

1 MR. LAKE: Thank you, sir.

2 MR. STEIN: Good afternoon. I am Jeff Stein, a
3 molecular biologist by training and Director of Regulatory
4 and Government Affairs for Novartis Seeds in North America.
5 Both in Chicago and here today, we have listened to many
6 speakers call for the labeling of foods whose ingredients
7 have been derived from crop plants that have been
8 genetically modified by the tools of biotechnology.

9 Individuals and groups that have expressed this
10 point of view have stated that they wish to have access to
11 foods that are free of the introduced DNA sequences, however
12 innocuous these sequences may be, or they wish access to
13 foods that are free of the expressed proteins, however safe
14 they have been proven to be, or they wish access to foods
15 that are free of unintended toxins or other unidentified
16 substances although the scientific evidence does not support
17 the presence nor the risk associated with these materials.

18 Regardless of the reasons, their call for this
19 choice is genuine. Speaking both as a consumer and a
20 representative of Novartis seeds, I wholeheartedly support
21 their desire for the option to purchase products lacking
22 these attributes.

23 Those individuals who wish to purchase foods that
24 are free of ingredients derived from genetically enhanced
25 crop plants should be able to do so. For members of the FDA

1 panel, clinical quantities of fresh and processed food
2 products that meet these standards are already available in
3 local and specialty grocery stores across the nation. These
4 products are grown and processed according to a strict set
5 of rules and standards including the absence of so-called
6 GMOs.

7 Food product that meet these standards carry the
8 label of "organic." Organic and processed foods provide a
9 choice for those consumers who wish to purchase products
10 that are free from introduced DNA sequences and newly
11 expressed proteins.

12 To meet the demands of consumers who wish to
13 purchase food free from these materials does not necessitate
14 the rewriting of the '92 food policy or the rewriting of
15 current FDA labeling guidelines.

16 MR. LAKE: Thank you, sir.

17 MR. GOLDBERG: Good afternoon. I am Gary
18 Goldberg, Chief Executive Officer of the American Corn
19 Growers Association. This issue of genetically modified
20 organisms, or GMOs, has placed the American farmer in the
21 middle of a dispute between seed dealers, chemical
22 companies, grain elevators, grain exporters, foreign
23 consumers and our own government.

24 While we have been told, under this current farm
25 program, to grow more crops for the marketplace, the

1 marketplace is rejecting what we grow. Our nation's farmers
2 pride themselves on growing the safest and tastiest food in
3 the world. Now our integrity is being questioned over the
4 issue of GMOs and we resent being put in this position.

5 Until we can instill confidence in the commodities
6 we grow, foreign buyers will continue to reject our products
7 and question our motivation. The questions over food safety
8 will not go away simply because our government threatens
9 foreign countries with trade sanctions. This leave our
10 farmers with the risk of planting crops in the spring that
11 may not be marketable in the fall because of growing
12 consumer unrest.

13 This uncertainty will continue until the FDA
14 restores consumer confidence. Therefore, the ACGA
15 recommends the following measures: one, conduct independent
16 clinical studies on the safety of genetically modified
17 foods; two, determine the consequence of cross-pollination
18 and its effects on non-GMO crops, our water and our soil;
19 and, three, mandate labels on all GMO foods, both domestic
20 and foreign, to fulfill the consumer's right to know what
21 foods they and their children eat.

22 We recognize that biotechnology companies have
23 made a sizeable investment in the research and development
24 of GMOs. That is not our concern. Our concern is the
25 investment that the American farmer makes in purchasing,

1 planting, nurturing and harvesting of crops that may not
2 have a readily available market.

3 The FDA must recognize the concerns and address
4 this problem head-on through testing and labeling.

5 Thank you.

6 MR. LAKE: Thank you, sir.

7 MS. MELNICK: My name is Rita Melnick and I am
8 here as a concerned consumer. Genetic modification is a
9 powerful tool. It can bring about great good but it can
10 equally bring about great harm. In these early days of
11 genetics, no scientist can guarantee with absolute certainty
12 the outcome and ramifications of genetically modifying our
13 food supply.

14 With genetics, we are modifying the building
15 blocks of life and, thus, should proceed with the utmost
16 caution. We must remember we are dealing with living
17 organisms, not inanimate objects.

18 I am also concerned with the use of antibiotic-
19 resistance markers for detecting that the GM transformation
20 took place. With antibiotic resistance in humans at an all-
21 time high, why use this type of marker? Why not some other
22 type of substance to measure the change. And, once the
23 change occurs, how many generations will it last?

24 What occurs when the mutation becomes recessive?
25 I want to know that the companies doing genetic modification

1 are answering these and other essential questions that I am
2 too ignorant to ask. Long-term testing must also be
3 performed, but these issues may take a back seat when the
4 company's main objective is the quest for profit.

5 Until we know with more certainty the long-term
6 effects of introducing GMOs into our food supply and our
7 environment, I propose that the FDA mandate specific testing
8 and criteria to be met for a product to be released on the
9 market. I also propose that mandatory notification be added
10 to the existing food label if the product contains or is
11 processed with GM items.

12 The consumer must have the right to decide whether
13 or not to partake in any ongoing experiment of the long-term
14 safety of GM foods.

15 Thank you.

16 MR. LAKE: Thank you, ma'am.

17 DR. SANTERRE: My name is Dr. Charles Santerre. I
18 am an Associate Professor in the Department of Foods and
19 Nutrition and Purdue University.

20 Does the consumer have the right to know if their
21 foods are bioengineered? The answer to this question is a
22 resounding, "Yes." The consumer has a right to know how
23 their foods are processed, produced, distributed and
24 prepared. Is the food label the proper place to inform the
25 consumer?

1 In a recent survey by the International Food
2 Information Council, most Americans do not desire this
3 information on the label. I agree that the label is not the
4 most appropriate place for this information. The consumer
5 would equate the fact that a food has been bioengineered
6 with the importance of nutrient information that is
7 currently on the label.

8 The NLEA of 1990 already requires a substantial
9 amount of information on the label. This information is
10 pertinent to prevention of osteoporosis, as in the case of
11 calcium content, or prevention of cardiovascular disease, as
12 in the case of fat and cholesterol.

13 To add new label information to products would
14 only dilute the most relevant information that is provided
15 on the label. Since bioengineered foods do not pose a
16 significant health hazard to consumers, there is no reason
17 for a labeling requirement.

18 Consumers can be informed by brochures placed in
19 grocery stores and by county-based outreach efforts such as
20 those programs delivered to the USDA's Cooperative Extension
21 Service.

22 Is our food supply safer due to bioengineering?
23 Yes; some bioengineered products required fewer pesticides
24 be applied in the field which reduces pesticides residues in
25 foods. Farmers growing bioengineered soybeans can use

1 herbicides that don't contaminate their ground water.
2 Insect-resistant corn has been shown to contain less cancer-
3 causing mycotoxins, and the compounds produced by the bT
4 corn are less toxic than other pesticides that would
5 otherwise be used to control insects.

6 Ultimately, bioengineering may allow us to remove
7 allergens from food to further decrease pesticide usage, to
8 increase the nutritional content of food and to further
9 enhance the food supply.

10 I support the FDA's current strategy for--

11 MR. LAKE: Thank you, sir.

12 DR. VAN BUREN: How do you do? My name is Dr.
13 Ariane Van Buren, the Environmental Director for the
14 Interfaith Center on Corporate Responsibility where we
15 represent religious institutions that have \$100 billion in
16 investments in the stock market.

17 These shareholders, this year, are engaged in
18 beginning dialogue, already last week and this week, with
19 twenty-four companies involved in genetically engineered
20 food. They are asking the Board of Directors to adopt a
21 policy of removing genetically engineered ingredients from
22 all products sold or manufactured by the company until long-
23 term safety has shown that these are not harmful to humans,
24 animals and the environment and, in the meantime, labeling
25 and identifying these products and reporting to shareholders

1 by August, 2000.

2 So we ask the FDA to require that labeling and the
3 safety testing.

4 A January 1999 Time-CNN poll indicated that
5 81 percent of Americans said that genetically engineered
6 foods should be labeled as such. The European Union
7 requires labeling of genetically engineered foods throughout
8 the European Union as well as Japan, New Zealand and
9 Australia.

10 The European Union additionally has suspended
11 approval of new genetically engineered organisms until a new
12 safety law for them is implemented in 2002. We believe that
13 this technology involves significant social, economic and
14 environmental risks. Our company should take a leadership
15 position, we feel, in delaying market adoption of
16 genetically engineered crops and foods until the safety
17 testing has been done.

18 Failure to do so could leave our companies
19 financially liable should detrimental effects to the public
20 health or to the environment appear in the future. So I
21 just want to mention that these are shareholders--

22 MR. LAKE: Thank you, ma'am.

23 DR. VAN BUREN: I will leave the names of the
24 twenty-four companies.

25 MS. BRODY: I am Charlotte Brody. I am a

1 registered nurse. I am the Organizing Director of the
2 Center for Health, Environment and Justice. But I am really
3 here today as one of those baby-boomer moms who reads the
4 labels, loves the labels, and really works hard to put
5 nutritious, healthy food on my family's table.

6 I don't want to serve my children arrogance. I
7 don't want to serve them the corporate arrogance that puts
8 some of these foods on the market. I don't want to serve
9 them FDA's arrogance.

10 I have read the science. I have heard the
11 testimony today. There is a whole lot we don't know. Even
12 with all of the flag-waving about sound science, I think if
13 we put the arrogance aside, it is, "maybe yes," "maybe no,"
14 "maybe sometimes." Maybe we need more testing.

15 While we are trying to work through the corporate
16 power and while we are trying to work through the arrogance,
17 I need to know what is genetically engineered. I need to be
18 able to make that decision but I don't think you are really
19 going to make it safely for me.

20 So the least you can do is mandatory reporting and
21 mandatory labeling. Thank you.

22 MR. LAKE: Thank you, ma'am.

23 MS. RICE-ARNOLD: My name is Elizabeth Rice
24 Arnold. I am Associate Director of the Institute of
25 Science, Technology and Public Policy, a non-profit

1 educational public-policy institute devoted to promoting
2 proven solutions and programs of prevention.

3 One of our areas of focus is sustainable
4 agriculture. We are here today to underline what has been
5 said many times before, that the government must reverse its
6 position and establish stringent, premarket safety testing
7 on these foods and keep them out of our fields and kitchens
8 until they are scientifically proven safe for our
9 environment and our families.

10 Until those protocols are in place, federal
11 regulations must mandate the clear and accurate labeling of
12 all genetically engineered foods. We, again, mandate the
13 labeling of genetically engineered foods, declare a
14 moratorium on the release of genetically engineered
15 organisms until the ecological impact of such organisms can
16 be established.

17 The Institute envisions a time when American
18 farmers will farm in full accord with the laws of nature,
19 fully utilizing nature's creativity to yield abundant,
20 healthy foods while protected the environment and insuring a
21 vigorous, diversified, sustainable agricultural economy.

22 We are the time in our world's history where we
23 can no longer afford to violate the laws of nature in our
24 haste for progress. Please, mandate labeling of genetically
25 engineered foods now.

1 MR. LAKE: Thank you, ma'am.

2 DR. THOMAS HOBEN: Good afternoon. I am Thomas
3 Hoben, Professor of Sociology and Food Science at North
4 Carolina State University. I have spent the past ten years
5 researching public knowledge and attitudes about
6 biotechnology.

7 Labeling questions represent one of the most
8 complex and ambiguous areas of survey research. What I
9 conclude from my own research and all the other surveys I
10 have reviewed is, "What you ask is what you get." On one
11 hand, opinion polls indicate that a majority of consumers
12 feel foods developed through biotechnology should be
13 labeled.

14 However, to put that in perspective, almost as
15 many want to know the country of origin for the food and an
16 even greater percentage feel the label should explain
17 whether or not pesticides have been used. It will be very
18 hard to set priorities for limited label space when
19 everything is very important to everybody.

20 A much more realistic approach to this question is
21 to first describe the current FDA policy; that is, that
22 foods will be not be labeled if they are unchanged. In this
23 case, then, about three-quarters of U.S. consumers actually
24 support your current policy.

25 Answers consumers give spontaneously over the

1 phone do not necessarily provide a sufficient basis for
2 public-policy decisions. It is more valid to use focus
3 groups that engage consumers in a thoughtful discussion.
4 Let me quickly summarize a few of those results.

5 We explored the case of biotech-produced chymosen
6 to learn that consumers really don't expect a label of the
7 food--in this case, cheese--has not been changed in some
8 material way. In fact, that has been your approach.

9 Next, we have found that consumers see much less
10 need for labels on processed foods compared to whole produce
11 items. We have also learned that many consumers don't place
12 much value on such labeling and appear unwilling to pay any
13 additional cost.

14 Finally, most consumers are already overloaded
15 with information and overwhelmed by choice when it comes to
16 food purchases and they mainly use the labels right now for
17 nutritional information. A system for voluntary labeling of
18 foods not produced through biotechnology would provide
19 meaningful choice to the concerned minority without imposing
20 costs on or denying benefits to the majority of consumers
21 who are generally quite supportive of biotech.

22 To do this, we need a much greater commitment to
23 education. Thank you.

24 MR. LAKE: Thank you, sir.

25 DR. WOO: I am Dr. Robin Woo at Georgetown Center

1 for Food and Nutrition Policy. First of all, I would like
2 to thank you all of the FDA. If I could have a big sign
3 saying, "I hired FDA," I would because I want to thank you
4 for protecting our food and our drugs. We are probably all
5 here and healthier because of you.

6 The Georgetown campus provides the program in the
7 Masters and Public Policy. Our nutrition program provides
8 education in areas such as this. Today's meeting is very
9 much the core of my class in public policy.

10 One of my students looked at Tom Hoben's data on
11 what is the most important factor in the acceptance of
12 public policy, and that is belief and trust in government
13 and regulators. With that in mind, I think you should take
14 to heart, as I know you will, everything that has been said
15 today about how to strengthen what you have already done
16 well in the beginnings of your regulatory process.

17 On another front, I think public communication is,
18 perhaps, one of your weakest areas of effort. That can be
19 improved by taking a team approach with your natural allies,
20 the joint groups of USDA, FDA and EPA, in creating a program
21 with those who communicate to the public, the educators, the
22 press, working with them to educate the educators, working
23 through AAAS and the science writers, telling them how they
24 can better relay some of the efforts you are doing.

25 Answer the press's questions when they are wrong,

1 directly, quickly. Provide summer education programs with
2 ADA. You heard the offer. You have got all those
3 nutritionists and dieticians out there waiting to help you.
4 Keep up your Internet, your 1-800 line.

5 I think labels and more regulations will naturally
6 happen as products become more consumer friendly because
7 there will be changes.

8 MR. LAKE: Thank you, ma'am.

9 DR. THOMAS: My name is Dr. John A. Thomas. I am
10 Professor Emeritus of Pharmacology and Toxicology at the
11 University of Texas Health Science Center at San Antonio. I
12 have had over three decades of experience in various areas
13 of toxicology and safety assessment including
14 biopharmaceuticals and transgenic drugs in food.

15 Given the brevity of my allotted time, I will use
16 two GM prototypes, namely soy and corn, to illustrate my
17 views of the safety for livestock and human consumption. In
18 my professional opinion, but GM corn and GM soya are safe--
19 that is to say, safe as conventional foods. More
20 importantly, these GM crops exhibit additional
21 characteristics that render them even safer for human
22 consumption.

23 For example, GM corn contains less mycotoxins or
24 aflatoxins. Aflatoxins have been associated with human
25 esophageal cancer. They have been associated with neural-

1 tube defects and aflatoxins are hepatic carcinogens in
2 rodents. Aflatoxins have also been associated with equine
3 leukoencephalomalacia as well as porcine pulmonary edema and
4 liver toxicity. Thus, GM corn with its aflatoxin content
5 represents an additional safe food characteristic.

6 Finally, and my second example, an important
7 advance in technology, is GM soy. GM soy is compositionally
8 similar to conventional soy. However, GM soybeans, as has
9 been previously mentioned, are used growing broad-spectrum
10 nontoxic, nonresidual herbicides. With GM soya, there is no
11 longer the need or concern about residual organochlorines
12 and organophosphates.

13 Epidemiologic studies have revealed a lower
14 incidence of breast, prostate and colon cancer in
15 individuals consuming soy products. Similarly, infant
16 formulas have used soy products for over 50 years. GM and
17 conventional soybeans are substantially equivalent.

18 Healthy and wholesome foods are important for
19 disease prevention. I believe GM foods fulfill this
20 criteria. The Twenty-First Century will be heralded by a
21 number of biotechnology breakthroughs including low-cost
22 oral vaccines.

23 Thank you.

24 MR. LAKE: Thank you, sir.

25 MR. FUCHS: Good afternoon. My name is Roy Fuchs

1 from Monsanto Company. My comments briefly address the
2 benefits of agricultural biotechnology, the effectiveness of
3 FDA's '92 policy and our efforts to provide the public with
4 better information on biotechnology products and issues.

5 Monsanto has conducted research and development
6 for almost twenty years to produce biotech products which
7 help farmers manage insect pests, weeds and plant diseases
8 more effectively. The use of these crops by farmers have
9 helped reduced pesticide usage, lessen soil erosion through
10 conservation tillage, improve feed and food quality and
11 lower food production costs.

12 For example, cotton farmers who chose to use bT
13 cotton only had to make, on average, one to two insecticide
14 sprays versus five to six in non-bT-fields. Researchers are
15 developing products with enhanced nutritional traits such as
16 healthier oils without trans-fatty acids. Scientists are
17 also working to improve the productivity of feed crops for
18 developing countries.

19 FDA's implementation of the '92 policy has been
20 effective. The policy, itself, is science based and
21 provides adequate guidance. It addresses relevant questions
22 for new products and methods and FDA assures that
23 appropriate safety questions are addressed and resolved
24 during the consultation.

25 We are committed to developing safe and nutritious

1 crops for farmers, food companies and consumers.
2 Comprehensive research studies are performed to evaluate the
3 composition, nutrition and safety of each of these crops.
4 We have, and will continue to seek, FDA's review of all of
5 our biotechnology products and will address and resolve all
6 safety issues before any product is sold commercially.

7 We are committed to communicating information
8 about our product. We partner with various educational
9 groups and organizations. Our Internet website at
10 www.monsanto.com provides links to hundreds of independent
11 sources and provides access to over 10,000 articles and
12 reports related to our products and biotechnology. Over 2
13 million visitors have accessed information on this site this
14 year.

15 Thank you for this opportunity to make comments.

16 MR. LAKE: Thank you, sir.

17 DR. TOZZI: Good evening. I am Jim Tozzi with
18 Federal Focus, a non-profit institute. If FDA decides to
19 change its current policies, the resulting proposed
20 regulation is going to be subject to the Paperwork Reduction
21 Act. Under the Paperwork Reduction Act, it is the Office of
22 Management and Budget, not the FDA, who makes the final
23 decision on the proposed rule.

24 One of the most important decisions that OMB will
25 make with FDA's advice, of course, is whether the labeling

1 requirements have practical utility. The determination of
2 practical utility must be based on a sufficient record to
3 withstand potential review. It is for that reason the Paper
4 Act was applied to labeling, to be sure that sound science
5 exudes and goes over passion.

6 For this reason, Federal Focus will be having a
7 symposium on biotech October 24 at Georgetown University
8 Conference Center. In doing so, we are going to look at the
9 existing system which you which, on preliminary reviews,
10 looks like it is working well, but not real well, the
11 difference being transparency.

12 We think that if you would have these meetings and
13 publicize the role of your sister agencies, the EPA and
14 USDA, and have them, in presence, on the panel would help.
15 We will give some recommendations for that.

16 We are going to look at three options; claims-
17 based labeling, identity preservation and FDA-mandated
18 labeling. To address the comprehensiveness of the system,
19 we are going to look at maintaining the current regulatory
20 GM or GM-specific review process, premarket review process.

21 Our report will be on the web and we ask for all
22 people who attended this to give us their view through our
23 website which is fedfocus.org.

24 Thank you.

25 MR. LAKE: Thank you, sir.

1 MS. WITTENBERG: My name is Margaret Wittenberg.
2 I am the Vice President of Governmental and Public Affairs
3 for Whole Foods Market, Incorporated, the world's largest
4 retailer of natural and organic foods. In addition to the
5 name Whole Foods Market, our stores are doing business as
6 Fresh Fields, Bread and Circus, Bread of Life, in Florida,
7 Well Spring Grocery and Merchant of Vino. At the end of our
8 1999 fiscal year, we had sales of \$1.6 billion.

9 With any new technology, it is the responsibility
10 of society to understand the technology and make sure
11 appropriate safeguards are in place. Regarding agriculture
12 biotechnology, the majority of our customers are very
13 concerned, asking questions that should have been explored
14 and answered in an objective manner before products from it
15 arrived in the marketplace.

16 The genetic modification of our food supply is a
17 very complex issue that truly requires input from all
18 stakeholders in the process, as we are having the
19 opportunity to do today. Accordingly, Whole Foods Market
20 urges the FDA to reconsider its decision not to require
21 labeling of foods that contain genetically modified
22 ingredients.

23 Your policy in 1992 concerning new plant varieties
24 stated that no special labeling is needed for foods that you
25 perceive at no different than conventionally bred food in

1 nutrition or in requirements for storage and handling.

2 However, we question whether this evaluation of substantial
3 equivalence truly constitutes sound science.

4 The term that is often bandied about is what those
5 in favor of agricultural biotechnology support and those
6 that question it don't. Judging a food primarily on the
7 amount of macro- and micronutrients is not enough to explore
8 risk and insure safety that are best evaluated through
9 toxological, biological and immunological testing.

10 Relying on the FDA's apparent definition of
11 substantial equivalence is wishful thinking without adequate
12 grounds on which to judge whether a product has short- or
13 long-term safety or not.

14 Science doesn't exist in a vacuum. Food choices
15 are also based on an individual's religious, ethical, social
16 or even personal decision of foods he wants to eat or the
17 technologies he wants to support.

18 MR. LAKE: Thank you, ma'am.

19 MR. ANDERSON: Thank you for the opportunity to be
20 here today. My name is Tony Anderson. I am a soybean and
21 corn farmer from Mt. Sterling, Ohio. In addition, I serve
22 as First Vice President of the American Soybean Association,
23 an organization that represents 32,000 producer members on
24 national policy issues important to all U.S. soybean
25 farmers.

1 My brother and I have farmed in partnership for
2 the last eighteen years. Both of us graduated from the Ohio
3 State University with a degree in agriculture. Furthermore,
4 I participate in a continuing education program for safe
5 pesticide application. My brother and I, like fellow
6 soybean producers, have worked hard to establish the quality
7 reputation that soybeans enjoy with consumers in the U.S.
8 and around the world.

9 If there were any legitimate basis for questioning
10 the safety of varieties derived through biotechnology for
11 animal or human consumption or to the environment, we would
12 be among the first to raise concerns. Like the consumers we
13 serve, farmers have full confidence in the FDA as well as
14 USDA and EPA to make these determinations.

15 The complete absence of sound scientific evidence
16 to support false and misleading claims about the safety of
17 biotech products gives everyone of us reason to support this
18 new technology. It is a tool for producing safer, more
19 nutritious crops more efficiently and more abundantly.

20 The American Soybean Association fully supports
21 the current process through which FDA reviews applications
22 for commercial introduction of biotech products. However,
23 if replacing this voluntary process with mandatory approval
24 would strength the FDA's ability to reassure consumers
25 regarding the safety of these products, we would endorse

1 such a change.

2 We believe the critics of this new technology do
3 not adequately consider the very real benefits of
4 agricultural biotechnology brings to the environment. While
5 we have great strides in reducing toxicity and usage of
6 pesticides in recent years, I hope that our friends in the
7 environmental community can see that the future of biotech
8 innovations will allow us to improve even more.

9 One of the greatest benefits of biotech crops is
10 our potential to slow the clearing of rain forests and other
11 nonagricultural lands in developing countries. By
12 increasing yields rather than expanding global acreage, we
13 can find the solution to feeding an additional 2 billion
14 people by the Year 2035.

15 Thank you.

16 MR. LAKE: Thank you, sir.

17 MS. TAKISE: Thank you very much for the
18 opportunity to participate in this meeting. I came from
19 Japan for this meeting. My name is Kaori Takise, a member
20 of Japan's Offspring Fund.

21 In April, 1996, the U.S. began the widespread
22 planting of GM foods before Japan had developed standards.
23 Therefore the Japanese government had to make rushed
24 guidelines and accepted the import of GM foods. Most
25 Japanese consumers, however, did not accept GM foods. The

1 Yomiuri newspaper conducted a survey and found more than 80
2 percent consumers did not accept them.

3 In spite of this, we are unable to make our own
4 choices about GM foods even after starting of labeling in
5 April 2001. On November 29, the Ministry of Agriculture,
6 Forestry and Fisheries proposed the labeling law that food
7 industries can label "segregated" even when food contains
8 large amounts of GM foods.

9 Due to pressure from the U.S., the Japanese
10 government made such mutilate proposal on labeling. The
11 Japanese consumers are furious about this proposal.
12 Therefore, if the U.S. ignores the Japanese consumer
13 preferences and exports agricultural products without
14 identifying GM foods, the Japanese will stop buying American
15 products.

16 For the sake of consumers, we believe that
17 labeling of GM products is essential. We believe that many
18 American consumers also agree with our opinion. In order to
19 respect consumers' rights, we ask you to institute the
20 strict labeling and separating of GM foods.

21 Thank you very much.

22 MR. LAKE: Thank you, ma'am.

23 MS. SMITH: My name is Sandy Smith. I am from
24 York County, Pennsylvania. I am speaking for Pennsylvania
25 Environmental Network, Pennsylvania for Responsible

1 Agriculture, Sludgebusters and York Greens. I have already
2 handed in a petition with 1500 names and have promised the
3 people that I would hand over the message, the message being
4 it is unbelievable that in a country of so many freedoms,
5 the American people are forced to buy and eat food that is
6 genetically engineered and grown in a soup of toxic
7 chemicals without even a warning label.

8 Not only is the FDA not looking out for the
9 welfare of the people, they are not looking out for the
10 American farmer as he loses competitiveness in the world
11 market by allowing his food to be grown.

12 We, the undersigned, demand labeled foods.

13 Thank you very much.

14 MR. LAKE: Thank you, ma'am.

15 MS. PORTER: Good afternoon. My name is Leah
16 Porter. I am the Executive Director of the American Crop
17 Protection Association's Biotechnology Committee. ACPA
18 members represents major manufacturers, formulators and
19 distributors of crop protection and pest-control products
20 including biotechnology products with crop production and
21 protection characteristics.

22 We applaud the FDA for holding these public
23 meetings to explain its policy and relate its experience
24 regarding the safety evaluation of food products derived via
25 biotechnology. ACPA member companies firmly support and

1 open and informed dialogue on how to reconcile technical
2 advances with human and environment protection.

3 ACPA supports those presentations that express
4 support of plant biotechnology and the coordinated
5 regulatory framework that fully examines food safety risks
6 and concerns. However, I would like to address a comment
7 from earlier today, a statement that there is an utter
8 absence of direct consumer benefit from current crops
9 derived via biotechnology.

10 A recent press release highlighted research that
11 indicates lower mycotoxin concentrations in insect-resistant
12 corn hybrids commonly referred to as bT corn. The presence
13 of mycotoxins can be directly related to insect damage in
14 crops. Additionally, mycotoxins, notably fumonisin, can be
15 fatal to livestock and is a probable human carcinogen.

16 Lower mycotoxin concentrations which result in
17 lower livestock and human health threats clearly represent
18 the direct consumer benefit. ACPA urges that the current
19 debate surrounding the safety of plant biotechnology be
20 based on thorough risk and benefit assessment.

21 Given the solid record of the U.S. regulatory
22 system in insuring food safety, we are confident that future
23 decisions will adequately protect human health and the
24 environment.

25 Thank you.

1 MR. LAKE: Thank you, ma'am.

2 MR. LEMIENX: Hi. My name is Joe Lemienx. I am a
3 healthfood store owner. The first thing I would like to say
4 is that I would really prefer to get my food from God the
5 way it is provided and not from scientists. I am opposed to
6 genetically engineered foods on both ethical and religious
7 grounds and I would like to see them removed from the
8 marketplace until they are proven safe for human consumption
9 and pose no danger to the environment.

10 I do not believe that this proof exists. Labeling
11 is better than nothing, but removal from the marketplace is
12 what I would like to see. Even Former President Jimmy
13 Carter, a supporter of some GE research, has spoken out for
14 a moratorium on genetically engineered foods until they can
15 be proven safe.

16 Second, I would like to say that I believe that
17 the FDA policies in regard to food safety show a total
18 disregard for human and environmental safety and support the
19 reckless behavior of chemical companies and their political
20 supporters.

21 Again and again, choices are being made for
22 corporate profits at the expense of public safety and
23 health. Instead of supporting sustainable agriculture that
24 respects and nurtures the earth, you continue to support
25 measures that rely on chemical solutions, that destroy the

1 soil of this country, pollute our waterways and fill our
2 plates with poison chemical pesticides.

3 And now you bring us "Frankenfoods." Genetically
4 engineered foods also pose a threat to the healthiest food
5 on this planet, organic foods. Because of the possibility
6 of pollen drift, organic foods can be compromised and
7 destroyed by this experiment.

8 I have spoken to companies who provide food to the
9 health industry who are unable to guarantee that their
10 products are GMO free because of the possibility of cross-
11 contamination from GMO fields.

12 Recently, you were asked to provide corridors
13 between organic fields and GMO fields and I understand that
14 you refused. Your reasoning, I believe, was that there was
15 no need for this since GMO foods are no different than
16 organic foods. I do not believe this and I do not choose to
17 be a part of this experiment.

18 I resent the fact that you will not safeguard
19 organic foods from this misguided experiment.

20 MR. LAKE: Thank you, sir.

21 MR. MENCHEY: My name is Steve Menchey. I am here
22 on behalf of the National Cotton Council. The National
23 Cotton Council does have a vested interest in food safety.
24 Some of our products go into certain food and feed products.
25 Our interest is great enough that we come to this meeting in

1 support of a sound and reliable food-safety regulatory
2 system.

3 The National Cotton Council supports the current
4 system of FDA review of food and feed products derived from
5 genetically enhanced crop varieties. We believe that the
6 process, developed in 1992, is sound and adequate to address
7 any concern about the safety of biotechnology. We also feel
8 the system is flexible enough to deal with future
9 technologies that will be developed.

10 The National Cotton Council supports FDA's policy
11 that mandates labels only when information provides useful
12 information pertaining to food nutrients, health or safety.
13 To require special labels because of political, marketing or
14 emotional reasons is not appropriate.

15 The mere presence of such labels unnecessarily
16 implies health and safety concerns. To mandate label
17 information referring to specific technology used to impart
18 plant traits into food crops would be an unnecessary,
19 unreasonable and unmanageable regulation that has no bearing
20 on the mission of the FDA.

21 Under the current system, there are no demands for
22 labeling of, for example, tomatoes that have been developed
23 through conventional breeding to have nematode or fusarium-
24 wilt resistance. The reason, of course, is that the food
25 constituents of these varieties are considered to materially

1 equivalent to varieties not containing those
2 characteristics, although the resistant varieties will have
3 different genes and different proteins than the conventional
4 varieties.

5 Similarly, we believe that same rationale should
6 apply to foods from plants that have been enhanced through
7 biotechnology, that labeling should be required only if
8 foods are shown to be substantially different, not simply
9 because of the type of technology used in the development.

10 Thank you.

11 MR. LAKE: Thank you, sir.

12 MR. JOHNSON: My name is Eric Johnson. Labeling
13 must be mandatory. That is my position. Here is why?
14 Substantially equivalent and generally recognized as safe
15 are claims that simply are not supported by the facts. I
16 would refer you to the memos made available as a result of
17 the Alliance of Biointegrity law suite. You can find them
18 on their website, although many of you may have your own
19 file copies already.

20 It looks an awful lot like the process of easy
21 approval for transgenic foods is driven more by political
22 influence than by science-based concern for human health or
23 the environment. Add to this the shoddy environmental
24 assessment work done with respect to transgenic virus-
25 resistant summer squash and with respect to butterfly- and

1 moth-killing transgenic bT crops, and the regulatory
2 framework for assessing transgenic crops and foods looks
3 incredibly weak.

4 Yet the FDA refuses, to this point, to mandate
5 labeling so that consumers can choose to be cautious when
6 their government won't be. This has to change. We need
7 mandatory labeling of all products that contain transgenic
8 ingredients.

9 MR. LAKE: Thank you, sir.

10 MS. McCULLUM: My name is Christy McCullum. I am
11 a doctoral candidate at Cornell University. This statement
12 has been prepared by Rodney Leonard, Executive Director of
13 Community Nutrition Institute and myself representing the
14 Institute for Agriculture and Trade Policy, Defenders of
15 Wildlife and CNI.

16 In 1992, FDA introduced substantial equivalence as
17 a regulatory device to permit genetically modified
18 ingredients to be substituted in foods for conventional
19 ingredients. This concept's validity as a basis for public-
20 health policy is now being questioned.

21 Consumers in Europe, Japan, Korea and elsewhere do
22 not accept the concept of substantial equivalence and,
23 therefore, will not accept foods with genetically modified
24 ingredients. Furthermore, European governments are
25 requiring labeling on all foods with genetically modified

1 ingredients.

2 The uproar in Europe and elsewhere over current
3 U.S. regulatory policy has caused substantial losses of
4 export markets for U.S. foods and food commodities. Thus,
5 mandatory labeling of all foods containing GM ingredients is
6 needed to prevent further damage to U.S. farmers.

7 The current practice and risk assessment defined
8 by FDA as a precautionary approach evaluates harm on a case-
9 by-case basis. This approach is based on a process of
10 linear analysis and reductionism.

11 Instead, the FDA needs to adopt a precautionary
12 principle as its guiding safeguard in public health. The
13 precautionary principle is based on nonlinear analysis.
14 Risks occur in complex systems from feedback, looping and
15 other nonlinear conditions. Harm in these systems is
16 inherently uncertain, unpredictable and can be examined only
17 through nonlinear analysis.

18 We invite FDA to insure public participation in
19 how to avoid future errors starting with citizen panels and
20 hearings on the precautionary principle as a regulatory
21 framework for a new FDA.

22 Thank you.

23 MR. LAKE: Thank you, ma'am.

24 MR. ABBOTT: Good afternoon. My name is David
25 Abbott. I am Past President of Purina Mills, Incorporated,

1 St. Louis, Missouri. I currently serve as Chairman of the
2 American Feed Industry Association.

3 Food safety and consumer confidence are top
4 priorities for my company as well as the feed industry. We
5 support sound science-based food-production systems. We
6 support government regulations that protect public health
7 and also enhance food production. We strongly oppose any
8 regulation based upon theoretical risk.

9 The use of genetically enhanced ingredients in
10 human and animal foods is rife for benefit analysis. The
11 promises of biotechnology are well-known. Most risks
12 associated with the science are largely speculative. The
13 great benefits of biotechnology must not be lost because of
14 relatively minor concerns.

15 We have excellent systems in place and working to
16 protect the safety of our food. FDA's feed-additive
17 approval guidelines provide for removal of unknown allergens
18 that may evolve. New test methods are becoming widely
19 available.

20 The voluntary industry-agency consultations are
21 successful. To mandate consultations would waste federal
22 and private funds, manpower and time. AFIA strongly
23 supports the current federal labeling policy. There is no
24 logical reason to label based upon a process or a production
25 practice if the information is of no value to the consumer.

1 We must educate consumers about the technology
2 that will transform and insure the safety of their food.
3 FDA can't be the industry's cheerleader but it can explain
4 the success of its consultation and review system that
5 assures the continued safe use of genetically enhanced foods
6 and feeds.

7 Consumers need facts, not fairy tales or horror
8 stories.

9 Thank you.

10 MR. LAKE: Thank you, sir.

11 DR. HAEGLEN: I am John Haeglen, nuclear physicist
12 and presidential candidate for American's fastest growing
13 political party, the Natural Law Party.

14 As a scientist, I am deeply concerned about the
15 genetic manipulation of food. I am concerned about the
16 health and environmental risks of this radical technology
17 which manipulates life at its foundation. The possibility
18 of unanticipated allergic and toxic reactions is already
19 well documented.

20 Even the FDA's own staff scientists have warned of
21 "the possibility of high concentrations of plant toxicants
22 in these experimental foods." And, of course, the
23 environmental risks from these experimental crops are
24 incalculable from the gene pollution that results from
25 breaking down genetic barriers put in place by nature.

1 Yet, our government has helped slip these foods
2 onto our grocery-store shelves without safety testing and
3 with no labeling. As a nuclear physicist, I have seen,
4 first-hand, the results of the hasty commercialization of
5 nuclear technologies that have threatened mankind with
6 extinction.

7 I am similarly concerned that short-term financial
8 interests of a few biotech firms are guarding the
9 commercialization of these equally dangerous genetic
10 technologies. Genetically engineered crops have not
11 fulfilled their promises of higher yields or environmental
12 benefits.

13 Since molecular biologists are, themselves, deeply
14 divided about the safety of these foods, there is no
15 scientific basis for the government's assurances that the
16 risks are minimal. That is why I have helped draft
17 legislation calling for mandatory labeling and safety
18 testing.

19 That is why thousands of Natural Law Party
20 candidates across the country will challenge their
21 incumbents on televised debates as to where they stand on
22 this crucial labeling legislation. It is time our
23 government fulfilled its responsibility to put the safety of
24 the American people first instead of serving as apologists
25 to the biotech industry.

1 MR. LAKE: Thank you, sir.

2 MR. GREEN: Hi. My name is Joey Green. I am an
3 intern organic farmer. I just came back from a six-month
4 hiatus in Austria. I can tell you that the Europeans will
5 not accept this technology.

6 I look around this room today and I feel like I am
7 not at a public comment hearing, I am at a lobbyist hearing.
8 It is all suits. It is all money. It is all special
9 interests. I am really appalled at this entire seminar.

10 I have been hearing all day there are no studies.
11 There is a Cornell study, the Monarch butterfly study.
12 There is a study by Dr. Putzai with the rats and the
13 transgenic potatoes. There is a study that is going on in
14 Norway by Dr. Terje Traavik documenting horizontal gene
15 transfer which we are not talking about here today. It is
16 available in English, if you want to read it.

17 Green lacewings and other beneficial insects are
18 dying in a Swiss report. At NYU, they did a study and they
19 found out that bT toxins don't deteriorate in two or three
20 or four or five days. Sometimes, they stay in the soil for
21 eight months killing all kinds of microbial and beneficial
22 insects.

23 This information I have heard today here is just
24 disheartening. We have been bought. Calvin Coolidge was
25 right. The business of government is business and that is

1 what is going on in this room today, and that is what is
2 going on in America.

3 Let me tell you something; Europe is not going to
4 accept this and, eventually, Europe's will, Europe's
5 political momentum, is going to sweep over this country and
6 this stuff is going to be gone. I don't want it labeled. I
7 want this stuff out of here.

8 MR. LAKE: Thank you, sir.

9 MS. ARNOLD: My name is Charlotte Arnold and I am
10 Policy Director with the International Center for Technology
11 Assessment. While labeling is an important issue, the
12 larger issue is that these foods have not been proven safe.
13 The agency has a legal duty not to allow genetically
14 engineered foods onto the market without safety testing.

15 FDA bureaucrats say that genetically engineered
16 foods are substantially equivalent to conventionally
17 produced foods. But agency scientists disagree saying that
18 genetic engineering creates new proteins that must be safety
19 tested. FDA bureaucrats say that genetically engineered
20 ingredients are generally recognized as safe, but FDA
21 scientists say these foods pose health threats.

22 These include: toxicity, by increasing levels of
23 existing toxicants and creating new toxicants; allergic
24 reactions, by creating new allergens and synthesizing
25 existing allergens; antibiotic resistance--people who eat

1 genetically engineered foods may become more susceptible to
2 bacterial infections; cancer--genetically engineered
3 hormones may increase the risk of breast cancer, colon
4 cancer and prostate cancer.

5 Immune suppression--tests linking genetically
6 engineered foods to immune suppression have been validated
7 by peer review. All of the scientific evidence reinforces
8 that these foods are not safe. Labeling is not a panacea.
9 You have a legal duty to insure that genetically engineered
10 foods are safe before they are put on the market.

11 FDA should be protecting consumers and not big
12 business.

13 MR. LAKE: Thank you, ma'am.

14 DR. HANSEN: Hi. My name is Michael Hansen from
15 Consumer's Union, the publisher of Consumer Reports. We
16 urge FDA to require mandatory safety assessments and
17 mandatory labeling of all genetically engineered foods in
18 order to assure safety. One reason is allergenicity. Becky
19 Goldberg, this morning, talked about allergenicity.

20 We agree with what she said. Pioneer did the
21 right thing. However, there will be companies that do not
22 act as responsibly as Pioneer did. Consider the Delcon
23 Shield IUD, the Shiley heart valve, asbestos and PCBs. FDA
24 must develop a detailed mandatory protocol for assessing
25 allergens.

1 Common known allergens present a new and
2 unnecessary risk in the food supply and should be
3 prohibited. Genetic engineering can also introduce new
4 toxins or increase natural toxins that are already present
5 in plants. Internal FDA memos recently made public show
6 that when the FDA was developing its current industry self-
7 regulatory proposals, staff from the Center for Veterinary
8 Medicine recommended FDA review of all genetically
9 engineered foods for potential toxicity problems, but they
10 were overruled.

11 The FDA says there is a vanishingly small risk
12 that antibiotic-resistance marker genes in genetically
13 engineered food will be transferred to disease-causing
14 bacteria. However, other experts, including the British
15 Medical Association, recommend a ban on the use of these
16 genes in GE foods, as does Consumers Union.

17 We commend the agency for its policy of mandatory
18 review of genetically engineered fish and animals as new
19 animal drugs. We urge FDA to be consistent and to adopt a
20 similar review for engineered plants. In sum, current FDA
21 policy is fundamentally flawed because it trusts that the
22 industry, domestic and foreign, will do the proper safety
23 assessments in testing to insure safety.

24 But, to assure safety, the public needs FDA to
25 require review and labeling of all genetically engineered

1 foods.

2 MR. LAKE:

3 MR. LAKE: Thank you, sir.

4 DR. VIDAVER: I am Ann Vidaver commenting on
5 behalf of the American Society for Microbiology. The ASM
6 commends FDA and concurs that its policy on bioengineered
7 foods provides safe foods, that the policy is scientifically
8 warranted and is reasonable and appropriate.

9 There are clear potential benefits to consumers
10 for products such as naturally decaffeinated coffee,
11 mycotoxin-free corn and allergen-free peanuts. Some of the
12 benefits of biotechnology, including improving our food
13 supply, can be seen on an ASM-sponsored PBS program Creators
14 of the Future to be shown tonight on public T.V. at
15 8:00 p.m.

16 The products of bioengineering, their composition,
17 nutrient value and safety should be the focus of FDA and not
18 the process by which they are made. Specifically, first,
19 ASM believes the FDA process is sound and has provided safe
20 products. Mandatory consultation by marketers may be
21 prudent and reassuring to the public.

22 Second, the ASM is not aware of new safety
23 information issues or tests for bioengineered foods
24 different than for foods currently tested according to FDA
25 guidelines. Third, future food products derived from

1 bioengineered plants include foods with altered composition
2 in oils, vitamins, antioxidants and minerals, an allergen
3 decrease or removal.

4 Safety issues raised by these foods are no
5 different in kind than those that have been developed over
6 nearly a century of testing. Regarding public information,
7 the ASM believes labeling should be based on significant
8 alterations in the composition of food rather than process.

9 Secondly, the ASM supports science education
10 efforts. The FDA, USDA and EPA should coordinate providing
11 information on policies and practices about bioengineered
12 foods relative to non-engineered foods.

13 Lastly, additional information can be made
14 available through 800 numbers, websites, leaflets and
15 various media. The American Society for Microbiology has a
16 full statement available.

17 MR. LAKE: Thank you, ma'am.

18 MR. JACOBSON: Hello. My name is Andrew Jacobson.
19 I am the President of the Natural Food Division of the Hain
20 Food Group. We are the largest supplier of natural and
21 organic foods to the organic products industry.

22 Obviously, food safety is the number-one concern
23 of all of us here. For the sake of our comment, though, we
24 would like to deal with the segregation of raw materials.

25 As a supplier and a manufacturer, we would like to have the

1 ability to buy non-GMO or GMO raw materials and process them
2 into finished goods as we see fit.

3 We also would like to start the process and ask
4 FDA to support regulation for that which will evolve into a
5 mandatory labeling requirement. We feel that consumers
6 should have the right to know what is in their products.
7 Labels should be representative of the ingredients that are
8 on them.

9 It is difficult today to get clean or good-lineage
10 products. We go to extensive testing. We try to use the
11 best ingredients but, again, we are not here to argue the
12 science. We just would like to get the segregation of the
13 raw materials while the debate goes on before it becomes
14 harder and harder to separate the materials that have been
15 put together.

16 Thank you for your time.

17 MR. LAKE: Thank you, sir.

18 MR. YODER: Good afternoon. My name is Fred
19 Yoder. I grow corn, soybeans and wheat in Plains City, Ohio
20 and am currently serving as a member of the Board of
21 Directors of the National Cornrowers Association
22 representing more than 30,000 farmers nationwide.

23 As you may know, approximately one-third of this
24 country's 72.6 million acres of corn were planted in the
25 biotech this past year. Consequently, corn farmers have a

1 tremendous stake in this new technology. Farmers are very
2 adept in dealing with the every-day uncertainties of the
3 business. However, it is excessive to expect farmers to
4 deal with the recent issues emerging around the issue of
5 biotechnology.

6 Simply, this country's producers now worry if
7 there will even be a market for the crop they are going to
8 produce. I have grown both corn and soybeans in biotech the
9 last two years. I am very comfortable with both the science
10 and the safety behind this technology. However, my
11 confidence in the products and my stewardship of the
12 technology will not insure consumer confidence in the
13 science.

14 The food safety determinations of the FDA are
15 critically important in this process. It is imperative that
16 the scientific assurances of safety come from the FDA and
17 other trusted regulators. The National Cornrowers
18 Association feels that the current science-based regulations
19 and processes being used by the FDA is vitally important to
20 assuring consumers of the safety of these products.

21 It has become clear that there are consumer
22 concerns. These concerns stem from a lack of understanding
23 of both the technology and the process of approval. To
24 insure the marketability of both biotech corn and to insure
25 our markets, the food products must not only be safe, but

1 the consumer must be assured that they are safe, also.

2 This role, the one of educating consumers, in one
3 of the critical ones and one that must be played by the FDA
4 and its team of experts. We join the FDA in the hopes that
5 these hearings lead to greater confidence for everyone. It
6 is only with greater awareness and confidence that these
7 technologies can advance in all sectors and lead to more
8 opportunity for both consumers and producers.

9 Thank you very much.

10 MR. LAKE: Thank you, sir.

11 MR. MEDLEY: Good afternoon. My name is Terry
12 Medley. I have responsibility for biotech regulatory
13 affairs at Dupont Nutrition and Health. I am delighted to
14 be here speaking today on behalf of Dupont. Dupont is a
15 science company dedicated to delivering science-based
16 solutions that make a difference in people's lives.

17 I would like to echo the comments of Director
18 Levitt this morning that we must do a better job of
19 engaging, listening to and addressing the questions, even
20 demands, of all stakeholders in this global debate.
21 Listening implies engagement and respect that requires
22 initiative, patience and the willingness to build
23 relationships that will provide a point of view and
24 perspective that may the counter to our own.

25 This is one reason I am happy to be here today.

1 Dupont concurs with and compliments FDA on this initiate to
2 hold public meetings to discuss the agency's oversight of
3 foods arrived through biotechnology. This type of
4 regulatory transparency and solicitation of public input is
5 critical.

6 We must support and adhere, and we support and
7 adhere, to the transparent and the comprehensive oversight
8 system of the U.S. government in regulating this technology.
9 We believe the U.S. regulatory framework has provided
10 American with an abundant, safe and affordable food supply.

11 FDA's statement on policies derived through new
12 plant varieties provides Dupont with guidance oversight
13 necessary to insure that we produce safe products. We are
14 committed to insuring safe and high-quality supply to the
15 world's consumers.

16 We urge the FDA to continue their efforts to
17 communicate their role in overseeing how new food and feeds
18 are introduced into the marketplace in order for consumers
19 to maintain confidence in that process as well.

20 Promises of biotechnology are great. As with all
21 new technologies, people want it done safely, ethically and
22 responsibly. We want the same.

23 MR. LAKE: Thank you, sir.

24 MR. DEBUS: My name is Tim Debus with the United
25 Fresh Fruit and Vegetable Association. We represent the

1 interests of producers and distributors of fresh produce.
2 We believe that mandatory labeling of food should be
3 reserved to communicate health information that consumers
4 must know, not interesting information that some consumers
5 might want to know.

6 We also believe in a consumer's right to know.
7 Everyone has the right to ask grocery stores and food
8 manufacturers anything about their product. If you cannot
9 get an answer to your satisfaction, then buy it from someone
10 who can answer you. That is consumer choice in a free
11 market and it does not require mandatory labeling.

12 Most Americans are not aware that eating at least
13 five servings of fruits and vegetables each day improves
14 health. If labeling is intended to provide consumers will
15 useful information for their health, then shouldn't our
16 priority be to inform the public about nutritious eating
17 habits rather than to segregate safe and equivalent foods
18 derived from biotechnology.

19 Instead of labeling for nucleotides, DNA and
20 genetic transformation, consumer health would be better
21 served by labeling for antioxidants, phytochemicals and five
22 servings a day. The benefit of labeling unchanged foods
23 should be viewed as inconsequential compared to the value of
24 informing consumers about the real public-health risk from
25 poor nutrition.

1 We believe FDA's current regulations and labeling
2 policy on biotechnology provide the necessary oversight to
3 balance the timely access to new technology and the
4 affirmation of safe food. We support FDA's commitment to
5 consumer safety and confidence, the reasonable policies
6 based on knowledge and experience.

7 We applaud FDA for the courage to continue to do
8 what is right. Let us maintain an open and constructive
9 dialogue on biotechnology but let us be mindful of our
10 priority to provide labeling on topics that matter most to
11 consumers, useful information for their health.

12 Thank you.

13 MR. LAKE: Thank you, sir.

14 DR. JAMES: My name is Clive James, Chairman of
15 ISAAA, a not-for-profit organization based at Cornell
16 University. Global acreage of genetically modified crops
17 increased from 5 million acres in '96 to 100 million acres
18 in '99. The top four countries are the U.S., Argentina,
19 Canada and China with the U.S. grown 72 percent of global
20 acreage and China assigned a very high priority to
21 biotechnology.

22 Global food security is a formidable challenge.
23 In the next 50 years, we must at least double crop
24 production on the same area of land. Conventional
25 technology alone will not allow us to double food

1 production. A combined strategy of conventional technology
2 and biotechnology offers the best probability of success.

3 The most compelling for biotechnology is its
4 potential contribution to global food security and the
5 alleviation of hunger in the third world where 840 million
6 people suffer from malnutrition today. ISAAA is a not-for-
7 profit organization established to alleviate hunger in the
8 Third World by facilitating the safe and responsible
9 transfer of crop biotech applications.

10 U.S. organizations are featured prominently in
11 ISAAA projects by generously donating technologies and
12 training young scientists from the Third World. The U.S. is
13 a world leader in crop biotechnology. It is important that
14 the U.S. maintain this commitment to GM crops.

15 In the absence of continued U.S. leadership,
16 developing countries would be denied the opportunity to
17 source U.S. technologies in their quest for food security
18 and condemn up to a billion people in the Third World to
19 unnecessary and unacceptable suffering from malnutrition,
20 hunger and poverty.

21 Thank you.

22 MR. LAKE: Thank you, sir.

23 DR. TOLIN: My name is Sue Tolin. I am
24 representing the American Phytopathological Society as a
25 member of their National Plant Pathology Board. The 5,000

1 members of APS study diseases of plants worldwide. We view
2 biotechnology and genetic engineering as an additional and
3 an essential tool in our constant battle to protect plants
4 from harmful microorganisms and produce a safe and
5 sustainable food supply.

6 APS believes the FDA consultation process has
7 achieved its intended purpose by initiating a science-based
8 review of recognizable risks; namely, toxicity,
9 allergenicity and nutritional composition. These were the
10 traits that could be started with in this review.

11 The FDA process should be continued but be
12 flexible and reactive to new scientific issues. A sunset
13 might be considered for specific cases of familiarity with
14 specific crops and traits. The FDA should make their
15 decisions in an open and transparent manner and focus on the
16 safety of food products.

17 We urge, also, cooperating with USDA, EPA as well
18 as plant sciences in the research community. We know of no
19 specific test that could be used exclusively to provide
20 greater assurance that food products from bioengineered
21 plants are safe to consume.

22 The APS recognizes the many potential benefits of
23 engineered crops and is particularly interested in crops
24 engineered to resist plant pathogens that are now currently
25 reaching the market. We realize that some new issues may

1 arise from the genetic constructs that are used but we will
2 quite willingly cooperate with FDA in the dialogue.

3 We believe that the policy of requiring labeling
4 only for significant changes should be maintained and we
5 urge that any label be informative and complete.

6 Thank you.

7 MR. LAKE: Thank you, ma'am.

8 MS. DAVIS: Good afternoon, or should I say
9 evening. I am Susan Davis. I am a registered dietician
10 speaking on behalf of myself. I am from the great state of
11 Maine and delighted to be in Washington.

12 Basically what I do is translate science into
13 useful information for consumers so they can make informed
14 food choices. Today, it seems like I spend an awful lot of
15 time clearing up consumer confusion. The current debate
16 among consumer groups who oppose biotech foods, researchers
17 and companies who are involved in this technology is
18 bringing consumer confusion to a new level.

19 The "he says, she says" arguments currently
20 embellished in the press don't serve the public. I
21 encourage an effective, comprehensive consumer-education
22 campaign using a balanced approach based on sound science.
23 Labeling of all biotech foods won't accomplish this. It
24 will further confuse consumers.

25 It is an oversimplified approach to a complex

1 technology that only education can help solve. All foods
2 containing biotech ingredients are not alike. Again, this
3 will just further confuse consumers.

4 In addition, most consumers are confident in the
5 oversight that is provided by the current regulatory
6 agencies. I would like to support the current FDA labeling
7 laws that identify those foods that are substantially
8 different or contain allergens. Those who wish to avoid
9 biotech foods can do so by choosing organic foods, which are
10 plentiful throughout the United States.

11 I would also like to comment that the biotech
12 foods that are currently available do have a tremendous
13 benefit to the consumer. These are in the area of the
14 environment. Any technology that reduces herbicides,
15 pesticides, fungicides should be applauded.

16 Thank you very much.

17 MR. LAKE: Thank you, ma'am.

18 MR. GRAY: Good afternoon. My name is Robert
19 Gray. I am representing the Organic Trade Association. The
20 FDA should label foods containing genetically engineered
21 organisms or their products because Americans want to know
22 what we eat and we have a right to that knowledge.

23 There are a variety of concerns about our food.
24 Some people want food that is grown in an ecologically
25 healthy way, others food that is prepared according to

1 religious principles and still others food that does not
2 contain animal products.

3 As proper scientific studies began to be made,
4 those that are both longitudinal and objective, we will
5 learn more about both the health and ecological effects of
6 this infant and radially different technology. But we must
7 act in the meantime.

8 The public interest lies in more knowledge, not
9 less. The businesses creating genetically engineered
10 product are free to make their claims but these claims
11 cannot be taken as proof of anything. Any unintended side
12 effects of these new organisms must be discovered and
13 obviated.

14 Until a full, independent testing program is
15 completed, the public interest is not served by denying the
16 public the choice of eating non-genetically engineered food.
17 This is especially important for the organic industry. We
18 have taken great care to offer our customers a quality
19 product without the use of synthetic processing materials or
20 ingredients.

21 Now we are faced with not only the problem with
22 contamination in the field, more fundamentally, even the
23 inability to choose non-genetically engineered minor
24 ingredients because they are not labeled. The burden of
25 labeling should not be on the producer of conventional or

1 organic food. They are not the ones introducing this new
2 technology.

3 The burden should be on the companies seeking to
4 market these new products. Our consumers eat \$5 billion
5 worth of organic food annually and have already made the
6 choice of what they want to eat.

7 Thank you very much.

8 MR. LAKE: Thank you, sir.

9 DR. DONALDSON: Hello. I am Robert Donaldson. I
10 am a plant scientist and Professor and Chair of the
11 Department of Biological Sciences at George Washington
12 University. My remarks or provided on behalf of myself and
13 the American Society of Plant Physiologists, a non-profit
14 society of 5,000 plant scientists.

15 We feel that the safety record of the FDA in this
16 area demonstrates that the agency is meeting its goal to
17 assure the safety of foods modified using biotechnological
18 techniques. We believe that the use of biotechnology to
19 transfer one or a few known genes can be safer and more
20 predictable than traditional breeding techniques which
21 transfer hundreds of sometimes unknown and sometimes harmful
22 genes.

23 Some of the most spectacular benefits of plant
24 biotechnology will offer to consumers will be the
25 development of more nutritional and safer foods. Food

1 allergens in wheat and milk products are being eliminated in
2 the laboratory by researchers using biotechnology.

3 Biotechnology is being used to develop high-
4 quality protein corn to battle protein deficiencies in
5 people's diets. Rice with higher levels of Vitamin A and
6 higher amounts of usable iron are being developed using
7 biotechnology.

8 Research using biotechnology to enhance the levels
9 of Vitamin E and other vitamins in food crops could help
10 prevent heart disease, Alzheimer's and cancers. Genetically
11 engineered offers powerful tools to improve the nutritional
12 content of food crops and, therefore, improve the health of
13 millions of people worldwide.

14 Plant scientists are modifying plants for use as
15 vaccines that may prevent deadly illnesses such as diarrhea,
16 cholera, hepatitis B and malaria. Clearly, plant
17 biotechnology offers profound benefits to people worldwide
18 and I feel that we owe the world our technology.

19 The FDA should continue to vigorously regulate
20 modified products in all food for their safety.

21 MR. LAKE: Thank you, sir.

22 MR. SCHMIDT: I am Dave Schmidt with the
23 International Food Information Council. The vast majority
24 of Americans support the current FDA labeling policy for
25 foods produced through biotechnology. Surveys commissioned

1 by the International Food Information Council and conducted
2 by the Worthlin Group from March, 1997 to October, 1999
3 indicate two-thirds to three-quarters of consumers find the
4 policy rational when it is explained to them.

5 Further research conducted among both Canadian and
6 U.S. consumers finds that most terms and jargon that have
7 been proposed for biotech labels worldwide would not be
8 understood and would provide unwarranted negative
9 connotations.

10 We should do everything we can to provide as much
11 information as possible to consumers who want that
12 information. In fact, in our October survey, four out of
13 five consumers agree it would be better to provide such
14 information off the label on websites, brochures and
15 telephone hot lines from credible government health
16 professional or academic sources.

17 Precious food-label real estate should be reserved
18 for vital health and safety information, not for social
19 statements. Regulators throughout the world, as well as
20 American consumers, are looking to the FDA to maintain its
21 science-based "food safety first" rational food-labeling
22 policy.

23 In order for consumers from Boston to Beijing to
24 realize the full promise of agricultural biotechnology, it
25 is important for FDA to provide steady leadership and resist

1 the cries to remove science and safety as the foundation of
2 food biotech regulation.

3 Thank you.

4 MR. LAKE: Thank you, sir.

5 MS. FRANCES: Good evening. My name is Valerie
6 Frances and I am speaking to you as a citizen. I have
7 worked nearly fifteen years as a public-health nutritionist
8 working in hunger, community food security and sustainable
9 agriculture. Fundamentally, I am here before you because I
10 feel betrayed as a citizen by the U.S. government and the
11 major biotech companies.

12 I am grateful that these public hearings are being
13 held but I truly wonder whether anything substantive will
14 come from them. It seems to me that we are embarking on a
15 dangerous path from which we cannot return and the
16 government is making a grave error in judgment by not
17 exercising more prudence.

18 Given the history of repeated assurances by the
19 government and corporations and a long list of technologies
20 such as pesticides, antibiotics or RbGH that were all
21 declared safe based on research and then to find out, a few
22 years later, that crucial evidence was not evaluated
23 properly or even suppressed and now are shown to be unsafe.

24 I have come to have little or not confidence in
25 the government's ability to exercise sound judgment in these

1 matters on its own. The bottom line is that we don't need
2 genetic engineering. This path primarily benefits those who
3 are reaping the profits. I do not appreciate being treated
4 as a guinea pig. It doesn't help farmers. I believe
5 genetic engineering violates nature and am deeply concerned
6 that we have no way of cleaning up any unintended
7 environmental catastrophes.

8 In addition, I feel using hungry people to justify
9 the use of GMOs to increase the profits of a few biotech
10 companies is emotional blackmail. Yes; I want to see
11 mandatory premarket testing. And, yes; I want mandatory
12 labeling. But what I really want is for us, as a country,
13 to embrace the vision of sustainable agriculture and
14 community food security.

15 Instead of channeling vast resources trying to
16 prove the safety of a questionable technology, let's take
17 the higher road and support on-the-farm community and
18 market-based research and education towards broadly
19 beneficial and life-affirming practices from the microscopic
20 to the human community level.

21 MR. LAKE: Thank you, ma'am.

22 MR. FREESE: My name is Bill Freese. Remember
23 the time when electricity was going to be too cheap to
24 meter, back in the 50's when federal officials assured us
25 that nuclear energy was safe, cheap and, above all,

1 inevitable?

2 Something similar is going on today with genetic
3 engineering. Like the Atomic Energy Commission of the 50's,
4 the FDA has taken on the contradictory roles of booster and
5 regulator of a dangerous new technology. Like the
6 government boosters of nuclear energy then, FDA officials
7 presume absolute knowledge they don't have and treat critics
8 with barely concealed arrogance and contempt irrationally
9 convinced that the only possible future is a genetically
10 engineered one.

11 For many in the FDA, genetic engineering appears
12 to be more religion than science. How else can one explain
13 the FDA's mystical dogma of substantial equivalence. This
14 is the notion that a novel life form created by gene
15 splicing to unrelated species is equivalent to its natural
16 precursor.

17 Why is it that such a novel creation can be
18 patented as a new invention but is, nevertheless, deemed the
19 same as its parent for regulatory purposes. Could this be
20 to spare its corporate creator the time and expense of
21 thorough testing to insure its safety?

22 This suspicion is born out by the FDA's outrageous
23 approval of Monsanto's bovine growth hormone, a drug banned
24 in Canada and the EU. Three former Monsanto employees or
25 contractors were hired by the FDA to rush BGH through the

1 approval process, a clear case of corruption.

2 The FDA fired Richard Burroughs, its point man on
3 BGH, for insisting on adequate safety testing because he
4 care more about protecting human health than corporate
5 profits. The made rush to exploit nuclear energy has caused
6 untold suffering and left a toxic legacy for future
7 generations.

8 Genetic pollution could have comparable,
9 irreversible effects. I urge the FDA to institute thorough
10 and mandatory premarket safety testing and labeling of all
11 new GE foods.

12 Thank you.

13 MR. LAKE: Thank you, sir.

14 DR. WOOTON: I am Dr. Percy Wooton from Richmond,
15 Virginia. I served as President of the American Medical
16 Association in 1997 and 1998. As a Past President of the
17 American Medical Association and as an internist who
18 specializes in cardiovascular disease and as a physician who
19 has seen thousands of patients in Virginia and the D.C.
20 area, I know humanity stands to inherit tremendous value
21 from biotechnology.

22 Biotechnology creates tools. In my career, I have
23 seen it give physicians the ability to save lives through
24 the advent of drugs and medical devices which did not exist
25 ten, twenty and thirty years ago. Currently, food

1 biotechnology is a tool that helps farms get more crops off
2 an acre of land than they did five years ago.

3 It also lets them use less fertilizer and less
4 pesticides. These tools benefit the environment, our food
5 supply and every consumer concerned with healthful food
6 production. In time, food biotechnology may enhance a
7 physician's ability to use food to improve a patient's
8 health.

9 Very soon, food manufacturers will stock shelves
10 with cooking oils containing less-saturated fats as well as
11 vegetables and fruits enriched with antioxidants. These
12 benefits will help people to control their weight and
13 expedite their ability to recover from illnesses.

14 If we abandon this technology because of what
15 might go wrong, these valuable tools will never make it into
16 the hands of physicians or their patients. I am here today
17 because I believe in the spirit of the AMA's position which
18 encourages physicians to be public spokespersons for
19 technologies that they feel will benefit the public.

20 My endorsement of biotechnology is built on my
21 faith in the FDA's existing review process. I know they
22 have established a system for evaluating foods produced
23 through biotechnology that has served us well and I support
24 its continence.

25 Thank you.

1 MR. LAKE: Thank you, sir.

2 DR. MESSING: My name is Joachim Messing. I
3 am Professor at Rutgers University and quite familiar with
4 plant biotechnology and I will speak here on behalf of
5 myself and my opinion, listening all day to the panels and
6 the different comments that have been made. You see I have
7 no written statement because many of the things that I could
8 have written down have been said.

9 My major concern is about this forum, that it
10 doesn't really help the public the understand the background
11 of the science. Recently, when I was in Europe, I
12 encountered a survey where people answered questions where
13 they would say, "only genetically altered tomatoes have
14 genes." And, "If you eat genetically altered foods, your
15 own genes get changed."

16 I think what is very important is that the forum
17 has to be followed up in coordination with the USDA to have
18 a more direct program in public education where the public
19 is really educated in the basics of the science that is
20 behind this new technology.

21 Thank you very much.

22 MR. LAKE: Thank you, sir.

23 MR. RIDDLE: Hello. My name is Jim Riddle, a
24 Founding President of the Independent Organic Inspectors
25 Association. To refuse to label GMO products fuels the

1 perception that the biotech industry has something to hide.

2 Transgenic mutations do not occur in nature.

3 GMO products are unique and can be patented. They
4 are not substantially equivalent. Transgenic crops have
5 never been part of the food chain or the human diet. They
6 must be recalled. Research shows that milk from cows
7 treated with RBST contains elevated levels of insulin-like
8 growth factor, IgF1. Elevated levels of IgF1 in humans has
9 been linked to increased incidence in breast, prostate and
10 colon cancer.

11 Milk from RBST-treated cows is not substantially equivalent.

12 Syndicated columnist Alan Guebert recently
13 reported that cows in South Dakota, when given a choice
14 between conventional corn fodder and bT corn fodder refused
15 to eat the bT corn fodder. This same phenomenon has been
16 reported to me by numerous organic inspectors. It seems
17 even though the bT corn fodder is not labeled, cows know
18 that it is not substantially equivalent.

19 Research in Great Britain shows that incidences of
20 allergic reactions to soy foods have increased at the same
21 time that GMO soybeans have been introduced. Sound science
22 shows that GMOs pose numerous environmental threats
23 including cross pollination with wild relatives to create
24 superweeds, long-term alterations to soil ecology, negative
25 impacts on non-target species and development of pesticide-

1 resistant pests.

2 There is scandalous collusion between the biotech
3 industry and the crossover to the regulators that must be
4 investigated before you can move forward with a clear
5 conscience. This technology must be tracked, labeled in the
6 short term and phased out in the long term.

7 Thank you.

8 MR. LAKE: Thank you, sir.

9 MR. BETZ: My name is Fred Betz. As a scientist
10 with the Environmental Protection Agency from 1976 to 1993,
11 I was directly involved in the development and
12 implementation of the coordinated framework for the
13 regulation of biotechnology that was published in June of
14 1986. During that time, I had the opportunity to work with
15 FDA staff as well as their critics on the review and
16 approval of biotechnology products subject to FDA and EPA
17 regulations.

18 Since then, I have been a regulatory consultant
19 advising developers of biotechnology products on regulatory
20 matters. It is from that perspective and body of experience
21 that I conclude that FDA has set forth a scientifically
22 sound and credible scheme for the regulation of foods
23 derived from genetically engineered crops.

24 The FDA's regulatory of bioengineered foods is
25 founded in a strong statute, the Federal Food, Drug and

1 Cosmetic Act. This statute has helped insure that the U.S.
2 food supply is among the world's safest, irrespective of how
3 the food has been produced.

4 FDA's 1992 policy embodies an important guiding
5 principle of regulatory science and public policy. This
6 principle is that the level of regulation should be
7 commensurate with the potential risks posed by the use of
8 the product. With this in mind, FDA has established an
9 appropriate, balanced, science-based regulatory scheme to
10 oversee the introduction of new plant varieties developed
11 through biotechnology.

12 However, this policy does not stand alone.
13 Rather, it is just one tool within a strong regulatory
14 framework. Under FFDCA, FDA can seize and stop sale of any
15 food considered to be unsafe, can require labeling of foods
16 as necessary and can require that a food additive clearance
17 be established.

18 In conclusion, I believe that FDA's regulatory
19 scheme has performed well. By all available standards for
20 judgment, the scheme has helped protect public health and
21 insured the continued safety in the nation's food supply.

22 Thank you.

23 MR. LAKE: Thank you, sir.

24 MR. COUNCELL: My name is Phil Councill, Jr. I am
25 a grain and vegetable farmer and I currently serve as

1 President of the Maryland Grain Producers Association. I
2 appreciate the opportunity to discuss biotechnology from a
3 farmer's perspective.

4 Maryland farmers have accepted genetically
5 enhanced crops. In 1999, up to 65 percent of the soybeans
6 and over 35 percent of the corn grown uses this technology.
7 We have confidence that USDA, EPA and FDA's review and
8 approval process for these genetically enhanced crops means
9 they are safe.

10 But having farmers believe that these products are
11 safe is not the issue. It is extremely important to farmers
12 that the consumers of our products know that they are safe.
13 FDA needs to do whatever is necessary to maintain consumer
14 confidence.

15 Not only are biotech crops safe; they are
16 beneficial to the environment. These crops are as close to
17 organic farming as production agriculture can come while
18 maintaining reasonable yields to feed a growing population.
19 My surprise is that the environmental community has not
20 insisted on expanding the use of this new technology.

21 My final point, as you must realize, is that any
22 regulatory changes made today may impact the farmer's
23 ability to market his crop for the next three years. As a
24 commercial seed grower, the seed that I plant in the spring
25 of 2000 will continue in the production cycle and markets

1 through the fall of 2002.

2 As you make your decisions in the upcoming months,
3 I urge that you develop standards to maintain consumer
4 confidence, make decisions that consider the agricultural
5 production cycle and that you make your decisions based on
6 science and not emotion.

7 Important issues regarding labeling; I can
8 segregate crops but I cannot guarantee zero tolerance due to
9 equipment contamination, handling contamination and cross
10 pollination. I support voluntary labeling and invite the
11 decision makers within the FDA to come to my farm and see,
12 firsthand, the benefits and concerns we have about biotech.

13 Thank you.

14 MR. LAKE: Thank you, sir.

15 MR. HUTCHISON: Hello. My name is Robert
16 Hutchison. I am a grain, vegetable and hog farmer from
17 Cordova, Maryland and a member of the Maryland Grain
18 Producers Utilization Board.

19 As a Board, we seek to expand our markets in many
20 ways and believe that biotechnology is an important tool in
21 accomplishing this goal. We can use biotechnology to
22 harness the energy of the sun in many unique ways. We can
23 produce crops for more specialized markets and for improved
24 environmental protection.

25 The marketing opportunities are endless. However,

1 to move forward, biotechnology research must be encouraged.
2 Future products offer an abundance of opportunities for
3 farmers to maximize the production of renewable resources
4 from our productive soils.

5 I would like to emphasize the importance of this
6 decision you make now by providing you with an interesting
7 quote from the early 1900s. And I quote; "We have recently
8 advanced our knowledge of genetics to a point where we can
9 manipulate life in a way never intended by nature. We must
10 proceed with the utmost caution in the application of this
11 newfound knowledge."

12 This statement was made in 1906 by a critic of the
13 work of a California-based geneticist, Luther Burbank, who
14 was carrying out research on hybridization. Crop hybrids
15 were introduced to the United States in 1920s. Had we
16 stifled this important research of the early 1900s, we may
17 still be producing twenty-six bushel average corn yields as
18 opposed to the one-hundred-and-thirty bushels of today.

19 We cannot suppress progress through fear and
20 emotion. We must move forward with adequate research and
21 testing. The American farmer will grow what our customers
22 request. We can revert to standard varieties of a few years
23 ago, if that is necessary. But that decision should not be
24 based on unfounded consumer fears.

25 Thank you.

1 MR. LAKE: Thank you, sir.

2 DR. MONRO: Good evening. My name is Doug Monroe.
3 I am the President of the Calvert Institute for Policy
4 Research which is a public-policy organization in Baltimore,
5 Maryland that believes that policy should be based on
6 rationality and not hysteria.

7 As everyone in this room is well aware, at least
8 ought to be well aware, artificially engineered food stuffs
9 have been consumed for centuries either as the result of
10 selective cross breeding or, more recently, the result of
11 genetic engineering, and no one is known to have died as the
12 result of this.

13 Quite the reverse; biotech improvements to fruits
14 and vegetables have been a blessing. We have created a food
15 supply that is the envy of the world, as we all know; safe,
16 wholesome and cheap.

17 So my point is really as simple as it is cliched.
18 "If it ain't broke, don't fix it." Labeling is no small
19 matter. This is, perhaps, something that has been
20 overlooked this evening. If anyone doubts the potential
21 impact of labels, consider the repeated demands for bigger
22 and evermore damning health warnings on cigarettes and
23 alcohol.

24 Labels frighten people. That is the whole point.
25 Labels on biotech foods will have the same result. For what

1 point? Scientist after scientist from the National Academy
2 of Scientists, National Research Council and the FDA,
3 itself, have declared biotech foods to be safe.

4 If biotech foods are subjected to labeling, as
5 others have said before me, this may very well create a
6 backlash against them, against what has been ruled a safe
7 food source. What will happen is very simple. Increased
8 use of pesticides, which will result in another hearing this
9 time next year with the same crowd who have been outside
10 demanding similar taxpayer-funded hearings as this, or the
11 alternative is supermarkets' increased reliance on organic
12 foods which sounds fine until you think it through.

13 Undo bioengineering and you undo progress on
14 disease-resistant crops, high-yield crops and so on which
15 means, in the long run, the public's increased consumption
16 of macaroni and cheese instead of produce, and that is
17 something no government agency should be a part of and I beg
18 you not to be a part of it, too.

19 Thanks a lot.

20 MR. LAKE: Thank you, sir.

21 DR. GRAHAM: My name is John Graham. I am
22 Professor of Policy and Decision Sciences at the Harvard
23 School of Public Health and Director of the Harvard Center
24 for Risk Analysis. Today, I would like to discuss the role
25 of the so-called precautionary principle and FDA's policy

1 toward bioengineered foods.

2 We have heard today there may be unknown health
3 and safety risk associated with bioengineered foods and that
4 regulators should apply some version of the precautionary
5 principle to protect the public from these unknown risks. A
6 stringent version of the precautionary principle that we
7 have heard today is that FDA should not approve any
8 bioengineered food until it has been proven completely safe
9 with long-term testing.

10 In evaluating whether such an application of the
11 precautionary principle would be reasonable, I would urge
12 the FDA to consider the following thought experiment which I
13 often pose to my students in public health. Imagine it is
14 1850 in the United States. Which of the following
15 technological advances would have satisfied this particular
16 version of the precautionary principle; electricity, the
17 internal-combustion engine, pasteurization, computers,
18 chlorination of drinking water, plastics and the Internet?

19 Although each of these technologies did, and,
20 indeed, still do, pose unknown health and safety risks to
21 the American population, I think we should be skeptical of
22 any formulation of the precautionary principle that FDA
23 would implement that would have halted or substantially
24 slowed the development of these technologies.

25 On the other hand, if a more nuanced version of

1 the precautionary principle, one that allows for a balancing
2 of risk and benefits and some risk taking for the purposes
3 of the technological advance can be formulated, it certainly
4 deserves serious scrutiny.

5 I also want to set the record straight that there
6 is, in fact, no "the" precautionary principle. There are,
7 in fact, a variety of them in different international
8 treaties, with different burdens of proof and different
9 formulations.

10 Thank you very much.

11 MR. LAKE: Thank you, sir.

12 MS. MELCAREK: I am Hillary Melcarek with the
13 National Coalition against the Misuse of Pesticides, a
14 national membership organization founded in 1981 to provide
15 the public with information on pesticide hazards and save
16 our pest-management strategies.

17 The public experience with synthetic pesticides
18 since their introduction in mainstream agriculture in the
19 1940s raises important questions that ought to be considered
20 as new technologies are introduced in food production and
21 pest management.

22 The chemicalization of agriculture has led to
23 increased insect and weed resistance, no improvement in the
24 percentage of crop loss due to disease and infestation,
25 contamination of ground water, adverse impacts associated

1 with chemical drift as well as harmful human health and
2 environmental effects.

3 None of this was known to regulatory agencies when
4 the technology was introduced and marketed as a new
5 revolutionary way to feed the world. GMOs bring with them
6 questions that parallel and, in many ways, far surpass those
7 that have been raised with pesticides.

8 If we have learned anything from our regulatory
9 missteps in the pesticide arena, we have learned that there
10 are uncertainties and unanswered questions resulting in
11 hazards and efficacy problems.

12 As this technology increasingly fails us, we now
13 see many of the same companies that produced and promoted
14 pesticides shifting to the biotechnology industry telling
15 the public that this is a safer way.

16 We urge FDA to immediately require labeling of
17 genetically engineered food, commodities and processed food
18 containing GE ingredients and additionally require thorough
19 mandatory premarket human and environment safety reviews of
20 these products.

21 Thank you.

22 MR. LAKE: Thank you, ma'am.

23 MS. FERRERA: I have attended an FDA-NIH dental
24 conference on the 4th of November, 1999 at NIH. The
25 Commissioner of the FDA stated she wanted open and frequent

1 communication with industry when developing a new product.

2 I want to know where does the consumer fit with
3 genetically engineered food? Where is the frequent and open
4 communication with the consumer when developing genetically
5 engineered food. I find the industry and the FDA to be
6 arrogant and condescending to the consumer.

7 The genetically engineered food is not safe and it
8 should be banned immediately.

9 Thank you.

10 MR. LAKE: Thank you, ma'am.

11 DR. SCHONBACH: My name is Mark Schonbach. I am a
12 small-scale vegetable grower, crop scientist. I am speaking
13 on behalf of the Virginia Association for Biological
14 Farming. I ask the FDA to mandate clear and prominent
15 labeling of all genetically engineered foods sold within the
16 United States.

17 This includes any foods which contain one or more
18 ingredients derived from genetically engineered organisms.
19 Such foods need to carry a label on their package that
20 includes the words "genetically engineered" or "genetically
21 modified" or a symbol which clearly expresses this so that
22 citizens can make an informed choice as to whether or not to
23 consume genetically engineered foods.

24 This is true for several reasons. First, we have
25 a reasonable expectation to know what we are eating. In a

1 recent article in the journal Nature, Dr. Eric Millstone,
2 Eric Brunner and Sue Mayer pointed out that genetically
3 engineered foods are not substantially equivalent to
4 conventional foods.

5 Genetically modified foods have been substantially
6 altered in their biochemical and nutritional composition.
7 The potential health effects of these alterations are thus
8 far largely untested and unknown.

9 Second, there are preliminary findings that
10 indicate GE foods may pose substantial health hazards, as we
11 have heard earlier this evening. I will not go into those
12 in detail.

13 Third, some U.S. citizens adhere to religious
14 practices or ethical codes that forbid them to eat foods of
15 animal origins or foods that have been genetically
16 engineered. Failure to provide the information through
17 clear labeling makes it much more difficult for such
18 citizens to be sure that the food they are buying meets the
19 requirements of their religious codes.

20 This could constitute an infringement of their
21 constitutionally guaranteed freedom of religion. Fourth,
22 many genetically engineered crops, particularly those
23 containing the bacterial gene for bT toxin and those
24 engineered for herbicide resistance pose significant
25 environmental hazards.

1 Citizens have the freedom to choose not to buy
2 products whose manufacturer or use is harmful to the
3 environment such as strong household chemicals. Thus, it is
4 only logical that we should have the freedom to choose not
5 to consume foods from genetically engineered crops that pose
6 environment risks.

7 Thank you.

8 MR. LAKE: Thank you, sir.

9 MS. WELD: Hi. My name is Amory Weld. I am from
10 New York City. I am not comfortable being a public speaker
11 but I feel strongly enough about this issue that I am
12 willing to do this, and I apologize for however garbled my
13 message is.

14 I am here as an individual and as a concerned
15 citizen, as an informed consumer and as an aunt to ten
16 nieces and nephews. My friend, Guy Watson, is to blame for
17 my being involved with this issue. Guy Watson has the
18 largest organic farm in England. The English government
19 made the mistake of planting genetically engineered maize
20 across the river from his sweet corn, thereby threatening
21 the organic certification of his crop.

22 They awakened a sleeping activist. He said to me,
23 "You Yanks are responsible for most of the genetically
24 engineered foods out there. You, Amory, should get up and
25 do something about this." And he was absolutely right;

1 eating organic is not enough.

2 So I contacted Laura Ticciati, who is the head of
3 the Mothers for Natural Law which is based in Fairfield,
4 Iowa and have since taken her petition to the Green Market
5 in Union Square of New York City. The petition calls for
6 the mandatory labeling of genetically engineered crops and a
7 five-year moratorium until there has been long-term testing.

8 There is a marked difference in public response
9 between now and a year ago when I started. A year ago, it
10 was hard to get people to stop and talk to me and now people
11 line up to sign the petition. I wanted to stand here and
12 say, "Don't underestimate the American consumer."

13 A movement is growing here. All kinds of people
14 have stopped to sign. By that, I mean all ages, all races
15 and all backgrounds. I am not just preaching to the
16 converted there. People want more information and what they
17 ask for, more than anything, is a list of the genetically
18 engineered foods that exist now.

19 MR. LAKE: Thank you, ma'am. For a non-public
20 speaker, you did just fine.

21 MS. BEANY: My name is Diane Beany. I am an
22 organic and ecological advocate. I am also an avid label
23 reader. I am one of those people who don't want to eat any
24 products including animal genes, insect genes, virus or
25 bacterial genes in any of my food. So labeling is a very,

1 very important issue to me.

2 I am a little shaken up because, coming in here--I
3 am generally a peaceful person, but they searched my bags,
4 like, four times. I had to empty my pockets twice. They
5 confiscated my lunch. I don't know whether to be
6 complimented or insulted.

7 Being here, I can't help but think back to
8 testifying at the USDA hearings on the National Organic
9 Program at Rutgers in New Jersey and what a powerful
10 experience that was and the passionate outpouring that
11 people had who were defending ecological organic ways of
12 growing food.

13 I am hearing some of those voices here but I am
14 also hearing a lot of vested interests protecting the bottom
15 line, wanting to keep Americans in the dark about knowing
16 about what is in our food supply. I am very concerned about
17 the FDA's very selective view of science, saying that people
18 who have questions about this biotechnology are anti-science
19 when there are a lot of very crucial scientific questions
20 and a lot of ecological knowledge that is being swept aside
21 in terms of their interests.

22 There are so many problems with these crops that I
23 couldn't even go into them. Generally, there is pollen
24 drift to the organic farmers, the antibiotic markers that
25 are fed to animals that are given large amounts of

1 antibiotics and the antibiotic resistance problems.

2 To determine their seed technology which, to me,
3 is the just the ultimate to having seeds that are
4 genetically engineered to poison themselves is just like the
5 height of moral bankruptcy to me. I demand that the FDA
6 should protect the democratic rights of the American people
7 and not abdicate it in favor of the chemical pharmaceutical
8 agribusiness giants.

9 Thank you.

10 MR. LAKE: Thank you, ma'am.

11 MR. HIGGINS: I am Yan-Chu Higgins. I hail from
12 the great state of Iowa. I would like to say that if we
13 think that transparency is the key to Indonesia's recovery,
14 then I don't understand why we can't have transparency as it
15 relates to our own food choices.

16 We also need to have a little bit more
17 transparency at the level of the FDA and of these much
18 vaunted agencies that have told us that biogenetically
19 engineered is safe. I am not buying it. I understand that
20 these people have interests. I understand that the
21 individuals with great credentials would tell us this, that
22 and the other because they are getting paid.

23 Now, that is fine and dandy because that is what
24 they are paid to do. At the consumer level, we simply want
25 to have the food that we want, that we can choose to have.

1 That is not a big problem. Sure; maybe the labeling is
2 going to scare a few people. Maybe it is going to actually
3 facilitate their own learning about the process.

4 Now, you guys are sitting up there and these
5 people have come in here and said this, that and the other
6 about how it is safe and that they know all of it. But I
7 don't understand how you can actually change an organism at
8 the genetic level and then claim that it is the same thing,
9 that physiologically, when it enters your body, the way your
10 body absorbs those nutrients or those aberrant nutrients is
11 the same thing.

12 You cannot play god. Do you believe in god? Do
13 you really? The hubris. This is really very serious, very
14 serious.

15 MR. LAKE: Thank you, sir.

16 MS. NEED: My name is Theresa Need. I am the
17 Director of the Farmworker Health and Safety Institute. It
18 is a unique consortium of three community-based farmworker
19 organizations that work with migrant farmworkers along the
20 East Coast, the U.S.-Mexico border, the Caribbean and in
21 Mexico.

22 I think it is very symbolic that I am one of the
23 last presented speakers here because farmworkers are on the
24 last rung of the ladder in our food system due to lack of
25 political power and clout.

1 Farmworkers are also on the front line of our food
2 production and, therefore, at the greatest risk of coming
3 into contact with pesticides and residues as they plant,
4 tend to and harvest the food that we eat. Now farmworkers
5 have another environment threat to their health; genetically
6 modified food.

7 Once again, they, along with farmers and community
8 members, are the guinea pigs for this biotechnology. Here
9 are some facts. A new study of Ohio crop pickers and
10 handlers found that bT can provoke immunological changes and
11 that long-term exposure might cause asthma or other serious
12 allergic reactions in the infected persons.

13 Farmworkers already have higher rates than the
14 national average of parasitic infections and tuberculosis.
15 This will further compromise their immune systems and
16 health. Most GE crops are designed to be resistant to
17 specific herbicides. Since herbicide-resistant GE crops
18 lead to greater herbicide use, exposures to higher levels of
19 herbicides, like glycosate, can lead to greater risk of
20 cancer.

21 Also, GE is affecting farmworkers in their home
22 countries, Approximately 94 percent of farmworkers come
23 from Mexico and GE is the biggest threat to their
24 biodiversity where there are 25,000 native varieties.
25 Therefore, we feel that there should be suspension of all GE

1 technology until independent and comprehensive studies have
2 been conducted on the health, environmental and economic
3 impacts, and studies need to be conducted based on the
4 precautionary principle.

5 We must assume that GE foods are not safe instead
6 of the current concept of substantial equivalence. In
7 addition, protection for farmworkers and farmers who are
8 already currently working with GE crops need to be protected
9 so they are not at greater risk.

10 Thank you.

11 MR. LAKE: Thank you, ma'am.

12 Let me ask, is there anyone on the speakers list
13 who has not yet had an opportunity to come to the podium?

14 Mr. Levitt?

15 **Closing Remarks**

16 MR. LEVITT: That brings us to the end of our
17 proceedings today. Let me, before we close, add or repeat a
18 few thank you's. First, is to all of you who came today and
19 shared your information with us; to my colleagues on the FDA
20 panel for patiently listening and probing questions to the
21 panelists we had up here.

22 I also want to thank a few people who never get
23 thanked, people like the people that are transcribing for
24 us. Even though you are getting paid, you have worked hard
25 today; the people on the FDA staff who prepare the room,

1 organize the speakers, people who came in from the field and
2 so forth. A lot of people worked hard to make this meeting
3 come off I think as officially as it did. I think it did
4 transpire very officially.

5 A few reminders. We do have our public docket
6 open. You can submit written comments in addition, whether
7 or not you have spoken orally. Again, we have our third
8 meeting in Oakland, California on December 13 for people,
9 really, who were not able to make the first two. We are
10 really trying to allow different people to come to each of
11 the meetings, as much as possible.

12 But, with that, we clearly got a lot of
13 information that was presented today. As I said at the
14 beginning, we are very much in a listening mode but we also
15 hope that people are listening to each other and that
16 everybody came away from today's meeting having a little
17 more to think about maybe than when we all came in.

18 So, again, thank you very much. This tends
19 today's session.

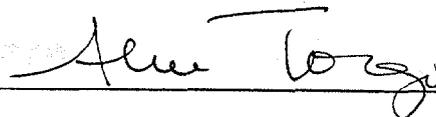
20 [Whereupon, at 6:15 p.m., the meeting was
21 adjourned.]

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C E R T I F I C A T E

I, ALICE TOIGO, the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

A handwritten signature in cursive script, reading "Alice Toigo", is written over a horizontal line.

ALICE TOIGO