4 So, in a word, we think that the future, the
5 potential of this technology to produce new products to
6 benefit consumers, the environment and the health of all of
7 us is dramatic and largely, as yet, untapped. And we look
8 forward to working with FDA to make sure, and other
9 agencies, to make sure that these products are developed in
10 the most responsible manner possible. Thank you.

11 DR. JANE HENNEY: Thank you, Dr. Giddings. Dr.
12 Jacobson.

13 DR. MICHAEL JACOBSON: Thank you and good morning
14 Commissioner Henney. CSPI is a non-profit consumer advocacy
15 organization that is focused on food safety and nutrition
16 since 1971. We've had many interesting interactions with
17 the FDA over issues such as sulphites, olestra, transfat
18 food labeling and others. And we appreciate this
19 opportunity to present our views on plant biotechnology.

20 Biotechnology, if used properly, holds out the
21 promise of increased yields, reduced use of pesticides and
22 better nutrition. But, if misused, it could cause great
23 harm. Current genetically modified or GM foods appear to be
24 safe, though GM crops certainly raise ecological concerns.

25 Most consumers know little about biotechnology.

1 However, increasingly partisan propaganda on all sides
2 rapidly may replace that ignorance with confusion. It
3 behooves government to build public confidence by adopting
4 strict rules to protect the environment and ensure safety
5 and choice to consumers.

6 I'd like to talk first about safety, then turn to
7 labeling. GMO's raise questions of allergenicity and other
8 safety concerns. The FDA strongly encourages, but does not
9 require, companies to conduct studies when a gene is
10 transferred from a plant or animal that causes frequent
11 allergies.

12 But, what if a protein newly introduced into the
13 food supply causes occasional allergic reactions. Or if a
14 new gene did not encode an allergen, but turned on dormant
15 genes that did code for allergens? Or if a protein lead to
16 a behavior disorder, an autoimmune disease, or other adverse
17 effect?

18 Another concern is that levels of naturally toxins
19 might be increased in GM plants. The FDA encourages
20 companies to screen for such substances, but does not
21 require them to do so and to provide the study results to
22 the agency. It may unlikely, but is not inconceivable, that
23 genetic engineering would introduce a novel toxicity as
24 suggested by the recent preliminary study on lectin potatoes
25 that Dr. Maryanski alluded to.

1 Risks of allergic reactions may be small, but they
2 are real. Other risks are speculative, but not
3 non-existent. The possibility of requiring routine toxicity
4 studies should be considered. At the very least, more
5 research in this entire area should be conducted. It is
6 impossible to prove with absolute certainty that something
7 is safe. But, it may be possible to do a better job to
8 assure safety than is now being done.

9 Currently the FDA asks companies to submit data
10 only when their crops contain gene products from plants that
11 commonly cause allergies or contain genes that code for
12 novel proteins. But, even that is not an absolute
13 requirement. So far, companies appear to be routinely
14 consulting with the FDA, but that voluntary system does not
15 maximize public confidence.

16 We urge the FDA to review the safety of every GMO
17 product before it is marketed and then approve it if it is
18 appropriate.

19 A second key issue is labeling. Labeling, of
20 course, should not be a substitute for safety. Every
21 biotech food must be safe. Yet, even assuming that biotech
22 foods are as safe as conventional foods, several
23 considerations indicate the need for labeling. People with
24 multiple or severe allergies, or with general safety
25 concerns, fear that foods they were always able to safely

1 consume might harbor new, unsafe substances.

2 Others fear that GM crops might harm wildlife or
3 promote pesticide resistance in insects or weeds.

4 Vegetarians and people with certain religious beliefs may
5 not want to eat foods containing gene products derived from
6 animals. Other people believe it is simply unethical to
7 move genes between distant species such as putting a gene
8 from an animal into a plant.

9 I think all of us can debate the merits of those
10 arguments, but those views are very strongly held and
11 labeling would enable those diverse groups of people to
12 avoid biotech foods if they so wish. The FDA should adopt a
13 strict definition of GMO-free and allow marketers of foods
14 that meet that definition to make a label claim.

15 The FDA, also, should require foods containing
16 significant amounts of biotech ingredients to disclose that
17 fact on labels. If a food contained a possible allergen,
18 the label should indicate the food from which the genes were
19 obtained.

20 One concern that is raised by labeling is that it
21 might mislead some consumers into thinking that biotech
22 foods are inherently riskier than other foods, or that
23 conventional foods are significantly safer than biotech
24 foods. The FDA should conduct consumer research to assess
25 whether additional explanatory labeling language might be

1 appropriate.

2 In summary, whether the potential benefits of
3 biotechnology are realized depends, in part, on whether the
4 FDA establishes tight new regulatory requirements that
5 maximize public confidence. We hope that the FDA takes
6 quick and sensible action. Thank you.

7 DR. JANE HENNEY: Thank you, Dr. Jacobson. Now,
8 Mr. Margulis.

9 MR. CHARLES MARGULIS: Thank you and good morning.
10 First I want to say that my mom will be delighted that I was
11 misidentified in your agenda as Dr. Margulis. You can call
12 me Charles. I'd also like to say that I appreciate how hard
13 the agency worked to try to accommodate everybody who wanted
14 to speak here today. I know a lot of people couldn't, and
15 I'm not sure of everybody at the Marriott is going to feel
16 that the solution is satisfactory.

17 So, in order to help out, Greenpeace has a room
18 down the street for public comment, starting at noon at 25
19 East Jackson Street, Room 241. We will take comments. I
20 invite anybody from the agency would would like to, to
21 attend and hear from the public. And we will also make a
22 copy of the tape available for the public record.

23 I do have some slides, so if the lights could be
24 turned down. I apologize if you can't see these, but they
25 are available if you'd like. One of our concerns is that

1 the FDA sometimes seems more interested in promoting
2 biotechnology than in scrutinizing the risks. The latest
3 example being the invitation to today's meeting, which fails
4 to mention the most widely grown genetically engineered
5 variety there beside tolerant varieties. And, instead,
6 sounds like the promotional literature of the industry.

7 Next slide please.

8 MR. ROBERT LAKE: Could someone lower the lights a
9 little bit, so the slides might show up a little better?

10 MR. CHARLES MARGULIS: Is that any better? Great.
11 So, next slide, please. As many of you know, then Vice
12 President Dan Quayle called the FDA's 1992 policy regulatory
13 relief for the biotech industry. Since 1992, there have
14 been close to 50 engineered varieties introduced in the
15 United States, with no FDA mandated approval process.

16 Next slide. The lack of an approval process has
17 lead criticism abroad and at home. Here, I don't know if
18 you can see this, Dr. James takes the FDA to task and says,
19 gee I can't even read it from here. Can somebody read that?
20 I'm sorry.

21 DR. MICHAEL JACOBSON: We can conclude that the
22 practices currently considered acceptable and promoted by
23 the FDA are not rigorous enough for future use. Dr. Philip
24 James.

25 MR. CHARLES MARGULIS: I didn't now this was going

1 to be a duet. Thank you very much. Another U.S. scientist,
2 Dr. Rebecca Goldberg, recently criticized the agency's
3 process as voluntary and secret. Dr. Goldberg noted that
4 the fact that the agency has no requirements for approvals
5 of altered crops means that the industry consultations with
6 the agency don't have to be made part of any public record.

7 Next slide, please. So, this voluntary and secret
8 process leaves the industry on the honor system. And we
9 should take a look at the track record of this industry.
10 This first example, an Asgrow genetically engineered squash
11 was submitted with an environmental assessment that was
12 characterized as having misleading data.

13 The next example, we heard this morning from
14 Dr. Maryanski extensively on the analysis of Round-Up Ready
15 Soybeans. These soybeans that Monsanto submitted, the
16 analysis was done on soybeans that were not treated with the
17 Round-Up herbicide. And this has lead to criticism from two
18 Australian scientists who also take FDA to task and say that
19 this product is in thousands of food products and that the
20 FDA cannot vouch for the safety of these soybeans.

21 Recently, Health Canada scientists found that the
22 leading biotech company, Monsanto, covered up studies that
23 showed problems with their engineered drug bovine growth
24 hormone. Next slide, please. The bovine growth hormone
25 example is instructive.

1 It's a very long and complicated issue which, if
2 folks want to hear more about this, if you haven't heard
3 enough about genetically engineered food today, you an go
4 tonight to Ann Sathers Restaurant at 929 West Belmont where
5 there will be a presentation discussing this issue in
6 detail. But, the FDA has been widely criticized for the
7 approval of bovine growth hormone and here are some
8 statements along those lines.

9 In a similar vein, a lawsuit filed by the
10 non-profit Center for Food Safety has unearthed several
11 documents that show that scientists within the Food and Drug
12 Administration warned that the agency's policy is inadequate
13 to deal with the food safety issues.

14 Now, there are several of these documents with
15 some quite alarming statements. I'll just read you a brief
16 one. We also heard about the flavr savr tomato this morning
17 and it was noted that that was a basis for the following
18 approvals.

19 In this document, Dr. Murray Lumpkin, who is the
20 director of the FDA's Division of Anti-infective Drug
21 Products, was talking about the flavr savr tomato, and in a
22 passage that's in all caps and underlined, he's talking
23 about the use of the antibiotic resistance gene and he says,
24 "It would be a serious health hazard to introduce a gene
25 that codes for antibiotic resistance into the normal floral

1 of the general population." This is a document that's
2 actually dated after the 1992 policy was finalized.

3 Next slide, please. Well, so where does this
4 leave us? It leaves consumers and the environment at risk.
5 All the products in this slide contain ingredients that are
6 likely to be made from genetically modified plants.

7 Next slide, please. This Nabisco teething biscuit
8 tested positive for genetically modified corn. Earlier this
9 year, the Gerber Baby Food Company announced that they would
10 stop using genetically modified ingredients in their baby
11 foods.

12 Next slide, please. And Kellogg's, interestingly,
13 tells consumers in Europe that they won't use genetically
14 modified ingredients in their cereals sold there. But, in
15 the United States they offer consumers no such assurance.
16 Why not? Well, they say the FDA has found that biotech
17 foods are safe.

18 Greenpeace urges the agency to stop providing
19 false cover for food companies, take genetically modified
20 foods off the market, and start regulating biotech foods.

21 Thank you.

22 DR. JANE HENNEY: Thank you. Dr. Taylor.

23 DR. STEVEN TAYLOR: Good morning, and thank you
24 for inviting me. I'm Steve Taylor, Professor and head of
25 the Department of Food Science and Technology at the

1 University of Nebraska. And I'm also co-director of the
2 Food Allergy Research and Resource Program at that same
3 institution. And I'm here, primarily, representing myself.

4 But, I did serve as chair of the 1996 Expert
5 Consultation convened by the Food and Agriculture
6 Organization and the World Health Organization on
7 biotechnology and food safety. And that was one of many
8 expert consultations that have offered advice to government
9 agencies around the world for the best approaches to the
10 safety evaluation of these foods produced by modern
11 biotechnology.

12 I'm a food safety scientist with interests in
13 naturally occurring toxicants and, especially, food
14 allergens, and so I've become involved in some of these
15 discussions. In my opinion, current genetically modified
16 foods on the market are safe for all consumers, thoroughly
17 tested by the industry, and appropriately evaluated by the
18 FDA and other government regulatory agencies around the
19 world.

20 I endorse the current FDA consultative process,
21 although I would also comment that the process could be more
22 transparent and, if it was, it might build more consumer
23 confidence in the process that was being used. Certainly, I
24 would also add that, although the consultative process is
25 not mandatory, I would agree with Dr. Maryanski's

1 observations that companies have thus far used it in every
2 case, to my knowledge, and I believe that in the United
3 States they will continue to do so.

4 I endorse the concept of substantial equivalence
5 in its use to focus safety assessments on the novel features
6 of biotech foods. There have been some approaches
7 recommended in some publications recently suggesting that we
8 do some sort of feeding trials with whole GM foods, and I
9 would find that the value of those tests would be very
10 difficulty to evaluate.

11 Such testing of whole GM foods in laboratories
12 would be tremendously unfocused, wasteful of laboratory
13 animal resources, and unlikely to detect any harmful
14 substances, if present. The novel proteins and their
15 products in GM foods are often present at very low levels
16 and their effects, if any, would not be detected by feeding
17 whole GM foods to lab animals.

18 And the results of the recent experiments
19 published in Lancet on feeding whole GM potatoes to
20 laboratory rats and the difficult interpretation and the
21 controversies surrounding that study, I think, endorse the
22 fact that this approach is unwise and controversial and
23 difficult.

24 I want to say a few words about the assessment of
25 the allergenicity of GM foods. And, in this regard, I would

1 like to be viewed, at least in part, as an advocate for the
2 allergic consumer. I'm on the board of directors of the
3 Food Allergy Network, which is the major consumer group in
4 the United States addressing food allergies. I've been an
5 advisor to FAO and WHO on food allergies, and I'm on the
6 Board of Scientific Advisors for ILSE's Allergy and
7 Immunology Institute.

8 Again, I think the current methods that have been
9 used to assess the allergenicity of the products currently
10 on the market are adequate. The FDA is quite clear in
11 stating that if DNA is transferred from a known allergenic
12 source, then the novel transgenic food must be assessed for
13 allergenicity. Companies are aware of this obligation and
14 are conducting the appropriate testing.

15 Millions of proteins exist in nature and in the
16 food supply, but only a few hundred of those proteins are
17 known to be allergens. So, the risk that novel proteins will
18 become allergens is probabilistically very small, especially
19 when the novel protein is expressed with foods at a very low
20 level.

21 However, that doesn't mean that I don't advocate
22 assessment of the allergenicity of these novel proteins. I
23 do. The allergenic potential of these biotech foods and
24 their novel proteins can be, should be, and is being
25 assessed.

1 And I served on a panel of ILSE's Allergy and
2 Immunology Institute and the International Food
3 Biotechnology Council to develop an assessment strategy to
4 evaluate the potential allergenicity of genetically modified
5 foods. That panel was chaired by Dr. Dean Metcalf, an
6 eminent allergist with our National Institutes of Health,
7 and was comprised of allergists, other with expertise in
8 food allergies, as well as representatives of the food
9 biotechnology industry, who educated all of us on some of
10 the aspects related to the genetic modification process.

11 For products containing genes from sources of
12 known allergens, there are tests that can be done. I was
13 involved in the assessment of a transgenic soybean variety
14 contain a brazil nut gene. No one knew, at that time, which
15 brazil nut protein conferred the allergenicity of brazil
16 nuts. But, a company wished to insert that gene into
17 transgenic soybeans.

18 They phoned me up, asked me to do the research.
19 They paid for the research. I did the research. I showed
20 that that protein was, indeed, the major allergen from
21 brazil nuts. They allowed us to publish the study, and they
22 discontinued the commercialization of this particular
23 soybean variety, which I view as endorsement for the fact
24 that the process works, even on a voluntary basis.

25 Questions have been raised about the products that

1 might be produced containing genes from sources with no
2 history of allergenicity. I believe that those products can
3 also be assessed for their allergenicity potential by using
4 the approach advocated by ILSE, which is sequence somology
5 assessments with all known allergens, both food and
6 environmental. And by assessing the digestive stability of
7 those foods and the novel proteins therein.

8 This assessment strategy advocated by ILSE and
9 IFBC has engendered considerable discussion, especially in
10 Europe. And I was privileged to participate in a discussion
11 conducted by a consumer group in the Netherlands back in
12 May, which I would say that the assessment from that two
13 days of discussion between consumers and scientists
14 concluded that the current approach is appropriate and
15 adequate, but future questions may, indeed arise relative to
16 the allergenicity of these novel proteins.

17 What are we going to do when we have novel
18 proteins that are stable to digestion? We may not have
19 tests that will allow us to appropriately do that assessment
20 and, so, I would say that these testing procedures do need
21 to be dynamic. And we do need to develop further
22 approaches, and we do need further discussion of what the
23 best approaches might be.

24 In the ILSE paper we also suggested that an animal
25 model would be a very good addition to this assessment

1 process for products produced containing genes from sources
2 of unknown allergenicity. However, there's not a validated
3 animal model. So, further research is necessary. And the
4 use of an unvalidated animal model would probably add to
5 confusion amongst consumers, rather than be beneficial.

6 But, I know that there's appropriate research
7 going on and would like to suggest that that research be
8 scaled up so that we could have an animal model that would
9 be appropriate and help to assure the safety of these
10 products for the allergic consumers, both now and in the
11 future. Thank you.

12 DR. JANE HENNEY: Thank you very much. Dr. Glenn.

13 DR. BARBARA GLENN: Commissioner Henney and
14 members of the Food and Drug Administration listening panel.
15 Thank you for giving the Federation of Animal Science
16 Societies the opportunity to provide comments today on the
17 scientific and safety issues of livestock feeds derived from
18 plants developed using biotechnology techniques.

19 I am Dr. Barbara Glenn, Executive Vice President,
20 Scientific Liaison for the Federal of Animal Science
21 Societies. I have conducted research in the area of protein
22 and energy metabolism by dairy and beef cattle for the
23 production of milk and meat over my career of 25 years.

24 I am an expert in the use of numerous feeds by
25 cattle, including digestion and absorption of nutrients for

1 milk production and growth. The Federation of Animal
2 Science Societies, FASS, is a professional organization made
3 up of approximately 10,000 scientists and academia,
4 government and industry, which exists to serve society
5 through the improvement of all aspects of food animal
6 production. FASS represents the combined membership of the
7 American Dairy Science Association, the American Society of
8 Animal Science and the Poultry Science Association.

9 Commissioner, as you requested, we will comment
10 today on newly emerging scientific information related to
11 the safety of feeds derived from genetically modified crops.
12 It has been estimated that the supply of food required to
13 adequately meet human nutritional needs over the next 40
14 years is quantitatively equal to the amount of food
15 previously produced through the entire history of humankind.

16 This poses a real daunting challenge to our global
17 village for several reasons. First, virtually all land
18 that's suitable for farming worldwide is not being farmed.
19 Secondly, destruction of tropical rain forests or wildlife
20 habitat is not really a viable option for environmental
21 considerations. Thus, we feel the only feasible solution is
22 to continue to develop new technologies which will enhance
23 food production efficiency.

24 Genetic modification of crops for livestock has
25 been conducted for many years. Plants to supply feeds for

1 livestock have improved over the years because new plant
2 varieties were developed using conventional techniques or
3 plant breeding and genetic selection. Crops to supply feed
4 for livestock produced through modern methods of
5 biotechnology, of course, are emerging from research and
6 development into the marketplace. Crops using these modern
7 methods of biotechnology are now referred to as genetically
8 modified crops as opposed to crops developed using
9 conventional plant breeding.

10 Both conventional and biotechnology techniques
11 have benefited agriculture. Corn grain, whole plant chopped
12 corn, corn stover and soybeans from the current genetically
13 modified crops have been fed to livestock, and compared with
14 the conventional feeds to determine the effects on feed
15 composition, digestibility and animal responses.

16 Chickens, sheep, beef cattle and dairy cattle have
17 been used in this research. These data indicate that
18 chemical composition of the genetically modified and
19 conventional feeds are substantially equivalent and they are
20 well within the normal range of values reported in the
21 scientific literature.

22 These data indicate that feed consumed,
23 digestibilities of feeds, nutrient absorption, growth, milk
24 production, milk composition and health of livestock that
25 are fed genetically modified and conventional feeds are

1 equivalent.

2 The digestive process in all livestock breaks down
3 the nutritional components in feeds, including protein, into
4 amino acids, and DNA into nucleic acids which are excreted.
5 Because the nutrients in these feeds are broken down into
6 smaller components, the plant proteins have not been
7 detected in milk and the plant proteins would not be
8 expected in meat and eggs.

9 These data and our understanding of nutrient
10 digestion, absorption and metabolism indicate that these
11 genetically modified feeds are safe for livestock to
12 consume. In addition, the food products from livestock
13 consuming these feeds are safe for human consumption, and
14 they will be a benefit to the nutrition and well being of
15 the world's population, especially targeting children in
16 developing countries.

17 In conclusion, FASS strongly recommends that
18 science be the basis for acceptance of genetically modified
19 feeds for livestock. FASS endorses the use of biotechnology
20 techniques to improve agricultural plants and animal
21 products. FASS believes that agricultural biotechnology has
22 the capability to improve the supply of livestock feeds and
23 healthful animal and plant food products and, thereby, help
24 to meet the nutritional needs of the world's population.

25 Commissioner, thank you for the opportunity to

1 provide this testimony. We would welcome any questions from
2 the listening panel. And, in the future, if we can assist
3 you, please call on us.

4 DR. JANE HENNEY: Thank you very much, Dr. Glenn.
5 Let me take the prerogative of the Chair and the advantage
6 that Dr. Maryanski gave us in terms of that extra 15 minutes
7 to have our questioning period open up for the next 45
8 minutes from the panel or your conversations and questions
9 to each other until 11:45.

10 We'll then break for our hour lunch and that will
11 give us an additional 15 minutes that we can use for the
12 open public comment later on this afternoon. But, with
13 that, why don't I open it up to the panel for questions to
14 our distinguished panelists.

15 And the person with the first question is always
16 the most reluctant, so whoever has the second question can
17 feel free to come up.

18 MR. ROBERT LAKE: Let me ask one that I think is,
19 or ask the panel to comment more on something that I think
20 is very important. One of the things I heard was a
21 suggestion that it would be helpful if the FDA process were
22 made more transparent. I would appreciate any, or for that
23 matter, all of the panelists to kind of speak to that a
24 little bit, if you have some thoughts. Because I think
25 that's getting at, in part, the issue of public confidence

1 in the process. And we would be very much interested in
2 hearing your thoughts on that.

3 DR. JANE HENNEY: I think that was first raised by
4 Dr. Jacobson. Do you have particular thoughts about that?

5 DR. MICHAEL JACOBSON: We haven't followed the
6 course of one of these GM foods, and so I don't have that
7 direct experience. But, on other issues, it is certainly
8 helpful to see proposed regulations come out in the Federal
9 Register, be presented with arguments on one side or
10 another, questions, have that opportunity for comments, and
11 then see an explanation of the FDA's response when it makes
12 its decision.

13 Rather than just telling the company privately, we
14 don't have any further questions. It's something similar to
15 the situation with gras substances, where industry has been
16 at liberty to just declare something gras. In the past,
17 many companies would petition the FDA to get an affirmation
18 of gras, FDA would publish that information in the Federal
19 Register. There was an opportunity for comments and then a
20 decision would be made.

21 Now, the FDA's moving away from that for the
22 so-called gras food additives. I think it's a mistake with
23 that, but I think with biotech foods, it should move more
24 towards that standard approval process. With information
25 available, comment periods, and explanation of a decision.

1 DR. JANE HENNEY: May I ask, perhaps, a bit of an
2 extension on that. With the flavr savr tomato, we clearly
3 used that as a prototype in terms of taking that to the Food
4 Advisory Committee for their comment. We also have other
5 vehicles well-known in other parts of the agency when we ask
6 advisory committees that are going to be commenting on new
7 pharmaceuticals about ready to move to market.

8 Rather than, necessarily, using the Federal
9 Register as the vehicle that communicates decision to the
10 public, what we have been doing more recently is using the
11 web site to then give the basis of our decision about an
12 approval of a product. In this particular case, the results
13 of a consultation of a product.

14 Would you see some of those, I think, more
15 immediate ways to communicate decision making or
16 consultation as ones that we ought to consider?

17 DR. MICHAEL JACOBSON: Well, you're asking the
18 wrong guy about the Food Advisory Committee. At times, it's
19 been the hand-picked committee chosen by the bureaucrats who
20 have a predetermined decision, predetermined result. And
21 they'll get it. You know, you appoint the committee, you
22 know who you're having, and they'll give you whatever
23 wanted.

24 I'm not saying that you can't get some useful
25 information. It's a cumbersome way for consumers to provide

1 input. People can't fly, the average person can't fly as
2 easily to Washington as can an industry official. The
3 Federal Register, newspaper publicity, that kind of thing
4 is, I think, is a better approach.

5 Or, an essential approach, in addition to an
6 advisory committee. I don't want to dismiss the notion that
7 those are useless.

8 DR. JANE HENNEY: Other questions.

9 MR. ROBERT LAKE: Were you wanting to comment on?

10 DR. STEVEN TAYLOR: Yes, I'd like to comment on
11 this point. It's been represented in the news media on a
12 number of occasions recently that no safety testing is
13 required by the FDA. And I think it's the perception of
14 some consumers that the companies are not doing any. And
15 they certainly don't have access to the data that has been
16 accumulated on any of these products.

17 As you know, substantial safety assessment data is
18 accumulated on these products and has, to now, been shared
19 with the Food and Drug Administration. When I said that the
20 process could be more transparent, I was, indeed, thinking
21 that some of this data could be shared with the public at
22 large through some widely available vehicle such as the web.

23 In some appropriate format such that the company's
24 proprietary data of how they constructed their crop might
25 not have to be shared, but that at least people would have a

1 chance to see that some safety tests had been done, those
2 results were shared with the Food and Drug Administration,
3 and the Food and Drug Administration had not raised any
4 questions.

5 DR. JANE HENNEY: Mr. Margulis.

6 MR. CHARLES MARGULIS: Yes, just briefly, I'd like
7 to comment. I think experience shows that it would be
8 unwise of the agency to always trust the data submitted by
9 the companies. And I think it would be a positive step for
10 the agency to require independent testing, peer reviewed
11 testing. Testing that's open to the public and that's not
12 done by companies that have a financial interest in the
13 outcome of the testing.

14 DR. JANE HENNEY: Dr. Hardy.

15 DR. RALPH HARDY: Yes, let me respond to the
16 transparency. I think anything that collective government
17 agencies can do to build trust is important. And, clearly,
18 the more transparent, and I would say the more forthcoming,
19 you can be, the better. Let me use an example from the
20 recent Senate Ag Nutrition Forestry Committee Hearing about
21 a month ago.

22 You're aware of the infamous or famous, however
23 you want to look at that, Cornell butterfly experiment.
24 Many people raised, after that issue came up, the fact that
25 the regulatory people had failed to recognize the impact of

1 BT plant products on non-target organisms.

2 Janet Anderson, in her testimony in early October,
3 said very clearly that in the regulatory approval, they had
4 looked, in fact, and considered that issue. And came to the
5 conclusion that it was relatively insignificant compared to
6 the impacts of other methods of pest control.

7 That was a very important piece of information to
8 get out there. Had that piece of information gotten out
9 almost synchronous, ideally synchronous, with the release of
10 all the press that came out, I think you would have killed a
11 lot of the excess press that surrounded that issue.

12 So, anything you can do to be more forthcoming, I
13 think, is very, very important to do.

14 DR. JANE HENNEY: Dr. Giddings.

15 DR. VAL GIDDINGS: Yes, Dr. Henney, I think it's
16 an excellent issue. It's an important issue. It's the one
17 that is most central, you know, the issue of public
18 confidence. And we will comment on that this afternoon in
19 our comments on the panel, the second panel.

20 But, just so it's very clear, industry is of a
21 view that virtually all the information that is discussed
22 with FDA in the course of these consultations could properly
23 and appropriately be shared with the public as broadly as
24 possible. Perhaps, taking an example from USDA and posting
25 it on your web page, or something like that, might be an at

1 least useful way to start.

2 The only exceptions to this would be in cases
3 where there is truly proprietary information, which should
4 be safeguarded under the usual strict rules that the
5 government applies for those cases. But, you know, we think
6 that we have an outstanding story to tell of benefits and
7 safety, and we would encourage the agency to do anything and
8 everything that they can to share these data with the public
9 at large.

10 DR. MICHAEL JACOBSON: I just, I wanted to
11 question something, an impression Steve Taylor left in my
12 mind. I worry that you're overly certain about the safety,
13 the freedom of allergenicity, of genetically modified
14 organisms.

15 And I say that partly because you and I dealt with
16 sulphites back in the early '80's. In 1981 sulphite
17 preservatives were safe. Everybody knew they were safe.
18 We'd been using them for hundreds of thousands of years in
19 wine and other foods. In 1982, the FDA proposed that
20 sulphites be declared gras, generally recognized as safe.
21 Ironically, the same year that allergic reactions were
22 discovered.

23 When we urged the FDA not to approve it as safe,
24 there was publicity and we began hearing from people or the
25 relatives of people who died two minutes after eating foods

1 treated with sulphites. And, eventually, the FDA put tight
2 limits on it.

3 But, that experience, I think, was very humbling
4 for a lot of people, allergists, chemists, people who know
5 the structure and say, "We know it. Therefore, it's safe."
6 And I think that defenders of biotech foods have to
7 acknowledge that there's a risk of some magnitude, unknown
8 magnitude, of allergy or food sensitivity. Some kind of
9 sensitivity that's not the normal immune system.

10 And, on the other hand, I think critics need to
11 acknowledge that there's no way to prove safety with
12 absolute certainty. You can always think of some other test
13 or other question.

14 I think what's needed is the strictest government
15 oversight to assure the public that every reasonable test
16 that can be done has been done. That the risks are at an
17 absolute minimum. I don't know if there's any way to do
18 post market surveillance. If somebody could figure out
19 something, that would be good. But, once something's in the
20 general food supply, there is no kind of unique segment of
21 the population that's either exposed or not exposed.

22 DR. JANE HENNEY: Dr. Taylor, do you want to
23 respond?

24 DR. STEVEN TAYLOR: Well, in my comments I said
25 that I did have some confidence that these materials could

1 be assessed for their potential allergenicity and, I guess,
2 I'll hold to that discussion. Certainly, there's a
3 magnitude of difference between the products that are
4 currently on the market, where the novel protein is
5 expressed at a very low level.

6 And, so allergies are caused by abnormal reactions
7 of your immune system to some protein that might exist in
8 food. And the immune system is more likely to react to the
9 proteins that are there in large amounts, rather than some
10 enzyme that's present at infinitesimally small amounts.

11 And, so that gives me some great degree of comfort
12 relative to this particular generation of biotech foods.
13 But, in the future, we are going to have foods with,
14 admittedly, altered proteins. And the transgenic soybean
15 that I referred to that was being engineered to address the
16 lathymine deficiency that's inherent in soybeans was one of
17 the first examples of that. That food was being engineered
18 to have an altered protein make-up.

19 Those foods, even if they're not containing genes
20 from known allergenic sources like brazil nuts, have to be
21 evaluated very carefully because major proteins are going to
22 be changed. But, I think FDA's current policy, if I'm not
23 mistaken, would view those foods as not substantially
24 equivalent to their conventional counterparts, and would
25 require additional safety testing, as well as, perhaps,

1 specific kinds of labeling that would distinguish those
2 products from other products in the marketplace.

3 So, I would say these future generations of
4 genetically modified foods will require us to be more
5 vigilant and, perhaps, even to come up with some new and
6 better testing procedures.

7 DR. JANE HENNEY: Dr. Taylor, maybe I can have Dr.
8 Maryanski respond to that point, as to whether, in our view,
9 that that policy would apply with respect to protein.

10 DR. JAMES MARYANSKI: Yes, in fact, Dr. Taylor is
11 correct in that if a food were modified to contain a new
12 protein or other substance that's there as a major component
13 of the food, that is one of the considerations that we would
14 expect to lead to either different testing or more extensive
15 testing. If that protein is not already understood to be
16 safely consumed.

17 DR. JANE HENNEY: And, I believe Dr. Giddings, did
18 you want to talk on this point?

19 DR. VAL GIDDINGS: I can't think of anything
20 useful to add to that.

21 DR. JANE HENNEY: All right. Questions?

22 MS. MARGARET PORTER: Let's see. Does this work?
23 I have a question for Mr. Margulis. I understood from the
24 conclusion of your remarks for you to be advocating that
25 currently marketed GMO foods be removed from the market.

1 Are you advocating that they be subject to a mandatory
2 pre-market approval process, as unapproved food additives?
3 Is that the process you would be advocating?

4 MR. CHARLES MARGULIS: Yes. We believe that would
5 be a step in the right direction and we hope that the agency
6 would mandate pre-market safety testing, as well as
7 labeling. We also feel that alternative approaches should
8 be looked at that don't have the risks of biotechnology.
9 And the agency should really reconsider its promotional
10 stance towards biotechnology and look at other approaches.

11 MS. MARGARET PORTER: When you reference the risks
12 of biotechnology, it would help me, as a listener, if you
13 could be, your slides, which we have for the record, but if
14 you could specify some of those, I think it would help in
15 the discussion.

16 MR. CHARLES MARGULIS: Sure. Well, Greenpeace, of
17 course, is primarily concerned with the ecological risks and
18 we're already seeing many of these in the lab and in the
19 environment. There are several laboratory studies that show
20 effects on non-target beneficial insects. There are three
21 studies from Europe that show that lay swings can be
22 adversely affected by BT crops. We also know that there's
23 laboratory evidence that the BT toxin from the crops can
24 build up in soil ecology and damage micro organisms, healthy
25 micro organisms in the soil. There's already field evidence

1 that genetically engineered crops are transferring genes
2 from crops to weedy relatives, and this is happening with
3 genetically engineered canola.

4 In fact, the biotech industry is already marketing
5 new herbicides to farmers in Western Canada who are having
6 problems with canola that's tolerant of Round-Up that's
7 growing as volunteer canola.

8 So, the strategy of the biotech industry is
9 clearly working already. That the problems that they're
10 creating with genetically engineered crops are being solved
11 with new toxic chemicals. These are just some of the
12 glimmers of biological pollution that I think we're already
13 seeing.

14 MS. MARGARET PORTER: Thank you.

15 DR. JANE HENNEY: Dr. Hardy.

16 DR. RALPH HARDY: Yes, I'd like to respond to
17 Mr. Margulis's comments. I think it's important that best
18 quality information gets conveyed to the public. And what
19 I'd like to suggest, and will be suggesting this in the NABC
20 statement on this area, is that there, in fact, be an open
21 forum.

22 An open forum where public interest groups who
23 have concerns can come to that, can put on their speakers.
24 We could provide speakers that might have different
25 viewpoints. Then we could go into workshops, which is the

1 real basis of the National Ag Biotech Council to address
2 issues.

3 Go into workshops where, in fact, with scientific
4 depth, we would look at the statements you're making and
5 we're making to see if the quality of rigorous science
6 supports the statements that are out there. We owe this to
7 the public at the moment. There is mass confusion out
8 there, and I'm very upset about the mass confusion that's
9 out there.

10 So, I would like to offer you and other
11 organizations that opportunity. We, clearly, we would work
12 together with you, keep the press out.

13 MANY VOICES: No.

14 DR. RALPH HARDY: Wait, no. If you're going to
15 have an open dialog, you need to have an open dialog where
16 people are not frightened about being quoted. The product
17 of that discussion clearly can be transparent.

18 DR. JANE HENNEY: Let's keep the discussion
19 respectful. I think you've made your point, Dr. Hardy and
20 Mr. Margulis, and I think Dr. Giddings had a remark to make.

21 DR. VAL GIDDINGS: Dr. Henney, I think it's
22 important to make sure the public record recognizes that the
23 particular issues raised by Mr. Margulis, in specific and
24 similar related issues in general, have been the subject of
25 extensive analyses and examination on the public record and

1 in scientific literature over the past 15 years.

2 And what was cited as examples of harm, are not,
3 in fact, that. The appropriate questions to ask are not
4 questions of what is the level of risk so much as how does
5 the level of risk of this new activity compare with the
6 level of risk of the activities we now presently undergo.

7 And, when you look at that, It's very clear that
8 the risks associated with new crops produced through
9 biotechnology are equal to or less than those of crops
10 produced through traditional breeding and present agronomic
11 practices.

12 Biotechnology is very clearly, the data and
13 experience show this abundantly, contributing to vast
14 improvements in sustainability of production agriculture.
15 And, you know, I'd love to get into this at great length. I
16 realize that these are ecological issues outside FDA's
17 strict, limited purview.

18 But, there's been a vast amount of expiration of
19 these issues over the past 15 years and it's there in public
20 record for all to consult.

21 MR. ROBERT LAKE: Let me ask the following
22 question. As you've all heard, the existing FDA policy, in
23 terms of consultations, is a voluntary one. We've just
24 heard a suggestion that a mandatory pre-approval process be
25 adopted in the future.

1 I guess I would like to explore the panel's
2 thinking about a possible intermediate option, which would
3 be to make the current consultation process mandatory. And
4 I would, you know, appreciate, I don't know who wants to.
5 Somebody, actually, I think, alluded to that and I would
6 like to hear one or more of you comment on that one way or
7 the other.

8 DR. JANE HENNEY: I think I saw Dr. Taylor.

9 DR. STEVEN TAYLOR: Well, certainly, if as
10 Dr. Maryanski indicated this morning, all of the companies
11 are approaching FDA now and sharing the information, there's
12 little difference between a voluntary process and a
13 mandatory process, except that you're insisting that they
14 continue to do what they're currently doing.

15 So, I don't view it as a major change in corporate
16 behavior. Because they're coming to you anyway. But, if it
17 was to be made a mandatory process, I think that might have
18 some, might make some difference in making the public more
19 trustworthy of the process.

20 And, I guess, I'd like to turn it over to some of
21 the consumer group representatives to comment on that.

22 DR. JANE HENNEY: Or, Dr. Giddings, did you have a
23 remark to make on this point? And then let's turn it over
24 to others.

25 DR. VAL GIDDINGS: Commission, I think the ground

1 truth reality is that the present consultation, although it
2 may be du jour voluntary in the view of FDA, we in industry
3 regard it as de facto mandatory. And, in fact, we also have
4 legal opinion which suggests that that's an appropriate way
5 to construe it, given the fact that as Dr. Maryanski very
6 clearly pointed out, the requirement to produce food that is
7 safe is absolute under the act.

8 And it applies to foods produced by whatever
9 techniques, technologies, mechanisms, procedures. And there
10 is not a company producing foods, or crops from which foods
11 will be derived, that would dream of introducing a variety
12 so improved without extensive consultations with FDA to make
13 sure that they'd overlooked nothing.

14 And that they would have the appropriate
15 assurances. They'd asked all the questions that FDA would
16 think appropriate. To do otherwise would be extremely poor
17 business practice. In our litigious society, you know, that
18 would leave them open to a whole host of liabilities very
19 easily resolved by the consultation process, which would
20 echo the internal review process that these companies are
21 undergoing anyway.

22 So, we think that there's a certain amount of
23 discussion of semantics here, which is somewhat in conflict
24 with the ground truth reality as we, as companies,
25 experience it. You know, we take the responsibility to

1 consult very seriously and do not consider, in fact, that we
2 have an option to do otherwise.

3 DR. JANE HENNEY: Dr. Jacobson, or I guess, we
4 have Dr. Glenn with her hand up first.

5 DR. BARBARA GLENN: Yes, I just wanted to say, for
6 the record, FASS and the animal, dairy and poultry
7 scientists feel that the consultative process, as it is, is
8 very adequate. And I think what we're hearing here is
9 simply the need to think about public education on whatever
10 that process is. Whether it's voluntary or mandatory.

11 So, you've already heard that from others, but I
12 wanted to endorse that again. That whether it's education
13 on a specific crop that's being submitted to you, it may not
14 be the issue. We've got public education that we've missed
15 in the process prior to that. So, whether this is voluntary
16 or mandatory may not be it. We need to educate folks as to
17 what you're doing.

18 DR. MICHAEL JACOBSON: This process should be
19 mandatory, but I think just the consultation isn't enough.
20 I think there should be a formal approval process. The
21 extent of the data required could depend upon the kind of
22 material being examined.

23 If there's a trivial change between two closely
24 related plants, it could be, perhaps, almost perfunctory.
25 Submission of data to the FDA. The FDA would have a certain

1 period of time to review the data and ask for more data, if
2 necessary. And then affirm that this is okay. Go ahead and
3 market it.

4 For more extensive changes, moving genes between
5 widely distant species, more akin to a food additive
6 petition. More data required. And then FDA approval.

7 And it could be that the FDA should start with the
8 most stringent requirements one can imagine in these early
9 years of biotechnology. And then, in five, ten, twenty
10 years, whatever, some period of time down the line, review
11 those. Were they strong enough as Steve Taylor mentioned?
12 Maybe we need to do new tests with new kinds of GMO's. Or
13 maybe in some areas we're overly protective.

14 The early days of recombinant DNA research went
15 through this, where there was great public controversy,
16 public meetings, marches, and so on, in the '70's. There
17 were strict requirements put in for labs doing recombinant
18 DNA testing and then, at some point, some of that was seen
19 as excessive and some of the concerns were reduced and the
20 requirements were reduced.

21 But, I think the public is nervous. The public
22 would like to reassurance of a formal FDA safe stamp of
23 approval, rather than some informal, oh, we don't have any
24 more questions, do what you want.

25 Or the voluntary nature of this process, the

1 quasi-voluntary nature of this process, leaves questions in
2 people's minds are some of these big companies telling the
3 FDA to stuff it. They've done enough work and they're going
4 to go out with it. It would be nice for the public to see
5 that the company has that report card from the FDA saying,
6 okay, it looks safe to us.

7 DR. RALPH HARDY: I would support the mandatory
8 consultation.

9 MR. ROBERT LAKE: Could the microphone be moved
10 down so the people in our remote can hear the comment, as
11 well?

12 DR. RALPH HARDY: Yes, I would support the
13 mandatory consultation. I think that helps to build,
14 basically, more trust. As we're hearing, it, in actuality,
15 is already occurring. I would not support the most rigorous
16 imaginable reviews as a starting point.

17 And I'd like to use as an example the use of micro
18 organisms to clean up toxic waste. There was an effort
19 several years ago to use genetically engineered microbes as
20 potentials to clean up toxic waste, a problem that's real in
21 this country. In my view, EPA made the requirements so
22 very, very difficult that there's hardly any of that work
23 going on.

24 So, what you do is if you ever do something like
25 that, you're going to remove, delay the benefits that can

1 occur from this area. And there are tremendous benefits
2 that I think can occur.

3 We have only to think about the recent report of
4 rice with increased beta carotene. There are half a million
5 people a year going blind in the developing world because
6 rice is their staple crop and they don't get enough vitamin
7 A.

8 So, there are real benefits here that I think it
9 would be a huge disservice to society if you made
10 overreaching requirements when there is no evidence at the
11 moment that there is a major problem.

12 DR. JANE HENNEY: Dr. Maryanski.

13 DR. JAMES MARYANSKI: Thank you, Dr. Henney. I
14 would like to follow on this theme, but from a little bit
15 different direction. We've been talking about the rigor of
16 the process itself. But, I recall that I believe Mr.
17 Margulis mentioned earlier that he had some concern that
18 products in the future might require testing or a different
19 approach than FDA has been using to date.

20 And this is something that we have been thinking
21 about a lot, also. And I think that it would be very
22 helpful for us to hear from the panel if there any science
23 that we have not taken into account. Is there any new
24 science that we should be thinking about in terms of the
25 guidance for testing that we are recommending to companies?

1 I think Dr. Taylor mentioned the possibility or,
2 of course, the desirability of having more information on
3 assessing food allergy. And that's something we have been
4 looking very carefully at. But, I think it would be helpful
5 to us to hear if there are either areas such as that, or
6 other areas that we would benefit from further testing.
7 And, if so, how?

8 DR. JANE HENNEY: Any takers?

9 DR. RALPH HARDY: Yes. I think the area of
10 secondary metabolites in plants. In time, there probably
11 will be genetic modifications that will increase secondary
12 metabolites as protectants against insects, pests, diseases,
13 whatever. And I don't think, I'm not aware, that anyone has
14 begun to think about how to deal with that. So, that's an
15 area where I think would be important.

16 I certainly would concur of more investment in
17 research to allow us to go beyond digestibility and sequence
18 comparison, which I think is what you said, Steve, is the
19 guidelines at the moment for allergenicity. To see are
20 there other markers out there that could help. How much are
21 we investing in research in this area?

22 DR. STEVEN TAYLOR: In the United States, nothing
23 at all.

24 DR. RALPH HARDY: So, I think that's a need.

25 DR. STEVEN TAYLOR: I would comment, reflect back

1 on the 1996 FAOWHO Expert Consultation and, as Dr. Maryanski
2 knows because he attended those sessions in Rome, we had a
3 lot of international debate about what you would best do for
4 products that are not substantially equivalent to their
5 conventional counterparts. And what kind of testing would
6 be suggested or mandated. And I think that dialog simply
7 needs to continue on an international level.

8 Those kinds of genetically modified crops have not
9 yet been produced and commercialized. But, the testing
10 better be available and internationally agreed upon before
11 the crops are moving toward commercialization or there will
12 be even more debate than there is today.

13 So, I would just suggest that, you know, the
14 United States can't view this in a vacuum. While we need to
15 be sure our consumers are safe, we also sell product to most
16 of the rest of the world and we need to invite their
17 opinions, as well.

18 DR. JANE HENNEY: Mr. Margulis.

19 MR. CHARLES MARGULIS: Thank you. Just a quick
20 example. An organization called the Center for Ethics in
21 Toxics did a study on Round-Up ready soybeans. As I
22 mentioned before, the Round-Up ready soybeans that were
23 submitted to the FDA were not treated with the herbicide.
24 So, the folks at CTOS tested the herbicide treated soybean
25 and they found altered levels of phyto estrogens in the

1 genetically altered soybean.

2 Now, before this paper was even published, the
3 biotech industry put out a review criticizing it and
4 dismissing it. But, I think these are the kinds of studies
5 that the agency should be conducting, that should be
6 conducted independently, and the agency shouldn't be relying
7 on the data from the companies. Because, obviously, there's
8 a history there of misleading the agency.

9 DR. JANE HENNEY: Thank you. Dr. Giddings.

10 DR. VAL GIDDINGS: Well, I'd like to strong object
11 to the characterization that was just placed before us, and
12 point out that companies have not interest in misleading the
13 agency. In fact, our practice is to be as open as possible
14 and respond to all questions the agency might have. Indeed,
15 to anticipate those questions and answer them in advance.

16 In the particular case with studies showing
17 altered levels of phyto estrogens, there is a vast body of
18 data which demonstrates the extraordinary variability in
19 phyto estrogen content, and other content, in soybeans. The
20 phyto estrogen content varies widely between different
21 varieties and same varieties grown under different
22 conditions.

23 And the report that was alluded to produced
24 results showing levels that fall squarely within the normal
25 range of phyto estrogen content in soybeans. It did not

1 show any significant difference from levels that are
2 commonly observed. The finding was, in effect, a
3 non-finding.

4 In terms of issues of the applicability or the
5 application of Round-Up, Round-Up herbicides are typically
6 applied very early in the growth stages, before soybeans are
7 even present. Before the plants have flowered. I mean,
8 this, again, is not a relevant issue and it's one that's
9 been thoroughly examined in the course of product
10 development and regulatory oversight.

11 DR. STEVEN TAYLOR: Can I make a comment? With
12 phyto estrogens your agency allows those materials to be
13 sold as dietary supplements. So, if we're worried about the
14 safety of those materials, I'd be much more concerned about
15 that application than this one.

16 DR. JANE HENNEY: Steve. Dr. Sundlof.

17 DR. STEVE SUNDLOF: Yes. Thank you. Dr. Hardy
18 made the statement that I caught. It said that we should be
19 focusing on what is rather than what if. And I heard
20 another comment in passing, and I can't remember which one
21 of the panelists made it, it was that we may need to do
22 something about monitoring after the fact because we can
23 never be smart enough to know all of the exact right
24 questions to ask before a product is actually out there on
25 the market.

1 And, so to address the what if question. I think
2 that the statement that was made was that there should be
3 some kind of system out there to detect any adverse effects
4 that might be resulting. I don't know what that system
5 would look like. That was the comment.

6 But, does anybody have suggestions or thoughts
7 about what kind of a surveillance system might be in place
8 that would give greater assurance if there are problems that
9 they could be detected?

10 DR. JANE HENNEY: Let me ask Dr. Jacobson to go
11 first since I think that was his comment. And then I think
12 Dr. Taylor wanted to make a comment.

13 DR. MICHAEL JACOBSON: I don't have any
14 tremendously insightful solutions to this problem. There
15 are a couple things. One would be to observe, to monitor
16 disease rates and see if there are new disease rates or a
17 jump in the rates of a particular malady that can be related
18 to the introduction of a biotech food.
19 Obviously, there are many changes occurring at one time.
20 But that might give some hints.

21 Another thing would be to urge allergists and
22 other physicians to keep their eye out for novel problems.
23 You know, are they running into sensitivities that they
24 hadn't seen before. Are there more people sensitive to
25 rice. You know, some obscure, something that doesn't

1 traditionally cause an allergy or causes very rare
2 allergies. Can we see a jump there?

3 You know, it's potluck, really, whether somebody
4 can identify one of these problems when you have the whole
5 country consuming these foods. And the problems that may
6 occur are at low levels. You'd think that if it were a
7 major problem, you know, the brazil nut gene, you'd see it.
8 That's a no brainer.

9 It's the low levels of small increases in
10 autoimmune diseases, maybe. You know, something where
11 there's no obvious, you wouldn't necessarily look for it,
12 Or a secondary metabolite or something that could
13 conceivably cause a problem. So, we're not proposing a
14 great system, but maybe throw the question out to the
15 medical community.

16 DR. JANE HENNEY: Dr. Taylor.

17 DR. STEVEN TAYLOR: Well, with respect to the
18 allergy issue, I think that we have to point out that we
19 don't have great baseline data. Nobody knows what the
20 prevalence of soybean allergy is with any degree of
21 precision in the United States or any other country today.
22 We also don't have clinical uniformity in the way that
23 physicians diagnose soybean allergies. So, there could be
24 some definite clinical arguments over which approach is the
25 favorite approach.

1 And, so advocating for some monitoring of future
2 prevalence of soybean allergy, for example, compared to what
3 it is today, presupposes that we have a decent system today.
4 And I would argue that we do not. And maybe we should. And
5 if we're going to do any form of surveillance, we would have
6 to have some decent baseline data from which to start.

7 Michael Jacobson mentioned the post-market
8 surveillance that was done on the sulphite episode. And
9 having reviewed some of that public information, there were
10 a number of adverse reaction reports in that data base.
11 Probably some small segment of them were pretty believable
12 and a lot of them were pretty unbelievable. And, so if you
13 just had a system where you allowed consumers to call in and
14 claim that their latest case of hives was due to genetically
15 modified food, you'd probably end up having a difficult time
16 sorting that out.

17 DR. JANE HENNEY: Dr. Giddings.

18 DR. VAL GIDDINGS: There's one thing that I think
19 is a little distressing about much of this discussion we're
20 having about allergies. Because much of it's coming from a
21 standpoint that seems to presuppose that biotechnology is,
22 in fact, going to exacerbate these problems.

23 As we have seen with the brazil nut example, you
24 know the one concrete case that's been put forward so far,
25 the system caught that before regulators even had a chance

1 to look at it. The company involved exercised an act of
2 corporate citizenship that must be commended. And they
3 decided that even though this was being developed for animal
4 feed, they would cease development because of the small, but
5 non-zero, potential risk some of it might get into the human
6 food supply.

7 Okay, so it's clearly not a problem in that
8 particular case. With other cases where we have, you know,
9 widespread allergies of unknown etiology. I suffer from
10 those. I'd give an awful lot to know how to deal with some
11 of those. I apologize to Dr. Glenn for disrupting some of
12 her remarks with some of my coughing which is a symptom of
13 some of that.

14 But, you know, it's important to realize that to
15 the extent biotechnology is being used in ways that are
16 relevant to allergenicity. There's a good deal of research
17 that's going on to take the common and widely known
18 allergies, and the foods that produce them, and modify them
19 so as to delete the genes, for example, from peanuts, that
20 encodes the protein which elicits the immune response that
21 leads to the allergy.

22 So, biotechnology is being used to solve this
23 problem. You know, in terms of the potential for genetic
24 phenomena such as position effect or regulatory changes that
25 might result from insertion and cause problems of this sort.

1 I mean, this is something which is very interesting in
2 theory.

3 But, you know, Dr. Jacobson you raised this issue.
4 I'd be interested if you know of any data to suggest that an
5 allergy has ever been created or exacerbated by the
6 introduction of a gene into a new crop variety. I mean, you
7 know, I'm unaware of any, but would love to know if there
8 are any such examples.

9 You know, the probability seems to be very small.
10 So, I think, you know, it has to be borne in mind and looked
11 at in context that, you know, many of these problems are not
12 problems that are limited to or unique to biotechnology.
13 Biotechnology is being used to solve them in many cases.
14 And, you know, it's important to keep that in mind.

15 DR. JANE HENNEY: Dr. Jacobson, would you like to
16 respond to that, or take a pass?

17 DR. MICHAEL JACOBSON: Well, I'd like him to breed
18 the cat allergy out of cats. I'd be grateful for that.

19 DR. VAL GIDDINGS: That can't be done.

20 DR. MICHAEL JACOBSON: Get a dog. I'm not
21 contending that there is an existing example, or that it's a
22 great risk. Rather, that the public would like the
23 reassurance that any risk is at the absolute minimum that
24 can be reasonably determined. And I would amend my comment
25 and say the strictest reasonable tests that can be done.

1 DR. JANE HENNEY: Well, I want to thank the panel.
2 We've reached the time for a lunch break. But, you have
3 provided us with what we wanted, both a provocative and
4 stimulating discussion of a wide range of views on this
5 topic. I think we'll be hearing from more of your
6 colleagues at our meetings in both Washington and Oakland.
7 And we will look forward to this.

8 Please remember that we intend to reconvene at
9 12:45. Again, there is a place for lunch one floor down at
10 a food court or many restaurants that are within a fairly
11 short proximity. We will be starting promptly, however, at
12 a quarter to one. So, again, thank you panelists, and thank
13 you audience for your attention and good preparation.

14 [Whereupon, a lunch recess was taken.]

1 A F T E R N O O N S E S S I O N

2 DR. JANE HENNEY: Well, it's 1:45, and it's time
3 that we reconvened. We did have a special request from one
4 member of the public who had asked for a special
5 accommodation that his two minutes be given at this point,
6 and we have tried to accommodate that. Then we will be
7 going to the regularly announced agenda, which will be a
8 presentation by Bob Lake, and then our panel members.

9 But Mr. Cohen, if you would take your two minutes
10 now, we'd appreciate it.

11 MR. COHEN: How does this work? Do I start the
12 timer?

13 MR. LAKE: We have people who will start the
14 timer. We'll do that later. You just do your two minutes.

15 MR. COHEN: Okay. Thank you. Do I have a mike?
16 Or can I use your mike?

17 MR. LAKE: You can have this one.

18 MR. COHEN: Okay. Do you want real science? I'm
19 here to give you real science. The greatest controversy in
20 FDA history was the approval process for Monsanto's
21 genetically engineered bovine growth hormone. FDA, the
22 first time, published something in a peer review scientific
23 journal, Science, August 24th, 1990. Here's the conclusion
24 from that study.

25 Quote, "The need to pursue more definitive studies

1 has already been stated as unnecessary because BST is
2 biologically inactive in humans and orally inactive.
3 Additionally, it has also been determined that at least 90
4 percent of BST activity is destroyed upon pasteurization of
5 milk."

6 That statement and conclusion was a lie. FDA
7 approved a study that was done in Guelph, Ontario when milk
8 was pasteurized in order to destroy it, for 30 minutes at
9 162 degrees Fahrenheit, where it should have been
10 pasteurized for 15 seconds. Even then, only 19 percent of
11 this hormone was destroyed, yet David Kessler testified
12 before Congress that it was all destroyed.

13 The one reason to take this hormone off the market
14 and the one reason that genetic engineering doesn't work and
15 the process is flawed is that Monsanto lied to the FDA.
16 They were supposed to tell you their research, what was
17 happening. Monsanto -- this isn't working.

18 SPEAKER: Yes, it is.

19 MR. COHEN: Monsanto created a fleek amino acid
20 when they made the genetically engineered bovine growth
21 hormone. They did this in 1992, did not tell you until six
22 months after the hormone was approved. You went to great
23 lengths to say that a different amino acid is okay if it's
24 at the interminus, amino acid number 191. Monsanto replaced
25 lysine number 144 with epsilon and acidalysine and Bernard

1 Violin, Monsanto's scientist published this in the July 3rd,
2 1994 issue of the Journal of Protein Science, a very obscure
3 British journal.

4 Genetic engineering doesn't work. Levels of IGF
5 1, which is the most powerful growth hormone in the human
6 body and identical in a cow's body, levels of IGF 1 increase
7 when treated with BGH. Even though C. Everett Coop said it
8 didn't, it does. That's the truth. Juskovich and Geyer had
9 that in their abstract. And last month we learned from the
10 Journal of the American Dietetic Association, Robert Henney
11 published the study, that milk drinkers, levels of IGF 1
12 increase in their blood serum ten percent. IGF 1 has been
13 called the key factor in breast cancer, prostate cancer and
14 lung cancer.

15 Madam Commissioner, tomorrow I'll have my not two
16 minutes, but two hours at the Center for Veterinary Medicine
17 to give them the real science. I've submitted this yellow
18 piece of paper which has the real science, and I hope you
19 have a copy. Thank you for giving me the two minutes.

20 DR. JANE HENNEY: You're very welcome. Now we
21 will go to a presentation by Bob Lake, as we enter into a
22 discussion surrounding our second question.

23 If you'll make your presentation, Mr. Lake, and
24 then we'll go to our panel members.

25 MR. LAKE: I hate to stand in front of our panel.

1 I'll at least try to stay, not being front of the
2 Commissioner. But I also want to be up here where people
3 can at least see me.

4 You heard this morning that the Food, Drug and
5 Cosmetic Act governed the safety of the foods we're talking
6 about. Let me just also point out that that same Act
7 governs labeling as well. The Act requires a number of
8 things, that a number of things be specifically on the
9 label. I guess the most common thing that people think
10 about today is the nutrition panel that we mandated back in
11 the early 90's.

12 It also, though, permits other information so long
13 as it is truthful and not misleading. One of the issues
14 relates to a common usual name, and just to go back to
15 something that Dr. Maryanski mentioned this morning, one of
16 the most basic pieces of information is well, what is this
17 food? And if, through genetic engineering or through other
18 means, the identity of something is changed so that it
19 properly ought to be given a different name, then that is a
20 part of the process. And canola oil, that he mentioned this
21 morning, is one such example. So that's one area of labeling
22 where the difference in the product would show up in the
23 difference in the name.

24 The other thing that I would point out is that,
25 you know, and I'm sure we'll hear more this afternoon about

1 voluntary labeling. Again, that is information that
2 manufacturers can put on labels of their own desire. Again,
3 it must be truthful and not misleading, and we hope to hear
4 some comment about all of that this afternoon as to what
5 either is or is not.

6 Let me also just point out a couple of other
7 things about existing labeling policy that are currently
8 required. If a product is changed in a way that has an
9 impact on the consumer from use of the product, such as for
10 instance, the presence of an allergen that would not be
11 expected. So if, for instance, the soy example, if the
12 Brazil nut protein had found its way into soy and caused
13 therefore additional number of people to be allergic to that
14 product, had such a product been on the marketplace, our law
15 and regulations would require that the presence of that
16 allergy causing protein be declared on the label. In other
17 words, it would have had to say something about Brazil nut
18 protein being in the product.

19 Also if there's a significant difference in
20 nutrition or some other characteristic that is material,
21 then that would, under existing policy, be required to be
22 disclosed on the label as well.

23 Now, before going to my next slide, let me touch
24 on one other thing that sort of came up this morning and
25 that is the availability of information that is presented to

1 the Food and Drug Administration on the safety of
2 bio-engineered foods as well as other safety information.
3 All safety information that comes to FDA is publicly
4 available.

5 Now, in the case of these consultations, the
6 process by which you would obtain the information that has
7 been given to FDA by companies, is through the Freedom of
8 Information Act, which is cumbersome. I think one of the
9 things we were hearing this morning and may hear some more
10 about this afternoon is a more user friendly way, as it
11 were, of making some of that information available to the
12 public. But I wanted to just clarify that it is publicly
13 available now. No safety information on foods is not
14 publicly available. All of that is publicly available.

15 Now, if I can go to the next slide. I know we're
16 going to hear a lot about labeling, and we are interested in
17 hearing about that. But we also are interested in
18 considering other possibilities, either separately or in
19 conjunction with labeling, for making more information
20 available to the public. And greater use of the World Wide
21 Web is one possibility, as well as some others that you see
22 there on the screen. And we would also invite your
23 suggestions on other possibilities as well. So with that,
24 let me sit down and we will devote the maximum amount of
25 time to listening for the remainder of the day. Thank you.

1 DR. JANE HENNEY: Thank you, Bob. We'll now turn
2 to our second panel on public information and labeling.
3 Again, each panel member will be giving brief opening
4 remarks and then the remarks will be followed by a
5 discussion among the panel members and with the FDA panel.

6 Let me review the questions that we have posed to
7 our second panelists to be addressed in their presentation.
8 The first is should FDA's policy requiring labeling for
9 significant changes, including changes in nutrients or
10 introductions of allergens be maintained or be modified?
11 Should FDA maintain or revise its policy that the name of
12 the new food be changed when the common or usual name for
13 the traditional counterpart no longer applies? Have these
14 policies regarding the labeling of these foods served the
15 public?

16 Second, should additional information be made
17 available to the public about foods derived from
18 bio-engineered plants? If so, what information? Who should
19 be responsible for communicating such information?

20 Third, how should additional information be made
21 available to the public, on the Internet, through food
22 information phone lines, food labels or any other means that
23 you might suggest?

24 The members of our second panel, for this
25 important discussion, are Dr. Marion Nestle. She's a