

1 some process to the issue of how do you establish there is  
2 something good, bad, truthful or not truthful, and in the  
3 realm of biological sciences we have hundreds of years of  
4 developing this infrastructure that we call science. It is  
5 wondrous. It is confusing to a lot of people but it is a  
6 marvelous technique that many of us have great faith in and,  
7 importantly, very importantly, this goes through a  
8 regulatory oversight process.

9 I would submit first-hand evidence with bovine  
10 somatotropin -- I mean, there is stacks and stacks and  
11 stacks of data that FDA has from all the companies that were  
12 seeking approval, and they went through lots and lots of  
13 processes to comply with the law, and all I am saying is  
14 that process is what we have today based on science. I  
15 think it is very good to make these decisions about is  
16 something suitable for entry into the food chain.

17 MS. FOREMAN: Just for the record, that is the one  
18 product out there that was subject to a mandatory pre-  
19 approval process and post-approval monitoring because it had  
20 to go through the new animal drug application process.

21 DR. ETHERTON: But in part that was because it was  
22 the first animal biotechnology that went through FDA and  
23 there was a learning process on both sides.

24 MS. FOREMAN: Well, if you want to apply that to  
25 all these other products I might feel a little better about

1 them.

2 MR. DRUKER: Also, that is not a very good example  
3 because that product, the bovine growth hormone -- it has  
4 become clear, and there is another lawsuit right now against  
5 the FDA brought by the Center for Food Safety challenging it  
6 because evidence finally came to light through the Canadian  
7 government that there was important evidence that was  
8 suppressed by Monsanto originally.

9 No other industrialized country in the world has  
10 approved that product, only the United States. By the way,  
11 it was approved during the era at the FDA when the deputy  
12 director for policy, Michael Taylor was there. Mr. Taylor  
13 had been an attorney representing the interests of Monsanto.  
14 Then he became appointed deputy commissioner of policy. He  
15 approved bovine growth hormone, made by Monsanto. He was  
16 overseeing the policy that approved genetically engineered  
17 foods in principle, and subsequent to that he went to work  
18 directly for Monsanto as vice president for public policy.  
19 This is hardly the kind of regulatory process that should  
20 instill consumer confidence. So, again, that example shows  
21 how weak the arguments are I think.

22 MR. LEVITT: It looks like the one thing we were  
23 able to predict is a diversity of views. On this question I  
24 will give Rebecca Goldberg the last word.

25 DR. GOLDBURG: Okay, I will try and keep my

1 remarks very brief. I wanted to just briefly touch on the  
2 matter of certainty of allergies since it was brought up and  
3 it was one focus of my comments.

4 Dr. Lehrer, I am somewhat surprised about your  
5 feeling so assured about the capability of assessing the  
6 allergenicity of many proteins. My understanding is that  
7 you are currently the biotech company Agrevo's consultant to  
8 look at the allergenicity of Agrevo's quinine CBT toxin for  
9 use in corn, which is now being evaluated by the U.S.  
10 Environmental Protection Agency for its allergenicity.  
11 While the characteristics of that toxin are somewhat unusual  
12 in terms of the protein stability, EPA, I understand, has  
13 enough uncertainties about assessing the allergenicity of  
14 that protein that it is planning tentatively to hold a  
15 science advisory panel meeting on the matter.

16 So, I would say that there is still a lot to learn  
17 about how best to assess allergenicity, and while there has  
18 been some good work done to point towards the sorts of  
19 characteristics that allergens have, bit steps, there is  
20 still a long way to go. Thanks a lot.

21 MR. LEVITT: Thank you. We are approaching the  
22 time for the lunch break. Carol Tucker Foreman was right  
23 again; we will not get there early. On any one of these  
24 items we could probably spend an entire day.

25 What we will do, I will give Jim Maryanski the

1 opportunity to ask one question of the panel. Then I have  
2 kind of a short wrap-up question and then we will break for  
3 lunch.

4 DR. MARYANSKI: Thank you, Mr. Levitt. We have  
5 had a lot of discussion about unexpected effects. FDA, of  
6 course, spent a good bit of its '92 policy addressing that  
7 issue. We have heard about the complex problem of L-  
8 tryptophan. Of course, it is even more complex than has  
9 been presented because there were over two dozen cases of  
10 EMS linked to L-tryptophan that occurred before engineered  
11 strains were used. We also, of course, have cases of the  
12 disease that were apparently induced by a related compound,  
13 hydroxy-tryptophan. So, the story is very complex.

14 We also have, of course, many products that are  
15 produced by fermentation, as that product was, that are on  
16 the market, and have been on the market for many years, ever  
17 since insulin was produced by fermentation. Of course,  
18 there are many pharmaceuticals and food ingredients that are  
19 produced through that technology.

20 But the question I really want to come back to, we  
21 were talking about what, if anything, should be done to  
22 change FDA's approach to looking at these products. If we  
23 are to consider asking companies to come in either on a  
24 mandatory basis or some other basis, we would have to think  
25 about what is the scope; what would be the nature of the

1 products that we would want companies to come in and talk to  
2 us about? Because, of course, it does mean committing our  
3 resources, our scientists, to making those reviews, and  
4 those reviews would be extended reviews that would, of  
5 course, take away time from our other public health  
6 protection activities.

7           So, I would be interested in hearing from the  
8 panel what kind of products they would think would really be  
9 the products that should fall under a review or a  
10 notification by FDA.

11           I would also like to ask the panel if they are  
12 aware of any scientific information. As I have heard it  
13 this morning, it sounds more like it is primarily a matter  
14 of enhancing public confidence which is, of course,  
15 important. But I am not aware of any scientific information  
16 that has been found by any other government -- and there is  
17 a number of these products that have been approved by  
18 countries around the world. So, in those evaluations I have  
19 not heard any different decisions than have been made in  
20 this country.

21           So, I would like to ask the panel if they are  
22 aware of any scientific findings by others that would bear  
23 on the safety of these products, and what would be the scope  
24 of products that should come to FDA in any system that we  
25 have in place? Thank you.

1 MR. LEVITT: Just for clarification, Jim, when you  
2 say scientific findings, do you mean results from studies?

3 DR. MARYANSKI: Yes.

4 DR. DAY: That is a very broad question, and I  
5 find it difficult to be concise in answering. But let me  
6 start by saying that I don't think we should treat the  
7 products of genetic manipulation any differently from those  
8 of conventional plant breeding, and I think this has  
9 occurred to others in the past. That is, if you are  
10 concerned about unpredicted effects, well, apply these to  
11 the products of crosses, hybridizations, between distantly  
12 related species in a plant breeding program.

13 Now, the difficulty comes in identifying what is a  
14 complete test of safety. There are tens of thousands of  
15 different proteins produced by plants. In the analysis of  
16 the Flavr Savr tomato, Calgene concentrated on the obvious  
17 nutritional components of tomatoes, and they looked to see  
18 if known toxicants -- there is an alkaloid called tomatine  
19 which is present in unripe fruit, to see if that were  
20 increased. They looked at a variety of other compounds, but  
21 how could they claim to have looked at everything because if  
22 they had looked at everything they would still be looking,  
23 and one questions what the value of such a complete  
24 analysis, assuming that it is possible, would be.

25 So, I think we are faced with identifying

1 standards that are going to be impossible to realize. If we  
2 insist on doing this, then we are going to drive up the cost  
3 of our food, and my question is why are we doing this? What  
4 evidence is there to convince us that this is a real risk  
5 either in the products of conventional plant breeding or of  
6 genetic manipulation?

7 MS. FOREMAN: Dr. Maryanski, I laid out, based on  
8 Mike Jacobson's suggestions last week, three different  
9 levels of review that you might use if you wanted to require  
10 some differentiation in review, and I am not going to go  
11 through them here; they are in my written comments.

12 Science is a part of the process of making public  
13 policy, and it is only one part. The other part does  
14 involve whether or not the public is confident with the  
15 process.

16 Dr. Day, I would be willing to bet you money that  
17 you are not going to see any reduction in the price of food  
18 in the United States as a result of the introduction of BT  
19 corn or any of the other products of biotechnology. The  
20 basic commodity price is such a tiny portion of the cost of  
21 food. We pay today for having our food wrapped two or three  
22 times, and processed and reprocessed, and then cooked for us  
23 so we can take it out and take it home. If the relationship  
24 between commodity prices and food prices were anywhere close  
25 to being tight, we would be out there buying pork for a dime

1 these days.

2           Again, I just want to finish -- I am probably the  
3 most sympathetic person in the public interest community up  
4 here to the products of biotechnology, but none of those  
5 that have been developed yet have any benefit to the  
6 consuming public. We keep hearing that there are those in  
7 the pipeline that will, but they are way back in the  
8 pipeline, way, way back. When they move to the front of the  
9 order and you begin to see vitamin A rice out there being  
10 used in developing countries to stave off blindness among a  
11 hundred million children that are at risk of it, then I may  
12 feel a lot differently about this process. It is that  
13 balancing that I think the larger public has in mind with  
14 regard to this process.

15           DR. GOLDBURG: I am not sure i can answer your  
16 entire question, Jim, although I know, or at least I suspect  
17 that at one time you wrote EDF's 1991 70-page proposal to  
18 the Food and Drug Administration about how the agency should  
19 regulate genetically engineered foods, and I think that  
20 proposal still stands.

21           That said, I would like to make a couple of  
22 comments. One is that I disagree with Peter Day and I don't  
23 think that the products of genetic engineering should be  
24 treated the same as those of traditional plant breeding. I  
25 think there are important differences between genetically

1 engineered foods and those derived from traditional plant  
2 varieties.

3           With genetic engineering the entire universe of  
4 genetically encoded traits is now available to put into  
5 crops and, therefore, into foods. For example, one can  
6 breed potatoes with other cultivated potatoes or maybe  
7 related wild potatoes. You can't breed a potato with a  
8 fish, or a chicken, or a moth, or a bacterium or a virus  
9 and, yet, all or most of those things have been done with  
10 genetic engineering.

11           So, I think that this universe of new traits, not  
12 new proteins at the moment, but in the future also altered  
13 biochemical pathways in plants that may produce new oils,  
14 new secondary plant products, all sorts of things opens up a  
15 universe of large changes to food that merit government  
16 regulation in a way that traditional plant varieties have  
17 not.

18           That said, I am not aware of any examples of  
19 dangerous products other than the ones I am sure you are  
20 already aware of, Jim, like the Brazil nut gene.

21           Finally, I think that when you ask this panel or  
22 ask in general are these products dangerous, I think you are  
23 asking the wrong question. Foods are not like pesticides.  
24 We don't ask are they dangerous; we ask are foods safe, and  
25 that is the question that the Food and Drug Administration

1 should be asking.

2 DR. MARYANSKI: If I could follow up, because we  
3 have a number of foods that come to market that I think, as  
4 Dr. Day indicated, are from germ plasm that is obtained from  
5 possibly inedible plants. We have plants that have been  
6 crossed, like broccoflower, where they are typical foods but  
7 they are plants that we know have many natural toxins. Are  
8 these examples that you would exclude from particular  
9 oversight by FDA?

10 DR. GOLDBURG: Well, I would welcome a look by FDA  
11 at this juncture at products of selective breeding.  
12 Although I have emphasized the differences between genetic  
13 engineering and traditional breeding, it is true that there  
14 are a number of techniques now commonly employed by  
15 traditional plant breeders, like embryo rescue, that have  
16 opened up the range of new traits that can be inserted into  
17 plants and into foods. It is conceivable that some of those  
18 inserted traits may bring some safety problems. It is  
19 possible that some breeding may elevate levels of secondary  
20 plant compounds that are dangerous to people. And, I think  
21 the FDA could do more to look at those products in addition  
22 to genetically engineered foods. If the current concern  
23 over genetically engineered foods motivates a greater look  
24 at plant breeding, I think that is a good thing.

25 MR. DRUKER: Following up on Dr. Goldberg's

1 points, Dr. Maryanski, in the case of making wide crosses  
2 between a potato with wild relatives, we already know what  
3 factors in potatoes are potentially problematic and so the  
4 way we were able to know to get those potatoes off the  
5 market was that people did experiments, and they found out  
6 that those levels were higher.

7           In the case of genetically engineered food, what  
8 many of the FDA's own scientists, and many scientists  
9 outside the agency that are suing it, and many others are  
10 saying is that there is a risk that we cannot completely  
11 quantify at the time, but a risk in the minds of reasonable  
12 scientists that there could be the production of toxins,  
13 carcinogens, allergens and other anti-nutritive elements  
14 that are completely unexpected.

15           Again I will refer you to the memoranda from Dr.  
16 Matthews from the Division of Food Chemistry and Technology,  
17 that is the problem; it is the unknown factor. Dr. Day, you  
18 were saying, well, you can't expect Calgene to have tested  
19 for everything; they would still be testing. What we can  
20 expect, and what the law demands, is that they must be  
21 tested and confirmed safe to a reasonable certainty they  
22 will not produce harm.

23           In the case of a genetically engineered food, the  
24 only way to begin to approach that standard is to subject  
25 each food to, first, rigorous, long-term animal feeding

1 studies, and the, if it passes those studies it would have  
2 to move on to clinical and human feeding studies because  
3 animals are often not the best model.

4           One reason the industry does not want to do that  
5 is that in the case of using a whole food that would be a  
6 very long, expensive and difficult process, but that is the  
7 law. If you don't want to follow the law, then the thing to  
8 do is to go to Congress, say, look, this is a great new  
9 technology; we think it will feed the world. Change the law.  
10 But that would bring the process out into the open and  
11 debate, and you would have many experts to tell you there  
12 are many other ways to feed the world without using genetic  
13 engineering. It is not a do or die technology. If it has  
14 so many inherent safety risks we don't need to use it. Or,  
15 we need to change the law. But, let's not do it  
16 surreptitiously, claiming we are following sound science and  
17 following the law when, in effect, we are violating sound  
18 science and violating the law.

19           Just to end with that point again, the mere fact  
20 we can have, obviously, people like Dr. Day and Dr. Etherton  
21 who can stand here and say I don't think there is a risk,  
22 but I can point to myriads, or at least scores and scores of  
23 other well credentialed experts who say they do think there  
24 is a risk. The law says, and the courts are clear, that you  
25 can't have food safety issues decided on competing

1 hypotheses. They need to be based on solid evidence.

2 I again invite you, Dr. Maryanski, if you have  
3 solid evidence that even one genetically engineered food has  
4 been confirmed safe to reasonable certainty of no harm, then  
5 bring it forth because clearly the Flavr Savr tomato wasn't  
6 and no other genetically engineered food, in my knowledge  
7 and the knowledge of our scientists, has passed that  
8 standard, and that is the situation that we are faced with.  
9 So, I think we need to be honest and forthright, and if  
10 genetic engineering cannot pass legal muster, so be it.  
11 Let's focus our resources on other ways for feeding the  
12 world.

13 MR. LEVITT: Dr. Lehrer?

14 DR. LEHRER: I agree with Dr. Day that first and  
15 foremost we should base any decisions on sound scientific  
16 principles. These decisions should not be made on emotion  
17 or hearsay. They should be made on terms of sound science.  
18 I think that is extremely important. hat

19 I do not believe that genetically modified foods  
20 should be treated any differently than other foods. In  
21 other words, I don't think that we should raise the bar for  
22 these foods to pass. We should use the same approach that  
23 we are using for other foods in our tests. Actually, in  
24 some cases, even with allergy, we have done this because  
25 many of the foods that we now have would not be accepted,

1 such as rice, corn, peanut, soybean, which all contain  
2 allergens and if they had to go through the approval process  
3 they would not be released.

4           Finally, I agree with two of the former speakers  
5 who indicated that they felt that the public being involved,  
6 particularly in terms of these kinds of conferences, is a  
7 very positive approach because I think that this will give  
8 the public an opportunity to express their concerns about  
9 these products. These concerns can be taken into account by  
10 the FDA. I think also the public may learn a little more  
11 about what goes into the process of assessing the risk of  
12 these products.

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

14           DR. ETHERTON: Thank you, Mr. Levitt. I would  
15 just echo the comments that Dr. Lehrer shared with you, that  
16 decisions about safety and efficiency with which new plants  
17 or animals produce food be based using scientific method,  
18 and the power of science and, as I have said earlier and  
19 will reiterate again, to go through a very rigorous, due  
20 diligence-based review by experts that is an inclusive, not  
21 exclusive, process and, as you have heard today, an  
22 opportunity where the public may comment.

23           My view and that of FASS is that the Food and Drug  
24 Administration is doing everything within the powers that  
25 science has, legal policy that mandates food approval, and

1 guidelines that they set forth. We have a very good system.  
2 It might need to be tweaked but it has served us well for  
3 many, many years. Thank you.

4 MR. DRUKER: I forgot, Dr. Maryanski, that in  
5 specific answer to what you asked, there are studies in the  
6 scientific literature that have documented the production of  
7 unexpected toxins in genetically engineered plants, and have  
8 documented the suppression of native gene expression by the  
9 insertion of foreign genetic material. In fact, some of  
10 those are referenced in literature that is in your own  
11 scientific record. If you would like some of that, I am  
12 sure that I could get some of our scientific plaintiffs to  
13 prepare you a memorandum on it. Thank you.

14 MR. LEVITT: Thank you, all. This really has been  
15 a terrific panel. Before everybody leaves, I am going to  
16 ask the panelists to answer quickly one -- I won't say one  
17 simple question but one short question with, hopefully, a  
18 short answer.

19 That is, if you could look ahead a year from now  
20 and say a year from now we all reconvene, and the FDA during  
21 that year had done "blank," what would that be? I would  
22 like to say if there was one thing FDA could do in the next  
23 year, you know, what would that be.

24 While you are thinking about that, because I kind  
25 of sprung that on you, let me just say a couple of things to

1 the people in the audience. Number one, I have to really  
2 compliment all of you. I have been to a lot of these  
3 meetings and rarely do we find an audience that is so  
4 attentive, that stays through every bit whether it feels  
5 like lunchtime or not. Clearly, there is a lot of interest  
6 from the public in this issue. I wanted to comment on that.

7           When we break for lunch, there is a cafeteria in  
8 this building downstairs. There are public eating places  
9 within a short walk. If you wander over towards the Metro  
10 station at Federal Center Southwest, you will find a number  
11 of luncheon places. If everybody doesn't go to the same  
12 place, there will probably be room enough to accommodate  
13 everybody.

14           With that, I have given you enough advance notice  
15 now. This afternoon, a lot of people, for their whole trip  
16 get only two minutes. You have had a couple of hours over  
17 here. You get between thirty seconds and one minute to role  
18 model for everybody else. A year from now, what would you  
19 like to see FDA have done?

20           DR. DAY: Mr. Chairman, could you start at that  
21 end?

22           [Laughter]

23           MR. LEVITT: All right. I was waiting for that.  
24 Why not? A little variety!

25           DR. ETHERTON: I would argue that FDA needs more

1 resources to higher additional folks, with resources and  
2 expertise in a number of areas, to allow them to be  
3 positioned to accelerate the review process once data has  
4 been submitted by the private sector companies. That would  
5 help.

6 MR. LEVITT: Thank you. Next?

7 DR. LEHRER: I agree with that. I would like to  
8 see more funding available to improve risk assessment  
9 methods, and I also think this type of forum is very useful  
10 for the public and should be continued.

11 MR. DRUKER: I would like to see the U.S. Food and  
12 Drug Administration uphold its statutorily mandated  
13 responsibility to protect the safety of the nation's food  
14 supply, and not to allow any new food additive on the market  
15 unless it has been established safe through sound scientific  
16 principles. If it does do that, then as a natural outcome  
17 all genetically engineered foods would have been recalled  
18 from the market; no new ones would be approved until each  
19 and every one was established safe according to the sound  
20 scientific principles that Congress wanted to be in place to  
21 protect our food supply.

22 DR. GOLDBURG: I would like FDA to revise its 1992  
23 policy in three ways. One is to remove the provisions of  
24 the policy that lower the bar for substances added to foods  
25 via genetic engineering compared to those added via food

1 processing.

2 I would like FDA to institute a mandatory  
3 notification requirement for marketing of genetically  
4 engineered foods.

5 Finally, I would like FDA to revisit its policy  
6 for labeling of genetically engineered foods.

7 MS. FOREMAN: I knew if we stayed around long  
8 enough I would agree with Dr. Etherton on something --

9 [Laughter]

10 -- which is the need for more resources for the  
11 Food and Drug Administration. If Jim Maryanski gets hit by  
12 a car going out to lunch, there is no biotechnology program  
13 at the Food and Drug Administration. It is as close to a  
14 one-man shop as has ever existed in government.

15 Your rule-making never takes only a year, but I  
16 would like you to have begun the process of having some  
17 mandatory review and approval based on the concerns raised  
18 by different kinds of genetically modified organisms, and  
19 certainly a policy for mandatory labeling.

20 MR. LEVITT: Dr. Day, you had the first word and  
21 you will have the last one.

22 DR. DAY: Thank you. Clearly, FDA is going to do  
23 some very deep thinking after this session and the one it is  
24 going to hold in California. FDA has a great  
25 responsibility, clearly, because it plays such an important

1 role in food safety.

2 I agree with the other panelists that FDA should  
3 reconsider how it sets about making its decisions, but I  
4 would urge them not to lower bars but to recognize that  
5 there are risks in the food supply from genetic manipulation  
6 and from conventional breeding, and I would hope that by  
7 this time next year they will be well advanced with further  
8 public debate to present a new approach. I doubt if we can  
9 all be satisfied with it, but clearly they need to continue  
10 to hold this in the light and reach a reasonable conclusion.

11 MR. LEVITT: Thank you, all. If we could have a  
12 round of applause?

13 [Applause]

14 Again, I thank everyone. My clock says it is a  
15 couple of minutes after one. We will reconvene promptly at  
16 two o'clock in this room.

17 [Whereupon, at 1:05 p.m. the proceedings were  
18 recessed, to be resumed at 2:00 p.m.]

## AFTERNOON PROCEEDINGS

**Session 3: FDA Policy: Labeling**

1  
2  
3 MR. LEVITT: If I could have everybody's  
4 attention, please? It is two o'clock and it is time to get  
5 started with this afternoon's session.

6 Before we get going, I have a couple of  
7 announcements. The first is a call to see if there is  
8 anybody in the audience that is hearing impaired and needs a  
9 sign language interpreter. We do have an interpreter  
10 available, and if there is anybody here who needs that  
11 service we will be more than happy to provide it. Please  
12 identify yourself to him. He is standing over here, to my  
13 right and to your left. Thank you for being available.

14 Second, if I could just make a request for people  
15 with cell phones -- while we couldn't quite hear them up  
16 here, I did get a number of comments from people in the  
17 audience. If you are in the audience and you have a cell  
18 phone, if we could ask you to turn it off while you are in  
19 here. Obviously, if you need to make a call you can go out  
20 into the hall and do that.

21 Finally, I think I will go ahead and introduce the  
22 panelists now, even though it will be a moment before we get  
23 to them, and in so doing note that we have one substitution  
24 from your program -- after Mr. Lake, of course.

25 On my immediate left is Dr. Mario Teisl, assistant

1 professor, Department of Resource Economics and Policy,  
2 University of Maine. Welcome down from New England.

3 Next, we have Dr. Mildred Cody, associate  
4 professor of nutrition, Georgia State University. So, we  
5 have northeast; southeast.

6 Next, we have Richard Caplan, environmental  
7 advocate, U.S. Public Interest Research Group. Welcome.

8 Next is our one substitution. I would like to  
9 welcome Richard Frank, an attorney with the law firm of  
10 Olson, Frank and Weide, who is outside counsel for the Food  
11 Distributors International and he is here substituting for  
12 Mr. John Gray who is listed on your program.

13 Next, we have Dr. Kendal Keith, president,  
14 National Grain and Feed Association.

15 Finally, we have Robert Cohen, founder and  
16 executive director of America's Dairy Education Board.

17 Our format this afternoon will be similar to this  
18 morning. We will begin with a summary of FDA's policy and  
19 program in the area of public information, including  
20 labeling. Mr. Robert Lake, who is our Director of  
21 Regulations and Policy and really, if you will, the senior  
22 person at CFSAN in terms of length of experience and  
23 knowledge on issues. Bob, welcome and we will look forward  
24 to hearing your presentation.

25 **Session 4: Public Information and Labeling**

1 MR. LAKE: Thank you. Actually, I had two slides.  
2 They both somehow managed to disappear but I have my hard  
3 copy so I will use that as prompts.

4 Again, let me add my welcome to all of you. This  
5 afternoon we are focusing on information, at least on this  
6 panel, and that includes labeling but it also includes other  
7 kinds of information.

8 As with safety, the governing statute is the  
9 Federal Food, Drug and Cosmetic Act which contains the  
10 definitions and standards that govern food labeling as well  
11 as food safety.

12 The principal requirement of the Act as it relates  
13 to labeling is that labeling cannot be false or misleading.  
14 The statute also, of course, has a number of very specific  
15 requirements. Most of you are familiar with the nutrition  
16 label on your food panel. That is mandated by statute and  
17 implemented by FDA regulations. But things as basic as the  
18 name of the food, I mean, that is a requirement that you  
19 identify what the food is on the food label.

20 Indeed, that is one of the areas where our  
21 labeling policy relative to biotechnology comes into play  
22 because if you modify something like canola or soy oil in a  
23 way that you change its characteristics -- and Dr. Maryanski  
24 used the example this morning of a soy oil that was modified  
25 to emphasize one particular fatty acid which made it more

1 acceptable for high temperature cooking, but it would not  
2 have been proper to identify it as regular soy oil because  
3 its characteristics had changed. So, in situations like  
4 that we require that the name of the product be modified to  
5 reflect the nature of the change.

6           The Food, Drug and Cosmetic Act also makes  
7 provision for labeling of material facts when you either  
8 have something on labeling that is incomplete -- it is sort  
9 of like once you start to tell a story you have to tell the  
10 story, that kind of notion, but also the notion that you  
11 need to tell people the consequences of characteristics of a  
12 product. This is another area where existing labeling  
13 policy with regard to genetic engineering comes into play.

14           Obviously, the presence of an unexpected allergen  
15 in a food has consequences to the consumers of those foods  
16 who might be allergic to that substance and, therefore,  
17 should that occur, FDA's existing policy would require  
18 labeling to alert the consumer that there is something in  
19 this product that might be an allergen that has been  
20 introduced by this technology, should that occur.

21           The other possible consequences that could affect  
22 labeling under existing policy would be significant changes  
23 in nutrition, or anything else that fundamentally altered  
24 the consumer's expectations with regard to the  
25 characteristics of the food.

1           We expect to hear this afternoon some discussion  
2 about mandatory labeling. We also expect to hear some  
3 discussion about voluntary labeling. Voluntary labeling  
4 raises the challenge of what is the message that the label  
5 is intended to convey to consumers; also raises the question  
6 of what the consumer's interpretation of the words on the  
7 label are going to be.

8           Again, going back to what I said a moment ago,  
9 label statements have to be truthful and not misleading. It  
10 is really the misleading component that is an issue here  
11 because it is possible to put truthful information on a  
12 label in a way that causes consumers to draw a conclusion  
13 that is false. So, this is the challenge that always faces  
14 anyone designing a food label, and it is a constant  
15 challenge to the Food and Drug Administration in our  
16 enforcement activities to try to assure that label  
17 statements, as they are commonly understood, will not  
18 mislead consumers.

19           The other thing I would like to emphasize is that  
20 while labeling is something that we are going to hear a lot  
21 about this afternoon, from our standpoint it should be part  
22 of a larger discussion about providing information to  
23 consumers. Statements on a label are certainly one way of  
24 doing that, but there are other possibilities as well that  
25 could be used either individually or in conjunction with

1 each other. For instance, the growing popularity of the  
2 worldwide web raises the issue of whether more information  
3 could be made available on the web. We have also some  
4 experience with 1-800 numbers, hotlines, things of that  
5 sort, and whether that kind of mechanism might be useful as  
6 a way of providing some information. There is also the  
7 possibility of brochures that would be perhaps made  
8 available in grocery stores or other retail outlets to  
9 provide additional information, and there may be other  
10 possibilities that I have not mentioned. We are hopeful  
11 that both in the panel discussion and later when we get to  
12 individual comments from the floor that perhaps there may be  
13 some ideas that we haven't thought about that might be worth  
14 considering.

15 So, with that, let me sit down and turn the  
16 program back over to Mr. Levitt for the next panel. Thank  
17 you.

18 MR. LEVITT: Thank you very much for kind of  
19 setting the context for this afternoon's discussion. Again,  
20 discussion will focus on providing information to consumers.  
21 Our first speaker is Dr. Mario Teisl, from the University of  
22 Maine, and again I would ask that each speaker try to limit  
23 yourself to about five minutes, and that will allow plenty  
24 of time for questioning and discussion back and forth. Dr.  
25 Teisl?

1 **Panel Discussion**

2 DR. TEISL: Thank you. Thanks for inviting me.

3 Good afternoon. There are many possible labeling strategies  
4 for genetically engineered foods. We could go on for hours,  
5 but to keep things simple I am going to discuss FDA's  
6 current policy and a policy where all genetically engineered  
7 foods exhibit a label stating something like this food may  
8 contain genetically engineered components. Components of  
9 this alternative usually state that it is a consumer's right  
10 to know that a food is genetically engineered.

11 Today I would like to use a benefit-cost paradigm  
12 to show that both of these approaches are limited. Under  
13 this paradigm, a labeling policy is justified if the  
14 policy's benefits are greater than its costs. But what are  
15 the costs and benefits of a labeling policy?

16 In general, the benefits of labeling can be  
17 measured by the label's ability to allow consumers to make  
18 choices congruent with their preferences. Firms that  
19 produce these goods also benefit as they are rewarded for  
20 the provision of these attributes.

21 However, labeling is not free. There are  
22 financial costs, the costs of providing the information and  
23 verifying the information. Some proportion of these  
24 financial costs will be passed on to the consumers in the  
25 form of higher food prices, reduced product choice or

1 possibly increased taxes or reduced ability for the FDA to  
2 monitor some other food safety problem.

3           More importantly in terms of labeling is that  
4 labeling can impose cognitive costs on some consumers.  
5 Simply increasing the amount of information content on a  
6 label may actual decrease the consumer's ability to process  
7 other more important label information. In addition,  
8 requiring specific information to be placed on a label  
9 imposes an opportunity cost in that the limited space on the  
10 product label could have been devoted to other potentially  
11 more useful and important information. Because information  
12 content is competing for valuable space on the label,  
13 labeling requirements have to be justified in terms of the  
14 importance of the required information. A prescription such  
15 as "more information is better" does not necessarily  
16 characterize an optimal labeling policy.

17           Now I would like to look at the current debate  
18 surrounding the labeling of genetically engineered foods.  
19 Under the benefit-cost paradigm, FDA's current policy is  
20 justified but limited -- justified because when health and  
21 safety are concerned the benefits of a labeling policy are  
22 likely to outweigh the costs. However, the policy is  
23 limited in that there may be other consequences, for  
24 example, environmental consequences, that are important  
25 enough to consumers that a regulated labeling program makes

1 sense under a benefit-cost framework. On the other hand,  
2 the consumer right to know position is also limited in that  
3 taken to the extreme all product attributes, no matter how  
4 irrelevant, would have to be disclosed. A decision to  
5 impose labeling requirements should recognize both the  
6 benefits and the costs.

7 Now that I have presented a viewpoint that a  
8 priori does allow foods to be labeled as genetically  
9 engineered, I want to present the attributes of a successful  
10 labeling program and analyze how a simple GE label would  
11 fare.

12 The success of labeling programs is usually  
13 contingent on five points. First of all, the label  
14 information must be new to consumers. The information must  
15 be understood by the consumer. The information allows  
16 consumers to differentiate products. It is seen as  
17 important by consumers and the information is seen as  
18 credible.

19 Let's take these points one by one. Point one,  
20 the information on the label is new to the consumer. By all  
21 indications, this we be true for even a simple GE label.

22 Point two, the label information is understood by  
23 the average consumer. Here we have a problem. Although  
24 most consumers in the U.S. are aware of the term genetically  
25 engineered, the majority does not correctly understand this

1 term.

2 Point three, label information must allow  
3 consumers to differentiate products. Again, here is a  
4 problem. A simple GE label will not allow most consumers to  
5 differentiate products in the matter they most desire  
6 because the process of genetic engineering can produce a  
7 wide variety of consequences. When making food choices, a  
8 consumer may want to know whether the food contains an  
9 allergen, or that the food contains higher than normal  
10 levels of antioxidants, or whether the food's production  
11 harms butterflies. A label that simply states "may contain  
12 genetically engineered components" is not helpful because it  
13 does not provide enough detail. Imagine if FDA replaced the  
14 nutrition facts panel with a good food label.

15 Point four, the label information is seen as  
16 important by a significant portion of the population. Given  
17 the previous point, it seems that a genetically engineered  
18 label would provide important information only to consumers  
19 who want to avoid genetically engineered foods simply  
20 because of the process. I do not know of any directed  
21 research that has indicated that a significant portion of  
22 the U.S. population desires such a label solely to avoid the  
23 process.

24 I have to clarify what I mean by directed  
25 research. It is a common tendency for consumers to state

1 that they want more information. If you ask them if they  
2 want more information about GE foods, they will say yes.  
3 However, you may find that consumers don't actually use this  
4 information until you experimentally test it. I will just  
5 defer discussion of point five for the moment.

6           Given the above, a sound labeling policy for  
7 genetically engineered foods will probably include the  
8 following: Number one, mandatory labeling of GE foods that  
9 are significantly altered from consumer expectations of the  
10 food.

11           Number two, mandatory label of any foods, not GE  
12 foods, that provide significant consequences. Further, the  
13 definition of consequences should be broadened to include  
14 the possibility of non-health and process-related  
15 attributes.

16           Number three, labeling falling under the  
17 aforementioned point should focus on the consequence, not  
18 the process.

19           Number four, only if directed research indicates  
20 that a majority of Americans want to know about genetically  
21 engineered foods, over and above knowledge of the  
22 consequences, should a genetically engineered label be made  
23 mandatory, buying this condition of voluntary labeling  
24 approach, similar to that of the kosher label, would be much  
25 more appropriate.

1           Now back to point five, the information is seen as  
2 credible -- the credibility of a label is at least partially  
3 a function of who is perceived as monitoring and enforcing  
4 the labeling program. It is unclear to me who should  
5 promulgate and enforce these labeling regulations because  
6 traditionally FDA and several other government agencies have  
7 been overseeing programs focusing on health and safety  
8 labeling, while other agencies have been charged with  
9 monitoring environmental claims. Further, I am not sure  
10 whether a label should even be administered by a  
11 governmental agency. Consumers often state that they find  
12 third-party non-governmental organizations to be much more  
13 credible. However, a governmental agency may be more  
14 credible than a non-governmental organization that has low  
15 name recognition.

16           One thing is clear though, whatever labeling  
17 policy we do proceed with, whether it is voluntary or  
18 mandatory, the labeling of the product should be  
19 standardized so as to decrease consumer confusion and  
20 increase label credibility.

21           I would just like to finish by pointing out that  
22 given the low level of consumer understanding of genetic  
23 engineering, the concepts, the complex nature of genetic  
24 engineering and its many possible many consequences, and the  
25 space constraints of many food packages product labels may

1 not be the best method of disseminating information about  
2 genetically engineered foods.

3 Possible alternatives to labeling have already  
4 been mentioned. For example, placing a list of foods made  
5 with genetically engineered components on the Internet, or  
6 publishing it as a book, similar to the Greed Guides that  
7 currently assist environmentally concerned consumers in  
8 making their product choices. Thank you.

9 MR. LEVITT: Thank you very much. Next is Dr.  
10 Mildred Cody, Georgia State University.

11 DR. CODY: Good afternoon. This afternoon I am  
12 representing the American Dietetic Association. ADA's  
13 mission is to promote optimal nutrition and well-being for  
14 all people by advocating for its 70,000 members. This 83-  
15 year old organization provides a sound analytic bridge  
16 between scientific research and consumer interest.

17 We commend the Food and Drug Administration for  
18 holding this series of meetings to share information about  
19 biotechnology. Few issues have engendered such interest and  
20 emotion, with views ranging from highly positive to highly  
21 negative.

22 ADA has actively monitored biotechnology issues  
23 since the early 1990s, and continues to bring a unique  
24 perspective to the complex issues surrounding biotechnology  
25 and its potential impact on our lives. ADA members have

1 expertise in science and consumer education, both of which  
2 bear on the questions surrounding food and food products  
3 derived from biotechnology.

4 We are committed to providing our clients, the  
5 American consumer, with accurate, science-based information  
6 on bioengineered foods in a way that is both understandable  
7 and balanced. ADA's position is that biotechnology  
8 techniques have the demonstrated potential to be useful in  
9 enhancing the quality, nutritional value and variety of food  
10 available for human consumption. Biotechnology can also  
11 increase the efficiency of food production, the efficiency  
12 of food processing, the efficiency of food distribution and  
13 waste management.

14 As part of the ADA five-year review cycle, we are  
15 reassessing this position, which will be published in the  
16 summer of 2000. With all food, nutrition and health issues  
17 related to biotechnology, we see our educational efforts for  
18 health professionals and their audiences as a major ongoing  
19 task. For example, ADA has launched an intensive three-year  
20 media and public education campaign on food safety. This  
21 campaign was developed after an ADA study showed a  
22 significant gap between knowledge and practice on a number  
23 of key issues related to food-borne illness. In less than  
24 six months this campaign has reached more than forty million  
25 consumers across the United States.

1           As we have heard today, biotechnology is broadly  
2 used in medicine and is increasingly applied to food  
3 production. While ADA believes that the U.S. regulatory  
4 system, based on scientific processes and public input,  
5 serves the nation's economic and consumer interest well,  
6 that does not imply that there isn't work to do. It will  
7 take a continuous effort for the regulatory system to keep  
8 pace with advancements in biotechnology.

9           In these meetings, numerous organizations and  
10 individuals have offered recommendations on how improvements  
11 should be made. We urge federal regulators to look  
12 carefully at the merits of these new ideas and approaches,  
13 and refine the U.S. system to best promote the safety of the  
14 U.S. food supply; to allow the continued advancement of food  
15 product and science techniques to serve over-arching  
16 economic, environmental and health needs; to increase the  
17 availability of nutrient-rich, high quality foods so that  
18 all may have access to healthful diets; and to provide  
19 useful, scientifically-based information to those who wish  
20 to know more, including health professionals and self-  
21 informing consumers.

22           This last point is where I will focus the  
23 remainder of my remarks. A recent national consumer survey  
24 found that two out of three consumers support foods produced  
25 through biotechnology and have confidence in FDA's current

1 policy for food labeling biotech foods.

2 We cannot afford to undermine this existing  
3 consumer confidence surrounding biotechnology. ADA supports  
4 labeling approaches that let consumers make informed  
5 decisions in their food selections. As we know, many  
6 complex factors affect food choices. The questions are can  
7 we develop labels that provide useful information without  
8 being misleading or confusing? Is the food label the best  
9 place for information on biotechnology, or would other  
10 mechanisms of communication better serve the public?

11 Healthcare providers, such as qualified dietetics  
12 professionals, translate sound science concerning safety and  
13 health needs to help individuals make appropriate food  
14 choices. In this light, we see the need for a comprehensive  
15 approach to biotechnology information dissemination and  
16 education. The coordinated oversight of biotechnology by  
17 FDA, USDA and EPA needs to be strengthened by the  
18 contributions of scientists and industries, healthcare  
19 professionals and educators, consumer organizations and  
20 others into a concerted national information initiative. No  
21 one group -- not government or industry, not scientists or  
22 consumer advocates -- can successfully address the  
23 information and trust gaps developing around biotechnology.  
24 But, together each can play to their strengths in support of  
25 a safe, nutritious and consumer-valued food system.

1           We believe U.S. consumers, accustomed to a system  
2 that has served them well, have been patient as the  
3 information on biotechnology comes together and is made  
4 available to them. It is now time to act. The American  
5 Dietetic Association stands ready to work with FDA and  
6 others in developing a communication strategy focused on  
7 bioengineered foods that will help consumers make informed  
8 food choices to optimize their health.

9           Thank you for allowing me the opportunity to share  
10 the American Dietetic Association views on this important  
11 issue, and thank you for your attention.

12           MR. LEVITT: Thank you very much. Our next  
13 speaker is Richard Caplan, U.S. Public Interest Research  
14 Group.

15           MR. CAPLAN: Good afternoon, and thank you all for  
16 your interest in this subject. My name is Richard Caplan  
17 and I am a clean water and food safety advocate with the  
18 U.S. Public Interest Research Group, or USPIRG. USPIRG is  
19 the national office for the state PIRGs advocate groups with  
20 offices around the country, working on consumer rights, good  
21 government and environmental issues. For over twenty-five  
22 years, the PIRGs have been one of the nation's leading non-  
23 profit, non-partisan organizations working in the public  
24 interest.

25           We are gathered here today on what, I have no

1 doubt, will prove to be a historic day. November 30, 1999,  
2 as I am sure most of you know, is an international day of  
3 action with regard to the World Trade Organization. Today,  
4 in cities around the world people are rising up to speak out  
5 against the non-accountable trade body that has made  
6 decisions antithetical to good governments. Rulings of the  
7 WTO have resulted in the weakening of U.S. environmental  
8 laws, demonstrating that the ultimate goal of the  
9 organization is to make trade and money superior to people  
10 and their true needs.

11           The WTO offers an interesting link to our topic  
12 today of bioengineered foods. Just last week, the director  
13 general of the WTO, Mr. Michael Moore, phoned the head of the  
14 World Health Organization and told her explicitly not to  
15 bring up the issue of biotechnology in the WHO right now  
16 because, as he said, I have too much on my plate.  
17 Unfortunately for those of us who care about public health,  
18 Dr. Brunman agreed and, thus, again as in so many other  
19 issues it is the consumer who must rise up to speak out  
20 against government complacency.

21           Since the public hearing held by the FDA in  
22 Chicago, on November 18, an interesting report was published  
23 in New Scientist magazine that further raised the vaunted  
24 claims of the proponents of bioengineered foods,  
25 demonstrating speculation upon which their claims are based.

1           It seems that the stems of genetically engineered  
2 soybeans were found to crack open in hot climates, resulting  
3 in crop losses of up to forty percent. It is important to  
4 note that this is not the first example of the promises of  
5 DNA experiments gone wrong. Problems have included a  
6 massive crop failure of genetically engineered cotton in  
7 1997. A list of controversial claims by proponents of this  
8 risky technology is long, including the safety of  
9 recombinant bovine growth hormone or rBGH.

10           As mentioned on the earlier panel, rBGH has been  
11 rejected in every major industrialized nation. In fact, a  
12 recent report by Health Canada indicates that the FDA  
13 misrepresented the findings of Monsanto's ninety-day rat  
14 feeding study. Even the heavily corporate-influenced  
15 Kodak's alimentary commission has refused to certify the  
16 safety of rBGH despite heavy pressure from the United  
17 States. Yet, we are forced to eat and drink products from  
18 cows injected with rBGH in secret because of prohibitive  
19 labeling requirements written for the FDA by a Monsanto  
20 employee. Surely, one would think products that are  
21 ecologically risky or offer no benefit to the consumer would  
22 not be allowed, but that does not appear to be the case  
23 here.

24           Regarding ecological risk, it was recently  
25 reported on the front page of The New York Times that,

1 quote, scientists who study the approvals -- and we are now  
2 talking about the USDA -- say the department has frequently  
3 relied on unsupported claims and shoddy studies by the seed  
4 companies, end quote.

5 In an analysis of 8,200 university research trials  
6 of genetically engineered Roundup-ready soybeans, published  
7 this summer, revealed that farmers planting the soybeans are  
8 using two to five times more herbicide than farmers growing  
9 conventional varieties. This is in addition to the fact  
10 that the trials displayed an overall yield drag of 5.3  
11 percent. The study also correctly points out that failure  
12 to test the crops for increased residues of Roundup, an  
13 herbicide that despite being linked in studies to non-  
14 Hodgkin's lymphoma, had its allowable residue limit  
15 increased by the EPA under pressure from industry.

16 The failure to adequately establish a system for  
17 premarket safety testing, the failure to demonstrate that  
18 these products are necessary or useful, as well as the  
19 profound ethical issues raised by altering the genetic code  
20 of living things in the laboratory and then releasing them  
21 in the wild, among many other reasons, have all resulted in  
22 the call to the FDA to change the way they are handling this  
23 issue, and the call is not a new one.

24 When the agency published its statement of policy  
25 in 1992, the public overwhelmingly indicated their desire

1 for the labeling of these foods, a request that was ignored  
2 by the FDA. Surveys between then and now have demonstrated  
3 the same strong and unwavering sentiment and, yet, the  
4 public's desires have been stonewalled.

5           Earlier this month, University of Maryland's  
6 program on international policy studies released the results  
7 of a poll that they conducted which, again, demonstrated the  
8 support of over eighty percent of the American public for  
9 labeling regimes of bioengineered foods. As other countries  
10 around the world are beginning to demonstrate, the labeling  
11 of these foods can be easily accomplished. The American  
12 public deserves no less.

13           The science of genetic engineering can be said to  
14 be crude, unreliable, uncontrollable and certainly  
15 unpredictable. The overstatements from industry that these  
16 products are safe simply because they have spent millions of  
17 dollars testing them is simply not true. Recent history has  
18 many examples, including cyclamates and silicone breast  
19 implants, teaching us that safety pronouncements from  
20 industry and regulatory agencies can later prove  
21 disastrously wrong. The United States must have strong  
22 regulatory oversight of biotechnology rather than allowing  
23 these products to be rushed onto the market before we know  
24 their long-term effects.

25           Labeling and long-term safety testing are only two

1 steps in that process and we should not go another day  
2 without them. It is unfair, unsafe and unwise. As the  
3 evidence continues to come out, it is no longer rhetorical  
4 to ask what the industry is trying to hide by not labeling  
5 these foods, and why the insurance companies will not touch  
6 bioengineered food.

7           The failure to properly handle this radically new  
8 technology does not fall solely on the shoulders of the FDA.  
9 Quite the contrary, the hearings they have organized are a  
10 wonderful opportunity to hear from many Americans who  
11 otherwise would not have direct contact with the agency.

12           There are several actions that need to be taken  
13 that are out of the FDA's hands, including ratification of  
14 the conventional and biological diversity for which it is  
15 shameful that the United States has not signed. But the FDA  
16 can, and should at a minimum do what it is obligated to do  
17 under the law of the Food, Drug and Cosmetic Act, as they  
18 were reminded in a recent letter from nearly fifty members  
19 of the U.S. House of Representatives -- label all  
20 bioengineered foods and require long-term premarket safety  
21 testing. Thank you.

22           [Applause]

23           MR. LEVITT: Thank you. Next is Richard Frank,  
24 counsel to the Food Distributors International.

25           MR. FRANK: Good afternoon. Thank you. I am

1 Richard Frank, outside counsel to Food Distributors  
2 International, and I am pleased to have the opportunity to  
3 speak to you today on behalf of our members and industry and  
4 to share our thoughts on genetically modified foods and  
5 labeling questions.

6           Food Distributors International is a trade  
7 association comprised of food distribution companies that  
8 supply and service both independent grocers and food service  
9 operations throughout the United States, Canada and nineteen  
10 other countries. We represent the mid-section of the food  
11 distribution chain between manufacturers on one hand, and  
12 retailers and restauranteurs on the other. We appreciate  
13 the interest and concerns of food manufacturers, but we also  
14 appreciate the interest and concerns of retailers and  
15 restauranteurs who must ultimately be beholden to their  
16 consumers.

17           Food biotechnology is extremely important to the  
18 future to agriculture and food product in the U.S. and the  
19 rest of the world. Biotechnology will enable us to increase  
20 crop yield, improve the nutrient content of foods, produce  
21 foods with better processing and storage characteristics and  
22 drastically reduce pesticides and other substances of  
23 environmental concern. In our view, the potential rewards  
24 of food biotechnology are enormous. It would be the height  
25 of folly to forego those rewards because of hypothetical

1 risks which, even if proven true, are small and soluble.

2           We were talking about food safety this morning. I  
3 have worked my entire career with FDA. You vote with your  
4 dollars. You have very limited dollars. FDA, through my  
5 entire career, has thrown their dollars in the food area at  
6 food safety. They are throwing their dollars today at food  
7 safety. It may be a little late for the discussion on  
8 genetically modified organisms, but the reason it is late is  
9 that it is not our most pressing food safety issue at all,  
10 and that is why FDA's limited resources have not really come  
11 in this direction until the press basically led them there.

12           On the issue of labeling, FDI and its members  
13 strongly support the FDA's current policy. That policy  
14 requires labeling of genetically modified foods only if a  
15 genetic modification results in a significant change in the  
16 composition, nutrition or quality of the product. We oppose  
17 a blanket mandatory labeling requirement of all genetically  
18 modified foods.

19           We agree with the FDA that only material  
20 information should be subject to mandatory labeling, and the  
21 standard for determining what is material must be based on  
22 science, not opinion polls. If a genetically modified food  
23 is not materially different from its conventional  
24 counterpart, for example, if it is as safe, of equal quality  
25 and has the same functional and nutritional characteristics,

1 mandatory labeling simply is not justified.

2 FDI does, however, support voluntary labeling. If  
3 a food manufacturer wants to indicate that its product does  
4 or does not contain genetically modified ingredients, it  
5 should be free to label the product with a positive  
6 statement about the modification and how it has changed the  
7 characteristics of the product or, for example, a biotech-  
8 free claim, provided that the statement is truthful and not  
9 misleading.

10 As the FDA has required in the past, a biotech-  
11 free label should meet two prerequisites. First, it must be  
12 substantiated. For example, if a bag of corn chips is  
13 labeled biotech-free, the manufacturer should be required to  
14 substantiate the claim by means of testing, procedures for  
15 segregating non-biotech corn or other reasonable means. We  
16 assume that a biotech-free claim would be allowed for foods  
17 containing a de minimis level of genetically modified  
18 ingredients. A level must be set.

19 Second, it must be clear from the context that no  
20 inappropriate claims of superiority are implied. If the  
21 context implies that a food label biotech-free is safer or  
22 higher in quality, then that claim is misleading unless it  
23 can be substantiated.

24 Voluntary labeling means that the marketplace  
25 rather than government regulators will determine whether

1 consumers truly value this information. Similar to the  
2 current labeling scheme for organic foods, it has the  
3 advantage of putting the cost of labeling, which may be  
4 substantial, on consumers who want biotech-free foods rather  
5 than spreading those costs among all consumers. Consumers  
6 who do not care, do not have to pay.

7           FDA policy on food biotechnology must not only  
8 ensure that genetically modified foods are safe, of equal  
9 importance, as Carol said this morning, it must ensure that  
10 consumers have confidence that genetically modified foods  
11 are safe. Given the widespread use of this technology, it  
12 would be very unfortunate if a large segment of the public  
13 believed these foods are hazardous. We believe this would  
14 require a multi-faceted educational effort which includes  
15 consumer and environmental groups, industry and government  
16 jointly explaining what food biotechnology is to the  
17 consumer, how it works and what it does to their food.

18           The Fight Back Food Safety Program might serve as  
19 a useful precedent where all sectors of the public, consumer  
20 and environmental groups, government and industry got  
21 together to work on food safety.

22           One means of ensuring increased consumer buy-in  
23 would be to improve the transparency of FDA regulation and  
24 oversight. FDA might not want to hear this, but the  
25 consuming public is not yet convinced completely that these

1 products are safe. If they are not convinced, at the end of  
2 the day the products won't sell. So, we need FDA to work  
3 with us and to step up to do the research and convince the  
4 public, if appropriate, that these products are completely  
5 safe. Better coordination between FDA, USDA and EPA would  
6 also be helpful.

7 Our industry is in the middle. It would be unfair  
8 to say that this thing is not broken at all, and it would be  
9 unfair to say it is totally broken. The truth is that there  
10 is a wonderful technology here with promise to feed the  
11 world, or at least a much higher proportion of it. We also  
12 need to educate the public on what this technology is and  
13 inform them where it is appropriate.

14 So, we need FDA to do what it has always done  
15 well, and that is to be in the middle and, after they have  
16 heard all of the rhetoric on both sides, to come up with  
17 some informed decisions and policies.

18 Thank you for giving us this opportunity to share  
19 our views.

20 MR. LEVITT: Thank you. Our fifth speaker on this  
21 panel is Dr. Kendal Keith, National Grain and Feed  
22 Association.

23 DR. KEITH: Director Levitt and members of the  
24 panel, we appreciate the opportunity to present this  
25 statement today.

1           Our thousand members of our association are  
2 commercial businesses that own and operate more than five  
3 thousand grain elevators, feed mills and processing plants  
4 throughout the U.S.

5           First, let me briefly comment that we are not  
6 aware of scientific evidence that would warrant FDA changing  
7 its science-based 1992 policy statement that provides the  
8 regulatory framework for foods produced from biotechnology-  
9 enhanced commodities.

10           To reduce the risk of product liability, as well  
11 as putative and costly prospect of having products removed  
12 from the market, it is our understanding that seed companies  
13 and technology providers have customarily entered into  
14 voluntary consultations with FDA on the safety and efficacy  
15 of biotechnology-enhanced commodities before releasing the  
16 products to the marketplace. However, to further enhance  
17 consumer confidence, we do not oppose FDA making this  
18 consultation process mandatory for agricultural commodities.

19           We are absolutely confident, based upon first-hand  
20 experience with the agency, that FDA professionals have the  
21 scientific expertise, objectivity and background necessary  
22 to critically and impartially analyze and render science-  
23 based decisions on safety.

24           Now, let me turn to public information issues that  
25 are raised in the Federal Register notice. We believe that

1 FDA's 1992 policy concerning the labeling of foods produced  
2 from biotech-enhanced ingredients is scientifically sound.  
3 Therefore, we are opposed to and recommend against any  
4 government mandated labeling regime. To require labeling of  
5 products based on unsubstantiated and unscientific grounds  
6 would ultimately undermine public confidence in FDA and the  
7 food system.

8           However, our association does not oppose voluntary  
9 labeling provided it is consistent with U.S. law. We  
10 recognize that voluntary labeling means that FDA will be  
11 called upon to develop guidelines to ensure that such  
12 labeling is not false or misleading, and we would offer the  
13 following recommendations:

14           If FDA proceeds to develop guidelines for  
15 voluntary labeling, we recommend that it do so for voluntary  
16 negative labeling. That seems to be the source of consumer  
17 demand to date.

18           The NGFA recommends also that if FDA develops  
19 guidelines for voluntary labeling, it confine the efforts at  
20 this time to food products, not animal feed. The available  
21 scientific data, we think, is very clear and demonstrates  
22 that the proteins in biotech-enhanced commodities are fully  
23 digested by the animal and are not transferred to meat, milk  
24 or eggs.

25           Also, it is logical to assume that if FDA develops

1 guidelines for voluntary labeling it is going to need to  
2 develop some kind of criteria. That could result in FDA  
3 stipulating a tolerance, or it could result in FDA creating  
4 a detailed and cumbersome process and certification  
5 approach. Frankly, we think that both of these approaches  
6 are problematic. As a matter of principle, our association  
7 believes that procedures concerning the process used to  
8 ensure the delivery of commodities, substantially free of  
9 biotech-enhanced traits, are best left to contractual  
10 arrangements in the marketplace between buyer and seller.

11           This issue of voluntary labeling though does raise  
12 another important issue of interaction and cooperation  
13 between government agencies, in this case between FDA and  
14 USDA. If FDA develops guidelines for voluntary labeling it  
15 will be even more important that our industry have the tools  
16 necessary to detect the presence of biotech-enhanced traits  
17 in raw agricultural commodities. The NGFA believes it is  
18 the biotechnology firms and seed companies that bear the  
19 principal responsibility to develop new testing technology  
20 in the commercial marketplace that will quickly and  
21 accurately determine whether grains or oil seeds contain the  
22 biotech-enhanced events. We submit that USDA's FGIS, or  
23 Grain Inspection and Packaging Stockyard Administration,  
24 does have a role in developing a process for validating the  
25 tests and accuracy and repeatability of such testing

1 devices.

2           Finally, we believe there is merit in FDA's  
3 signaling its intentions on whether it plans to develop  
4 guidelines for voluntary labeling as soon as possible. We  
5 understand the pressure the agency is under, but we also  
6 understand that farmers today are trying to make decisions  
7 on the next planting season which is coming up very soon, in  
8 the spring of 2000.

9           We thank you again for the opportunity to comment  
10 today. We sincerely respect and appreciate what FDA is  
11 trying to accomplish in providing objective information on  
12 the food safety to the public. Thank you.

13           MR. LEVITT: Thank you very much. Our final  
14 speaker on the panel is Robert Cohen, founder and executive  
15 director of America's Dairy Education Board.

16           MR. COHEN: Hi, everybody. I have to apologize  
17 first, I don't have a prepared statement like the other  
18 panel members here. All I am going to give you are some  
19 facts.

20           I have a copy of the Federal Register. It says  
21 here, advertising this meeting, FDA is not aware of  
22 information that would distinguish genetically engineered  
23 food as a class from other foods. I am going to give you  
24 some information today, guys. The greatest controversy in  
25 FDA history was the approval process for Monsanto's

1 genetically engineered bovine growth hormone. We shouldn't  
2 be here today. We should not be in this room, and I  
3 shouldn't be here because in 1994 Congress had a Bill that  
4 was going to require mandatory labeling of all foods that  
5 were influenced by genetic engineering. And, I waited, and  
6 I got my congresswoman to co-sponsor that Bill; 181 Congress  
7 people co-sponsored that Bill.

8           You know what, I learned how Congress works that  
9 year because for six months they stalled the Bill; twelve  
10 members of the Dairy Livestock and Poultry Committee, they  
11 stalled the Bill until the 1994 session of Congress expired  
12 and the Bill died. And, I was so upset I investigated these  
13 twelve men and found that collectively they took \$711,000 in  
14 PAC money from companies with dairy interests, and four of  
15 the members of the committee took money directly from  
16 Monsanto.

17           We have a lot of political intrigue and some real  
18 science here -- we have science fiction. We have a  
19 combination of John Grisham, and we have a combination of  
20 Stephen King because Nikita Krushev said that what the  
21 scientists have in their briefcase is terrifying. I have  
22 some interesting things in my briefcase to share with you  
23 today.

24           When Monsanto made their genetically engineered  
25 bovine growth hormone, they noticed a couple of problems

1 right towards the end, right before approval. They noticed  
2 that laboratory animals were getting cancer, and they  
3 noticed that cows were getting mastitis, ulcers on their  
4 udders; they were putting more pus and bacteria into the  
5 milk. So, Monsanto arranged -- we heard from Dr. Maryanski  
6 this morning. Dr. Maryanski talked about the pure Food,  
7 Drug and Cosmetic Act. What he didn't tell you was that in  
8 1958 Robert Delaney, a Congressman from New York, put in a  
9 Delaney Amendment. It was named after him. The Delaney  
10 Amendment stated that if a food additive caused cancer it  
11 was not to be approved -- pretty good law, right?

12 Well, Monsanto got their attorney, Michael Taylor  
13 from the firm of King and Spaulding -- by the way, when they  
14 started in 1979 they groomed their attorney now in the  
15 Supreme Court, Clarence Thomas, the same law firm --  
16 Monsanto's attorney, Michael Taylor wrote and minimized the  
17 Delaney Amendment, he wrote a scientific paper that was  
18 published in The Journal of Toxicology -- lawyers, they  
19 write in law review journals but this lawyer wrote in The  
20 Journal of Toxicology a de minimis interpretation of the  
21 Delaney Amendment which became the new protocol, the new  
22 standard operating procedure at FDA. They minimized cancer.  
23 Michael Taylor was hired by the Food and Drug Administration  
24 and became the second most powerful man there, Monsanto's  
25 attorney. He wrote the standard operating procedures. In

1 other words, we see cancer; ignore it.

2 Margaret Miller, Susan Sechen, Monsanto's  
3 scientists, were hired by the FDA to review Monsanto's own  
4 research. Margaret Miller knew cows were getting mastitis.  
5 The first week at the FDA, December 3, 1989, she was given  
6 broad power -- and here is an effect of genetic engineering  
7 nobody has considered -- she knew cows were getting sick  
8 from the genetically engineered hormone; she changed the  
9 amount of antibiotics that farmers could have in their milk.  
10 She changed it from one part per million to one part per  
11 hundred million. This is a fact. She increased it by 100  
12 times.

13 There is a hero of mine in the audience, Michael  
14 Hanson from Consumers Union. Consumers Union tested milk in  
15 the New York Metropolitan area and found the presence of 52  
16 different antibiotics in milk samples. FDA published, on  
17 August 24, 1990, the first time ever in a peer-reviewed  
18 journal, in Science -- Science was started by Thomas Edison,  
19 in the 1880s -- they published a review of bovine  
20 somatotropin, BGH, the genetically engineered cow hormone.  
21 It that review there were seven tables from data. Five of  
22 those tables came from one study, authored by Richard  
23 Odaglia and Deslex. This is the famous 90-day study. Guess  
24 what, it was actually a study lasting for 180 days.

25 When I first heard about this in 1994, I flied a

1 Freedom of Information Act request for that study and I say  
2 from the data that the average spleen of a lab animal  
3 increased 46 percent. I called the FDA and spoke to Dick  
4 Teske and said, 46 percent? You said there were no  
5 biological effects. He said, that is not statistically  
6 significant. I said, well, let me see the raw data. He  
7 said, it is a trade secret. I called Monsanto. They  
8 laughed at me; they said it is a trade secret; you will  
9 never see it. I am smart. I filed a Freedom of Information  
10 Act request, but I didn't realize you can't find out the  
11 study.

12 I went to federal court. I said, Your Honor,  
13 spleen increase of 46 percent, that is leukemia. I met with  
14 FDA on April 21, 1995 and found out that this was actually a  
15 180-day study. In Canada they had the study. I have a  
16 letter here, an internal memorandum: This is to advise you  
17 that the copies of reports, letters, etc. for drug  
18 submissions have been stolen from my files. This was stolen  
19 from a scientist's file in Canada. They stole the second  
20 half of the 90-day study.

21 We have real science here. I am going to talk  
22 briefly about the real science because when Monsanto made  
23 this hormone they had to tell the FDA -- they had to draw a  
24 chart of every amino acid, the 191 amino acids. When FDA  
25 wrote their paper in Science magazine, they wrote that one

1 amino acid changed. It was a different hormone than the  
2 naturally occurring one. At the same time, somebody hired  
3 C. Everett Koop to come and say that genetically engineered  
4 milk and good old wholesome milk is indistinguishable.  
5 Well, it wasn't.

6 Well, something happened to the hormone that  
7 Monsanto made. The FDA said there was one change; the end  
8 amino acid was methionine. But if there was a change in the  
9 middle of the protein there could be disastrous results.  
10 They cited Jerome Moore. I got Jerome Moore's paper. He  
11 said if there is a middle of the chain protein change there  
12 could be Alzheimer's, or sickle cell anemia, or diabetes.  
13 Monsanto, four months after the hormone was approved, one of  
14 their scientists, Bernard Violand, published, in the July 3,  
15 1994 issue of the journal Protein Science evidence that  
16 Monsanto made a mistake. Oops! Monsanto created a freak  
17 amino acid. Did you ever see that movie, "The Fly" with  
18 Jeff Gold where the fly comes in and he becomes half human  
19 and half fly? Monsanto created a freak amino acid.  
20 Monsanto admitted it but didn't tell the FDA. Gentlemen,  
21 the hormone that is on the market today is different than  
22 the one you tested for seven years.

23 Monsanto spent 500 million dollars, submitted  
24 55,000 pages of information to you, learned late in the  
25 process that they created a freak amino acid. That is what

1 was tested on laboratory animals, and it didn't matter  
2 because FDA said to Monsanto, you know something, it is safe  
3 because when you pasteurize milk you destroy the hormone.

4           They performed this research up in Ontario by Paul  
5 Groenwegen, and I got his study. To this day, FDA thinks --  
6 it is on your web page -- that ninety percent of the bovine  
7 growth hormone is destroyed by pasteurization. What Paul  
8 Groenwegen did, working with Ted El Sasser and Brian  
9 McBride, two Monsanto scientists, was to pasteurize milk for  
10 30 minutes at 162 degrees Fahrenheit, and when I read that I  
11 said, wait a second, milk is pasteurized for 15 seconds at  
12 that temperature, not 30 minutes. They intentionally tried  
13 to destroy the hormone. They only destroyed 19 percent of  
14 it. Somebody lied.

15           At that moment, FDA said to Monsanto because you  
16 destroy it by pasteurization, you don't have to do further  
17 toxicology studies. You don't have to develop a test for  
18 this hormone in milk. And, you know what, it is now safe to  
19 drink. They developed a zero day withdrawal; they  
20 determined it was safe to drink.

21           We have a lot of political intrigue here. We have  
22 an interesting situation with revolving door policy at FDA.  
23 I mean, where is the ex-FDA commissioner? Guess who he is  
24 working for. He is working for Monsanto --

25           MR. LEVITT: Mr. Cohen, I need to jump in. I

1 think in fairness of time and the fact, as I think you know,  
2 this panel is supposed to be addressing labeling --

3 MR. COHEN: Yes, I know, but we have a labeling  
4 issue here. We have a right to know. I listened to  
5 comments here about multi-faceted educational efforts we  
6 need. That is called brain-washing. I don't want a multi-  
7 faceted educational effort; I want a double helical  
8 structure on a piece --

9 [Applause]

10 -- of food that I am going to buy in the  
11 supermarket because I have a right to know, because the  
12 bottom line is mistakes were made, and when I hear from the  
13 American Dietetic Association, I want to remind you that  
14 Monsanto gave you \$100,000 to set up a toll-free hotline  
15 about the bovine growth hormone. Mistakes were made. We  
16 have political intrigue here, and the bottom line is we have  
17 a right to know what we are eating. Thank you.

18 [Applause]

19 MR. LEVITT: Thank you. Before we get to the  
20 questions -- I will take a little responsibility for this, I  
21 note that I neglected to read at the beginning of the panel  
22 and I will read it now for the record and to kind of set the  
23 stage for the questions.

24 There were three questions that were in the  
25 Federal Register devoted to the public information labeling

1 which we would like to try to get addressed as we get into  
2 the questions. The first one is should FDA's policy  
3 requiring labeling for significant changes, including  
4 changes in nutrients or the introduction of allergens, be  
5 maintained or modified? Should FDA maintain or revise its  
6 policy that the name of the new food be changed when the  
7 common or usual name for the traditional counterpart no  
8 longer applies? Have these policies regarding the labeling  
9 of these foods served the public?

10 So, that question really goes to when FDA  
11 currently requires labeling, is that the right thing to do?  
12 That is what that question says.

13 Number two, should additional information be made  
14 available to the public about foods derived from  
15 bioengineered plants? If so, what information? And, who  
16 should be responsible for communicating such information?

17 So, that is do we need to do more?

18 Three, how should additional information be made  
19 available to the public, for example, on the Internet,  
20 through food information phone lines, on food labels, or by  
21 other means?

22 Mr. Lake addressed some of that in terms of when  
23 he made his opening comments. So, I just wanted to get  
24 those kind of on the record and kind of, you know, focus us  
25 a little as we get into the questions and answers.

1 In fairness to the FDA people who have sat here  
2 patiently all day, I am going to start with the people who  
3 did not get to ask questions this morning. So, we will  
4 start with Catherine Copp. We will go to Mr. Lake, and then  
5 we will try and see if we can make one run through.

6 **Panel Answers to FDA Questions**

7 MS. COPP: Thank you, Joe. I would like to ask  
8 the panel, and I think there are several members who are  
9 particularly well suited to address this question, about  
10 helping us get some ideas about the means to assess the  
11 misleading or not misleading nature of labeling, primarily  
12 voluntary labeling. In particular, my question is this, if  
13 the agency were to support a policy of voluntary labeling  
14 that would allow something like GMO-free or not genetically  
15 engineered, what would be a credible way to assess consumer  
16 understanding of that term and avoid what I believe Mr.  
17 Frank referred as an implied claim of superiority? So, what  
18 kind of information can be utilized to assess that and rule  
19 out, frankly, that implied claim.

20 Maybe, Mr. Teisl, you could start because you did  
21 talk about consumer perception? Thank you.

22 MR. TEISL: Yes, typically when you provide  
23 information on a food label you need to have a large enough  
24 percentage of the U.S. population to understand what it is  
25 the label is talking about. If it is information that is

1 new or confusing or vague several things can happen. One is  
2 the label doesn't do anything. You know, if a label says  
3 something and most people don't know what that means, well,  
4 you are not going to get much of a reaction.

5           Alternatively, what could happen is that people  
6 will refer back to either their prior expectations of the  
7 food or just relate to what they have heard in the media.  
8 Okay? Not just the media but alternative sources of  
9 information.

10           For example, if I was going to say what about  
11 putting an irradiation label on food, I think most Americans  
12 don't really know what irradiation is. And, we have  
13 actually done some research where we have looked at people's  
14 reaction to it, and you have two reactions. Some people  
15 say, oh, well, that means like nuclear power stuff, and  
16 things like that, and I don't like that. On the other hand,  
17 some people say, oh, well, that reduces the level of E. coli  
18 in food. I heard that and I like that.

19           But here, with respect to biotechnology, you could  
20 have really quite a range of information being put out, and  
21 all truthful information. I mean, you are going to get some  
22 information in the media that says, you know, rBGH promotes  
23 ulcerations in cattle udders, and things like that, and that  
24 has some health concerns. You will also see that, well, you  
25 know, they are developing cauliflower with increased levels

1 of beta carotene and that is good for cancer risk reduction.

2           What happens there is that if you slap just a  
3 biotechnology or genetically engineered labeled on a food,  
4 you know, you are going to get different reactions from  
5 different people not based on what their perceptions are but  
6 given what kind of information they have already picked up  
7 on. To me, if you just provide a GE label, it is not so  
8 much that it is misleading but it probably will not reduce  
9 uncertainty in consumers' minds about what the food is but  
10 will, actually, possibly increase the uncertainty that  
11 people have because, you know, in the background over the  
12 last several years or months they have heard all these  
13 different things about genetic engineering.

14           So, is it misleading? In a sense it is misleading  
15 because what the consumer really wants to know is how does  
16 this affect me, and how does this affect the environment,  
17 how does this affect the health of my family and, if  
18 anything, it is those consequences that need to be conveyed  
19 directly, particularly with respect here because there is a  
20 diverse array of consequences possible. So, really the  
21 thing is that if you just slap a GE label what you are doing  
22 is you are requiring the individual to go out and learn  
23 about it. Even after they have learned about it, they may  
24 be even more uncertain about the food product than they were  
25 in the beginning. So, does that answer your question?

1 MR. COHEN: May I comment on that?

2 MR. LEVITT: Yes, please.

3 MR. COHEN: I like simple and stupid. I am  
4 drinking some simple and stupid water here and there is a  
5 kosher label on it; I know what it means. I want to see a  
6 double-helical structure on everything that is genetically  
7 engineered without an explanation. I just want the right to  
8 know. Monsanto, out there, you are going to win because if  
9 you put a double-helical structure on everything that is  
10 influenced by genetic engineering, tomorrow wake up and  
11 ninety, ninety-five percent in your supermarket are going to  
12 have that label. Then, the public's perception is going to  
13 be, my goodness, it is not so bad.

14 For the record, I may talk against Monsanto and  
15 genetically engineered milk, I believe that one day genetic  
16 engineering is going to solve a lot of our problems. I  
17 believe in genetically engineered foods. I watched a robot  
18 in "Forbidden Planet" make a hundred bottles of whisky. I  
19 grew up on this stuff. I don't believe in mistakes, but I  
20 believe in genetically engineered foods. You can win. You  
21 are paranoid; you are scared that the public is not going to  
22 buy your product if it has a label. Do it for all products.  
23 Today's New York Times said that there were between ten and  
24 thirteen million species of life on this planet. You are  
25 not going to be able to monitor each one and the cost is

1 going to be prohibitive. Just put a label on it so we know.

2 [Applause]

3 MR. LEVITT: Would other panelists like to address  
4 the question of consumer understanding of the labeling?

5 DR. KEITH: Just briefly. Of course, we support  
6 voluntary labeling not mandatory but, in my mind, the best  
7 thing you could do is establish some kind of a standard.  
8 The grain handling system, the grain marketing system cannot  
9 deliver grain with one hundred percent purity of either  
10 biotech or non-biotech. So, there has to be some reasonable  
11 tolerance established if we are going to go to that kind of  
12 a standard. Over time, the public understanding will grow  
13 as to what that means. For those consumers to whom it is  
14 important, they will have a choice. I think that is what we  
15 would stand behind. We need to serve consumers. We want,  
16 as an industry, to have access to the maximum number of  
17 consumers. To do that, you have to give choice.

18 MR. FRANK: A couple of points, first of all,  
19 FDA's policy with regard to food safety aspects -- I think  
20 your labeling policy needs to support your food safety  
21 policy. So, if you have concluded that these products are  
22 GRAS, at least some of them, then you have to have a  
23 labeling policy which, in essence, concludes that a  
24 statement that suggests superiority or that suggests that a  
25 genetically modified food is inferior or unsafe, that would

1 be misleading because I think that would run contrary to  
2 your conclusion that the product is GRAS.

3 MR. LEVITT: Excuse me, so when you say -- correct  
4 me if I am wrong, you are supporting voluntary labeling, how  
5 do you have a voluntary label that says something like GM-  
6 free without it being misleading under that paradigm?

7 MR. FRANK: I don't think GM-free by itself  
8 necessarily would be misleading. With regard to BST, you  
9 required, and the court upheld, the conclusion that there  
10 had to be another statement that there is no evidence that  
11 BST-free is any safer or necessarily any different than milk  
12 that was coming from animals that were given BST. Now, that  
13 is the conclusion that you reached in that case and that  
14 certainly would be a good precedent.

15 A couple of other points, it is almost impossible  
16 to confront the issue of the right to know. I mean, do you  
17 want a rose in your garden? Why, of course you want a rose  
18 in your garden. Would you like a hot fudge sundae? Of  
19 course. Would you like it to be fat-free? That is even  
20 better. So, it is really hard to confront or to respond to  
21 people who want more information.

22 So, at least this early you have to say to  
23 yourself if the information is at least marginally useful  
24 people should have a right to it. But let's look at fish  
25 for a second. He wants to know whether or not these things

1 have genetically modified organisms in them. Well, salmon,  
2 is it from a river near Seattle or is it from a river in New  
3 York? Well, I want to know because it matters to me because  
4 the water may be different. But salmon is not labeled that  
5 way simply because it is just not important enough; it does  
6 not rise high enough in the interest scale. Now, if someone  
7 is proud of salmon from near Seattle, they will say so.

8           What state does it come from if it is meat? Is it  
9 Kansas beef or is it Nebraska beef? Now, that is important.  
10 And, if you are a farmer from Kansas you might want to buy  
11 Kansas beef, and if Kansas beef farmers are proud, then they  
12 will label their products Kansas beef, as long as it is  
13 true.

14           So, voluntary labeling allows people to extoll the  
15 virtues of their product. They can say that it is GMO-free.  
16 The question is does this rise to the level where it should  
17 be mandatory? And, I say no because you have determined  
18 basically that these products are safe. Only if you have an  
19 allergenicity problem, if you have a nutritional problem, or  
20 a significant quality difference do you require the  
21 labeling.

22           The final model I want to put on the table, and  
23 this goes back to my crazy thought that combined consumer  
24 education may be a good idea where consumer groups and  
25 industry and government come together -- pasteurization --

1 now, there aren't too many people in this room who drink  
2 milk that is not pasteurized, if you drink milk at all, but  
3 when pasteurization first came out the public was totally  
4 alarmed. The Robert Cohen's of the world ran around and  
5 said, "my God, we're heating milk; we're killing milk; we're  
6 making it unsafe for our babies." There was a huge hoopla  
7 about pasteurization, and that probably was a decent thing  
8 to do because it was a new technology and people weren't  
9 that comfortable with it. Now pasteurization is not only  
10 welcomed, it is demanded. Ninety-seven, ninety-eight  
11 percent of the milk in this country, if you are willing to  
12 drink the milk at all --

13 MR. COHEN: I am not.

14 -- but the vast majority of the milk in this  
15 country is pasteurized and consumers demand it. Why?  
16 Because they are educated.

17 The other end of that is irradiation, which some  
18 people call cold pasteurization. Now, the public, for the  
19 most part, is just beginning to understand the benefits of  
20 irradiation. Some people would prefer not to have it, but  
21 it can make your meat and poultry, for example, even safer  
22 than it already is. But people are very concerned about  
23 buying something labeled "irradiated." It is because the  
24 environment out there is not yet hospitable to that type of  
25 term.

1           What I am suggesting is that consumer education,  
2 along with a voluntary labeling program may help consumers  
3 better understand what GMOs are, and they may deduce they  
4 don't want them, or they may decide that, indeed, they are  
5 positive. But, we do need some education here.

6           MR. LEVITT: Thank you. Any other comments on  
7 this question, please?

8           DR. CODY: I think that labeling, voluntary or  
9 mandatory is not going to be useful without public  
10 education. With public education, the public can contribute  
11 to this dialogue. Without education it is very difficult to  
12 make a contribution, to make your wishes known. Also, with  
13 education consumers can make personal food choices with more  
14 confidence. Whether they choose this food or this food,  
15 they know why they have made those choices. So, I would  
16 submit that labeling without education is really not  
17 effective, regardless of how we measure it.

18           MR. CAPLAN: Just very quickly, first of all, the  
19 issue of voluntary labeling is somewhat moot because  
20 voluntary labeling is already allowed. Products can be  
21 labeled as GE-free currently. So, whether or not to  
22 establish a regime of voluntary or mandatory is somewhat of  
23 a false dichotomy because voluntary labeling is allowed and  
24 the question should be when are we going to institute a  
25 mandatory labeling regime?

1           The question of information to consumers is  
2 somewhat troubling to me because at what point do you say  
3 that all information -- for example, should consumers have  
4 to know what the USRDA for vitamin C is in order to have  
5 that be labeled on a product? There shouldn't be exams as  
6 one enters the supermarket in order to determine what  
7 information they can or cannot be provided with. I think  
8 the reality is that consumers do know about this subject  
9 and, when asked, do want to know about this information.

10           So, in terms of what kind of information they are  
11 or are not entitled to, I think given that the American  
12 public has repeatedly asked for this information, I think  
13 they should be allowed to. Finally, I would just point out  
14 that the label that is current proposed on the Bill in the  
15 U.S. House for labeling is decidedly neutral. It simply  
16 states whether or not a product does contain genetically  
17 engineered food. There is no value judgment there. It is  
18 very straightforward. It is not misleading. It is not  
19 vague.

20           MR. LEVITT: Thank you.

21           [Applause]

22           I will turn to Mr. Lake.

23           MR. LAKE: Thank you. In the opening remarks a  
24 couple of the panelists talked about a desire to have FDA  
25 set standards, so I am going to challenge each of the

1 panelists to give us some of your thinking about that.

2 Again, I am going to start at this end and work on down.

3           The question really arises out of a couple of the  
4 answers really to this last question which suggested a  
5 problem that I have heard before, and that is that things  
6 may be at a point today where it is literally not possible  
7 to guarantee that anything is absolutely free of genetically  
8 engineered material to some small extent.

9           So, my question then, and I think this is  
10 particularly important if there is to be a lot of voluntary  
11 labeling of the GM-free variety, what is the appropriate  
12 standard for a cut-off for genetically free? I asked this  
13 question in Chicago and got answers ranging from a tenth of  
14 a percent to three percent. Let me ask each member of the  
15 panel what your thoughts on that would be.

16           DR. TEISL: I am not a biologist or anything --

17           MR. LAKE: From a consumer perception perspective.

18           DR. TEISL: Well, the thing is, of the research I  
19 have seen, no one has really asked that question. So, it is  
20 hard for me to say what most consumers think about this. I  
21 don't know what research you are quoting, but from several  
22 of the studies that I have looked at in U.S. markets,  
23 particularly a New Jersey study, people don't have a clear  
24 understanding of what genetic engineering is, particularly  
25 when compared to -- they don't even have a clear

1 understanding about traditional plant breeding, much less  
2 genetic engineering. So, without, you know, doing some  
3 really directed research where you first provide that  
4 information to survey participants then, after you have  
5 given them the information ask them, okay, now that you know  
6 this, what standard would you set at? I don't know of  
7 anyone that has done that yet. So, even if someone has  
8 asked it in a general survey, I don't think that number  
9 would mean anything, to tell you the truth.

10 DR. CODY: First of all, I don't know what you  
11 would measure. If you look at a commodity in the  
12 marketplace you may have a mixture of soybeans that have  
13 come from this plant and this plant. If you can't tell  
14 which one is genetically bioengineered, then I think what  
15 you are looking at is a label that is similar to some of the  
16 labels that we see for fats and oils and for candies. So,  
17 you might see an oil that is labeled "may contain" soybean  
18 oil, cotton seed oil, peanut oil because you may have a  
19 mixture and, because you don't know, you label with all of  
20 those adjectives. You might also see a label that is  
21 similar to some of the candy labels now that say "may  
22 contain peanuts" not because the candy contains peanuts but  
23 there may be peanut dust from a previous line that has  
24 contaminated the product and may be an allergen for people  
25 who are reading that label. So, I think, you know, without

1 being able to make a measurement it is hard to decide what  
2 amount would trigger a label declaration.

3 MR. CAPLAN: My understanding is that technology  
4 currently available already allows us to detect the content  
5 of genetically engineered material in the range of one-tenth  
6 to one one-hundredth of one percent, and I expect that as  
7 the demand for products that do not contain genetically  
8 engineered material increases, our ability to further refine  
9 that technology will improve. So, I would advocate for a  
10 threshold that is as low as possible, as low as  
11 technologically possible.

12 MR. FRANK: I have written down five reasons why  
13 you might want something on a label. The most important I  
14 wrote down is food safety. The second would be  
15 allergenicity. The third would be religious reasons. The  
16 fourth would be political reasons, and the fifth would be  
17 pure curiosity.

18 It strikes me that the first two should definitely  
19 prevail -- food safety or allergenicity. So, obviously, if  
20 there is a food safety problem with one of these products  
21 FDA is going to move forward and do something about it.  
22 Allergenicity does not require a product to come off the  
23 market. Peanuts cause allergies and we are not banning  
24 peanuts, so they should be labeled. So, if it is  
25 allergenicity, that should go as low as you can go.

1           Then, for religious reasons, I guess that can be  
2 quite important to people. So, the level of detectability,  
3 how well can you detect something there that people would  
4 care about from a religious standpoint?

5           For political reasons -- I have less sympathy for  
6 that, and for pure curiosity I have no sympathy at all.

7           [Laughter]

8           So, it strikes me that the rule should be the  
9 level of detectability if you want to make a "free" claim.

10           MR. LEVITT: Thank you. Any other comments on  
11 this?

12           DR. KEITH: I would be concerned doing it on the  
13 basis of the level of detectability because just because you  
14 can detect it doesn't mean it is practically possible. The  
15 tighter you ratchet it down, the more impractical it is for  
16 someone to deliver that product consistently to the  
17 marketplace and actually provide a product that is  
18 relatively biotech free.

19           MR. COHEN: FDA approved Monsanto's hormone as the  
20 label, and the people at the FDA, the commissioner, said it  
21 is indistinguishable from normal milk. It doesn't work; it  
22 is not bioactive. Many years later Canada reviewed it and  
23 they said that the ninety-day rat study submitted by  
24 Monsanto showed that rBST can be observed intact from the GI  
25 tract following oral administration. We learned new things

1 about thalidomide --

2 MR. LEVITT: Right, so what level of  
3 detectability, in answer to the question?

4 MR. COHEN: The answer is women, in your lifetime  
5 you make the equivalent of one tablespoon of estrogen. That  
6 is all. It works on a non-molecular level, many of these  
7 hormones, and we react to chemicals. You don't want to take  
8 just one nanogram of LSD; you will be in the sky with Lucy  
9 with diamonds. The bottom line is that if it has a product,  
10 keep it simple because you are looking at something that you  
11 are going to have twenty million different rules -- make one  
12 rule. If it has any genetically engineered product in it,  
13 put a double-helical structure on it and then we have a  
14 right to know. And, it is simple because -- you know this,  
15 tomorrow everything is going to have a label, or almost  
16 everything, and you solve the problem and the public will  
17 then accept it. Monsanto, you will win but give us the  
18 right to know.

19 DR. TEISL: May I make one point?

20 MR. LEVITT: Yes, one follow up.

21 DR. TEISL: Yes, one thing that you have mentioned  
22 twice is that you want to keep it simple. The thing is, in  
23 labeling research what people want is not necessarily  
24 simple. What you are advocating is let's get rid of the  
25 nutrition panel on this thing and just call it "good."

1 MR. COHEN: No, I am not arguing that.

2 DR. TEISL: That is simple but it is vague.

3 MR. COHEN: Genetic engineering, radiation, kosher  
4 -- these are different concepts here. It is a new era. We  
5 have the Internet out there which has pretty much leveled  
6 the playing field, and there are people who are not happy  
7 about the way things have gone.

8 The fact that Robert Lake put me on this panel  
9 shows that there is a desire to listen to the public comment  
10 and to take the best shot at genetic engineering. I believe  
11 in the stuff. Don't let me fool you, I believe in genetic  
12 engineering.

13 My family drove in the summer through the Midwest  
14 and we ate the BT corn because it is a protein. I don't  
15 think it is a problem. I have studied at the issues; I have  
16 looked at the research. I am not going to have them drink  
17 the milk because I have also studied the research. If I  
18 release what I have here, the second ninety days, this is  
19 trade protected information and I would go to jail for  
20 fifteen years. I am not going to release it, guys. But,  
21 the bottom line is we have a right to know whether it has  
22 been genetically engineered. Remember thalidomide.  
23 Remember the lessons we learned with diethylstilbestrol.  
24 Half of the things FDA approved, we learned a surprise  
25 within six months. Sometimes it is a good surprise,

1 sometimes it is a bad surprise. Just give us the right to  
2 know.

3 DR. TEISL: But just to respond to that, you may  
4 understand the research in terms of the biology and stuff  
5 like that, but if you look at the consumer research, the  
6 labeling research, the information dissemination research,  
7 it is not true that people just want a simple good or bad,  
8 or this or that. They want to know -- here are the things I  
9 care about: I care about the safety of my food. I also  
10 care about the environment. You know, I want to know if my  
11 tuna is dolphin safe or not. I don't want to know if it is  
12 just good for the environment.

13 For the last several years I have been focusing  
14 solely on environmental labeling of a lot of different  
15 products, and people do not react, nor do they want, nor do  
16 they trust a label that is just some sort of seal of  
17 approval that says, oh, this is environmentally friendly or  
18 this is good for you. What they think of that, is they  
19 think -- pardon the expression -- that it is a bunch of  
20 marketing BS. If you truly want a genetic engineering label  
21 to work, you are not going to just slap GE on the product  
22 because the chances are people are going to say, "huh?  
23 What's that? That doesn't mean anything to me."

24 If you want, with it is for environmental reasons  
25 or food safety reasons, an information piece on a product to

1 actually affect consumer behavior, you have to tell them the  
2 information that is relevant to them. So, what you first  
3 have to do is find out what do consumers care about with  
4 respect to this food or that food.

5 MR. COHEN: But, we are about to find out because  
6 I am going to ask them. We have some pretty angry people  
7 out there; I spoke to some before. Would you be content if  
8 the FDA, on every food --

9 MR. LEVITT: Again, we will have a lot of people  
10 that --

11 MR. COHEN: -- would you be content with a warning  
12 label?

13 [Applause]

14 DR. TEISL: That is three of them.

15 [Laughter]

16 What you need to do --

17 [Applause]

18 MR. COHEN: A simple label -- raise your hands,  
19 anybody. All those not in favor of a simple label, raise  
20 your hand. Okay, it is split.

21 MR. FRANK: The problem with the double-helix and  
22 the redura symbol more than anything else, is they are more  
23 of a political statement than an information statement, and  
24 I am not sure people fully understand them, and they are  
25 used for political purposes. I mean, I agree that you need

1 to understand what goes on there, Joe.

2 MR. LEVITT: Next, I will turn to Mr. Hubbard.

3 MR. HUBBARD: Let's talk about a non-label. The  
4 food label that the FDA developed in the early '90s has been  
5 very popular with consumers, and the agency has been fairly  
6 protective of making quick and easy changes to that.

7 If, however, a consensus were to emerge among the  
8 government, consumers and industry that people want to know  
9 about GMOs and need to know but, yet, not put it on the  
10 actual package itself but provide the information through  
11 alternative means, such as the Internet and 800 numbers,  
12 would that accomplish the objective that consumers are  
13 looking for, or would that make it too difficult?

14 MR. COHEN: It is my perception that your  
15 perception is that the press and the small group of fanatics  
16 are stirring up emotions on this issue. That is my  
17 perception and I see at least one head shaking over here,  
18 yes. You believe there is no credible research despite the  
19 fact that Monsanto created the freak amino acid. We have  
20 evidence that mistakes were made. That is all I want to  
21 see, no more mistakes. I think the FDA should create an  
22 office called the office of the devil's advocate and look at  
23 this research and interact. If it is good and safe, great;  
24 I am all for it. I believe in it. But if you make a  
25 mistake, correct it. At least label it and identify it and

1 give us a right.

2 MR. LEVITT: I will tell you how I interpret that,  
3 I interpret that as you don't like the idea of information  
4 outside the label. But it would be useful if we tried to  
5 answer a little more directly to the questions asked,  
6 especially as we are repeating things that have been said  
7 before.

8 MR. COHEN: You are correct, I don't want to see a  
9 lot of information on a label. It is too confusing. That  
10 is what many people want to do, confuse people. Keep it  
11 simple.

12 MR. LEVITT: Okay. Do other panelists want to  
13 speak to the issue of should there be a way to provide this  
14 information to the consumers outside of the product label  
15 itself, through other available mechanisms such as the  
16 Internet, such as brochures or literature, or 800 numbers?  
17 If so, how would you go about designing that?

18 DR. CODY: I would like to respond to that.

19 MR. LEVITT: Please.

20 DR. CODY: The big answer is yes, we would like to  
21 see better information, more information, accessible  
22 information. Having the information available in scientific  
23 literature is not enough. Most consumers in the United  
24 States do not have access to that literature and, if they  
25 did, reading it is not an option; it is too complicated.

1 What we would like to see is information that is accessible.  
2 That means understandable. It means that people need to  
3 have access to information on more than one level. You may  
4 have scientists and health professionals and others with  
5 science backgrounds who get this much information but, in  
6 order to use that information, they have to know how to  
7 communicate it to people who have specific and general  
8 questions. That means that if I call a hotline and I am  
9 concerned about catsup, that I have someone who can address  
10 my concern within the context of catsup. They are not going  
11 to give me a thirty-minute lecture on the history of  
12 bioengineering. They are going to be able to answer my  
13 question and then perhaps take me a little bit further by  
14 sending me to a web site, sending me to a pamphlet, telling  
15 me somebody else I can contact.

16 But that becomes cyclical. There are going to be  
17 people who start at the Internet and need to know how to  
18 send their question to someone. That is easy enough to do  
19 now. But most consumers are not able to take the  
20 information directly from the research literature. They are  
21 not able to take it from a very general statement to the  
22 specific, and answering questions takes more than just  
23 putting information out there. Thank you.

24 MR. CAPLAN: I would absolutely support the  
25 dissemination of more information about foods produced

1 through biotechnology through the Internet and through  
2 brochures but it is imperative that does not serve as a  
3 substitute for labeling, particularly as the vast majority  
4 of people do not have access to the Internet and would never  
5 be able to access that information, nor do I look forward to  
6 the prospect of people being issued a cell phone as they  
7 walk into the grocery store to call as they walk from  
8 product to product. I think information is useful. I think  
9 it should be out there, just as I support the provision of  
10 the food quality and protection act that has never been  
11 implemented, which was to provide information to consumers  
12 about pesticides on foods. I do think more information is a  
13 good idea, but I don't think it should substitute for  
14 labeling.

15 MR. FRANK: I knew that my brethren from the  
16 University of Michigan and I would finally agree on  
17 something. More information is sorely needed. I mean,  
18 right now -- and I think the industry deserves some blame  
19 for this; I think FDA deserves some blame for it -- is that  
20 there has been virtually no consumer buy into these  
21 products; I am not sure consumers know what they are.  
22 Having FDA take the lead, maybe with USDA and EPA, with a  
23 fight-back type program -- it doesn't have to be propaganda;  
24 not everything about GMOs is positive; some have failed but  
25 some are wonderful. I think as Carol said this morning, if

1 we come out with a rice product that has vitamin A and iron  
2 in it that could help, you know, serve some of the needs in  
3 Asia, I think the consumers will gravitate to these  
4 products. So, consumer education, with you taking the lead  
5 in your magazine, on your web site -- I saw Donna Matthews  
6 here this morning with Giant Food. They have done a  
7 wonderful job of doing brochures at the front of their  
8 stores. You know, maybe the wholesalers who I work with or  
9 the retailers could take the lead and do some brochures.  
10 But people really don't have any idea what GMOs are, and the  
11 press has been fairly sensational about it so what they are  
12 reading is not terribly positive.

13 MR. LEVITT: Was there one other comment? You  
14 want to say one more thing?

15 DR. TEISL: There was some confusion in my mind  
16 exactly what you meant by what other information do you  
17 want. Do you want information out there related to a  
18 particular food product that is on the label? Is that what  
19 do you mean, or are you just talking about general  
20 education?

21 MR. HUBBARD: I think we are talking about a  
22 general approach, but let's say you have a given consumer  
23 who is concerned about GMO foods and wants to know that, and  
24 various web sites, 800 numbers, various other kinds of  
25 information other than label can get them there -- they can

1 go to their cereal manufacturer or their bread manufacturer  
2 or whatever, and learn where the GMO-free products are and  
3 then go purchase those, is that a consumer benefit? Is that  
4 helpful as opposed to having literally millions of packages  
5 with a label on it that tell everyone, including many people  
6 who don't care to know this piece of information, would that  
7 be a useful option for FDA to examine?

8 DR. TEISL: Well, I have a couple of comments.  
9 One is that there is a distinction between information that  
10 is provided on a label, where the benefit there is to allow  
11 consumers to make comparisons across products in terms of  
12 some sort of quality attribute, which is inherently  
13 different than an educational piece.

14 Now, one approach, because some of these issues  
15 are so complicated, is that if a product were labeled that  
16 it has a genetically modified organism in it, blah, blah,  
17 blah, go to www. to learn more. If that approach is used, I  
18 think that is okay as long as the information is two-fold on  
19 that site. One is sort of general information about GMO  
20 but, if it is supposed to be linked to the label, that  
21 information has to link to that food product somehow so that  
22 if a consumer goes to that web site -- what they want to  
23 know is how is that product different over and above just  
24 some sort of general information about genetic engineering.

25 The other thing that I am a little worried about

1 is that let's say FDA decides, okay, we are going to go  
2 start putting information about genetically engineered  
3 foods, blah, blah, blah, on the web, my concerns is that  
4 then we are going to be here a year or two from now  
5 debating, well, you know, the information you put on the web  
6 is not real; it is not supported by science, blah, blah,  
7 blah. Then you start getting into this controversy of what  
8 side are you taking. Are you taking Monsanto's side? Are  
9 you taking what the pure science says? That sort of thing.  
10 I mean, if I were a public policy official I would be a  
11 little concerned about deciding what types of information  
12 are going to be placed in some sort of information piece.

13 DR. LEVITT: The next question is from Steve  
14 Sundlof.

15 DR. SUNDLOF: Thank you. I heard Dr. Keith say  
16 that if there is labeling, whether it is voluntary or  
17 mandatory, there needs to be some verification method to  
18 determine the truthfulness of that labeling. The charge was  
19 that that responsibility should fall on the companies that  
20 develop biotech compounds. Short of actually developing  
21 analytical methods to detect genetically engineered  
22 organisms, are there other kinds of programs that you could  
23 envision which would give some assurance that the labeling  
24 was truthful?

25 MR. COHEN: I would like to answer that. Leave it

1 up to the manufacturer to put a label on. If you find out  
2 they are not telling the truth, you fine them. You take  
3 their food off the market. That is going to be a pretty  
4 good way to keep them honest.

5 I went to your website. I went to FDA's website  
6 before I came here. I wanted to see information, what you  
7 had there on the bovine growth hormone. August 22, 1990,  
8 the Journal of the American Medical Association published a  
9 review, two independent doctors, of this hormone, David D.  
10 Barbano and Michael Daviday. David Barbano is the man who  
11 has written, on your website, a complete review of the  
12 hormone.

13 When I went and I pulled that journal article, I  
14 found out that David Barbano worked for Monsanto. So when  
15 you talk about information on the Internet, how are we going  
16 to monitor what is going on? The answer is, monitor it by  
17 hoping that companies put the fact, the truth, that they  
18 label it.

19 If somebody blows the whistle on them and you find  
20 out they are not telling the truth. It is up to you. You  
21 have been there pretty good as a regulatory agency. If  
22 somebody lies to you, fine them.

23 DR. KEITH: Dr. Sundloff, I think it would be wise  
24 to put the burden back on the companies that want to make  
25 the claim and ask them, maybe, to submit periodic data on

1 their compliance with that. We would expect any food  
2 company that delivers a product to the marketplace that  
3 wanted to label it as such would stand behind that in many  
4 other respects and would voluntarily do that.

5 It is in their interest to do what they say they  
6 are doing and for their customers. So I would think you  
7 would get some very good voluntary compliance with that.

8 MR. FRANK: I don't have any answers on what  
9 analytical method would be appropriate, but you have got a  
10 precedent with regard to health claims and nutrient content  
11 claims for food. The responsibility lies with the company.  
12 They don't have to periodically submit anything but FDA,  
13 periodically, you take samples when you have enough  
14 resources to do stuff like that, and you test products and  
15 you have a continual program of doing that.

16 I can guarantee you if someone comes out with a  
17 GMO-free version of a breakfast cereal that companies who  
18 don't have a GMO version will go have that breakfast cereal  
19 tested. The competitive market will address that issue and  
20 you will be getting a direct or an indirect communication  
21 if, indeed, it is not GMO free.

22 In terms of the analytical methods, that would  
23 have to be left to scientists.

24 MR. CAPLAN: I would simply add that there would  
25 need to be a setup so that farm products can be tracked

1 throughout the process with verification and periodically  
2 there would need to be analysis as to whether or not  
3 labeling claims were truthful. That is something that can  
4 be easily accomplished and should be in place to assess  
5 whether or not labeling claims of GE-free are, in fact,  
6 accurate, which is something that could easily be done as is  
7 being demonstrated abroad.

8 MR. LEVITT: We will skip over Ms. Copp and jump  
9 to Dr. Maryanski.

10 DR. MARYANSKI: Thank you. I think I would like  
11 to hear from the panel a little bit about regardless of  
12 whether labeling were done on a mandatory basis or a  
13 voluntary basis, we have to think about what foods are going  
14 to be labeled. If we think about the diversity of foods in  
15 the grocery store--we have, of course, fresh fruits and  
16 vegetables, apples, pears, tomatoes and so forth, potatoes.

17 We also have many processed foods, the ingredient  
18 label. There are a number of countries around the world  
19 that are thinking about labeling, either have implemented  
20 regulations or have them under consideration. I think that  
21 what appears to have happened is that there is a sort of an  
22 easy decision in the beginning that we should provide this  
23 information to consumers, somehow, but then the reality  
24 begins to set in when the labeling is actually done.

25 So I guess what I would like to hear is if one is

1 to provide information through labeling, how would one think  
2 about the kinds of foods that really would be labeled taking  
3 into account the spectrum of the whole foods to the  
4 processed foods to highly processed foods such as vegetable  
5 oils where scientifically there won't be a method to  
6 determine whether the oil is or is not derived from any  
7 particular kind of crop.

8           So there is a gamut of things. We have, of  
9 course, enzymes used in foods. We have other ingredients  
10 that are essentially minor components of the food but are  
11 produced through organisms that are developed by modern  
12 biotechnology.

13           So, in terms of thinking about labeling, we would  
14 have to think about the diversity of kinds of products in  
15 terms of what falls within the scope of labeling.

16           MR. LEVITT: Who wants to start?

17           MR. COHEN: My perception is that you believe  
18 that, twenty years from now, we are all going to be eating  
19 the stuff and not really care about the issue any longer. I  
20 think that is my perception of what you believe. I think  
21 that is the way it is going to be.

22           I think our future is in genetically engineered  
23 foods. That being the case, it is just a matter of time  
24 before everything is so influenced. That is why it is  
25 important today to change it overnight, to put that label

1 on, just a simple ladder turned sidewise, rotated, the  
2 double helical structure, Watson and Crick's structure of  
3 DNA.

4 Put a simple label with no explanation and  
5 tomorrow America wakes up and goes, "Wow. I didn't know  
6 that." And that is the end of the issue. It is simple.

7 MR. FRANK: It is significantly more complex than  
8 that. The Department of Agriculture--I learned this about a  
9 year ago--they probably held since the late 1870s and 1880s,  
10 I am going to say maybe 5,000 rulemakings in their history.

11 The rulemaking that drew the most comments in the  
12 history of the Department of Agriculture is on organic.  
13 What is organic? How do we label it? First, there was a  
14 hew and cry we need to label for organic. And then, when  
15 all the people in the organic industry got together, there  
16 were 3,000 of them there with 100,000 ideas.

17 So it was not and is not an easy issue to address.  
18 It strikes me that, first of all, there is a big difference  
19 between mandatory labeling where you have to say something  
20 includes a GMO and voluntary labeling where you are calling  
21 out a positive attribute or you are saying GMO-free.

22 If you are focussing on the first model where you  
23 mandatorily label something as containing GMOs, how much?  
24 If it is a processed product, it is 1 percent? It is half a  
25 percent? What if it is citric acid which is an ingredient

1 in tomato sauce which is in a jar or a can and the citric  
2 acid, which is one-tenth of 1 percent of the product, was  
3 made from bT corn?

4 At that point in time, do you have a double helix  
5 on that?

6 MR. COHEN: Yes.

7 MR. FRANK: That is a political statement. It  
8 certainly is not a food-safety or an allergenicity issue. I  
9 think you need to take it both from the mandatory standpoint  
10 of where would it make sense, where would you draw the  
11 lines, where would you be communicating information of some  
12 value.

13 And then, on the voluntary system, whether it be a  
14 positive or a negative statement, again, you need to look at  
15 where would you be providing value to the person buying the  
16 product.

17 MR. CAPLAN: If I understood you correctly, Dr.  
18 Maryanski, you are asking because there is such a wide range  
19 of products affected, how would we institute labeling? Is  
20 that correct?

21 DR. MARYANSKI: Yes. Are you proposing that  
22 everything should be labeled or is there some umbrella, some  
23 set of products that really would need to be labeled?

24 MR. CAPLAN: I would propose that any product that  
25 has been made through techniques of genetic engineering

1 would be labeled and, regardless of whether or not it is a  
2 fruit and vegetable which labeling can easily be  
3 accomplished for. Processed foods that contain genetically  
4 engineered material also can be tested and found to contain  
5 that material should also be labeled.

6 So, regardless of how widespread the technology  
7 has become which was done, in a sense, secretly because  
8 people were not informed that it was happening regardless of  
9 what has happened in the past, if a mistake was made it  
10 should be corrected and products that were made through  
11 genetic engineering should be labeled as such.

12 DR. KEITH: I think my response on that would be  
13 that we think the market has a wonderful way of finding out  
14 who really wants labeling. Companies have a way of sorting  
15 out consumers and their needs and finding out which  
16 customers really want that information. That is the reason  
17 we support a voluntary labeling approach at this stage  
18 because we think the companies may go out in the marketplace  
19 and find out who really wants that information and provide  
20 it as such.

21 If you impose it on the entire system, you impose  
22 a cost on the entire food system. Everyone pays that cost  
23 whether they want the information or not.

24 MR. LEVITT: Any other comments on this?

25 DR. CODY: I think the very basis of labeling is

1 you want to make a truthful claim or declaration. When you  
2 are talking about fresh fruits and vegetables in the  
3 marketplace, I don't really see how that would be possible  
4 in most grocery stores because short of labeling every  
5 single apple, every single banana and such, you wouldn't  
6 necessarily know because suppliers are bringing them in from  
7 all over.

8 For highly processed products like sugar, oil and  
9 others, again, you wouldn't really know. There is not a way  
10 to detect it. I think we are talking about documenting a  
11 process most of the time and not a product. That becomes  
12 very complicated when you are looking at verification.

13 So I think looking at individual foods becomes a  
14 bigger issue than just putting a label on everything, or  
15 putting a label on some things because they may contain the  
16 product. It needs to be much better thought out than that.

17 DR. TEISL: I would like to respond. If you were  
18 to require a mandatory--and, particularly, I think if you  
19 were going to have a voluntary labeling program, you would  
20 have to, I think, impose basically the same standards on  
21 everything. The reason I say this is if you say, "Okay;  
22 only cereals have to be labeled but not cans of soup," that  
23 means consumers, when they go in the grocery store, have to  
24 know that there is a difference, a different standard, for  
25 different types of processed foods, for example.

1 This is particularly true if it was voluntary  
2 because, otherwise, people would have no idea that this  
3 aisle has nothing labeled and this aisle has some things  
4 labeled. They wouldn't understand that there is a  
5 difference in the standard between those two aisles.

6 The other comment is with respect to fresh foods,  
7 currently, individual apples are already labeled.

8 DR. CODY: Some of them are.

9 DR. TEISL: Most of them are in the stores that I  
10 shop at. So I don't see the idea, if you were going to have  
11 a label, that it would be that much more of a problem to  
12 have it on things like apples and stuff, unless maybe small  
13 stores; you might have an exemption for them. But I think  
14 consistency would be key.

15 **Summary Remarks**

16 MR. LEVITT: We are coming to the end of our time  
17 for this panel. Let me thank all the members of the panel.  
18 I will, as I did this morning, give everybody more or less  
19 30 seconds for a quick wrap-up. For those who were not here  
20 this morning, the wrap-up question is; looking ahead, a year  
21 from now, if there was one thing that FDA could do in the  
22 area of public information, labeling or otherwise for  
23 genetically engineered products, that would be "blank."

24 Some people have already very clearly already said  
25 what that is so I am expecting some repetition. But I think

1 it is nice at the end to kind of summarize, if you will.  
2 Again, I would ask people to limit it to labeling or to  
3 other areas of public information and to try to do that  
4 quickly.

5           When we finish that, we will be taking a short  
6 break before we get into the final public presentations.  
7 Starting at the back, and as we have been doing, with Mr.  
8 Cohen.

9           MR. COHEN: Remove genetically engineered milk  
10 from the market because the evidence is in. Label  
11 everything that has been influenced by genetic engineering  
12 so those Monarch butterflies with legs outside accept the  
13 fact that their foods are labeled. That's all they want.

14           DR. KEITH: We would recommend serious  
15 consideration be given to a voluntary labeling regime for  
16 negative labeling on food products alone. Feed products  
17 should stand alone, different.

18           MR. FRANK: We think that FDA should continue to  
19 show leadership and support its current policy and make it  
20 more transparent and encourage a nationwide education  
21 program and a debate, like this one. This is wonderful.  
22 People are learning things.

23           MR. CAPLAN: I would support mandatory premarket  
24 safety testing and full environmental review of all  
25 genetically engineered products. I would not support, and I

1 don't think the FDA should support, any products that have  
2 not had that examination on the market. And then, any  
3 products that do meet that test, should be labeled as  
4 genetically engineered.

5 DR. CODY: In terms of labeling, to conduct some  
6 social marketing-based tests to determine what consumers  
7 want, and then some studies to determine what consumers  
8 understand now and what they need to understand in order to  
9 use the labeling effectively.

10 MR. LEVITT: Dr. Teisl, you had the first word at  
11 the beginning. You will have the last word here.

12 DR. TEISL: I guess the main things I would like  
13 to see is that simple labels--i.e., some sort of general,  
14 vague disclosure--was not put forward because I don't think  
15 that helps people make choices. I think what helps people  
16 make choices and, incidently, increases the credibility of a  
17 label, is that relevant details about--not just the food  
18 quality or safety but also other information about the food,  
19 the production, the environmental consequences of the food,  
20 are also detailed.

21 I think if you are looking for something that is  
22 really going to effect consumer behavior and allow people to  
23 make choices that fit what they want, you need to keep it  
24 detailed and provide the consequences and not just some sort  
25 of vague disclaimer of whether it is GE or not.

1 MR. LEVITT: Thank you.

2 Let me again thank all the members of the panel  
3 for this second series of presentations. My clock says that  
4 it is five minutes to 4:00. We are a couple of minutes  
5 behind, but not too bad. We will reconvene in fifteen  
6 minutes at about ten minutes after 4:00.

7 Thank you very much.

8 [Break.]

9 **Public Presentations**

10 MR. MENDELSON: I am No. 2 on the list. My name  
11 is Joseph Mendelson. I am the Legal Director for the Center  
12 for Food Safety. We are a nonprofit, environmental  
13 sustainable agriculture and human-health interest group here  
14 in Washington, D.C. We are currently serving as a lead  
15 attorneys in the law suit against the FDA that is awaiting a  
16 decision at this very time from the U.S. District Court.

17 I am glad the public hearing now begins at 4:15 in  
18 the day. I am also personally affronted that I am told  
19 about how much education I need and then everything will be  
20 all right. Please allow me to return the favor and remind  
21 and reeducate the FDA on what it knows already, how the  
22 American public feels on this issue.

23 In 1992, when the FDA issued its food policy, it  
24 received thousands of public comments. Those comments  
25 overwhelmingly told you three things: one, the public wants

1 mandatory premarket safety testing; two, the public wants  
2 mandatory environmental review before these foods are  
3 commercialized; and, three, when they do come on the market,  
4 the public wants mandatory labeling.

5           The FDA did not respond to those comments in any  
6 official way. In 1993, the FDA, again, took public comments  
7 on labeling. It received thousands of letters, again, from  
8 consumers saying it wants mandatory labeling. The FDA did  
9 not respond.

10           In 1994, the FDA held a public conference on  
11 allergenicity. It has not done anything with that data.  
12 The bottom line is the FDA's refusal to act has led to our  
13 filing of a law suit. Regardless of the decision that comes  
14 out of that law suit, it is time for the FDA to act on what  
15 the public is telling it. Be a servant of the American  
16 public, not a slave to industry.

17           MR. LAKE: Thank you, sir.

18           MS. O'LEARY: Patricia O'Leary, just interested  
19 consumer. Food resulting from seeds that have been  
20 genetically altered is essentially no different from that  
21 resulting from traditionally bred seed is incompatible and  
22 inconsistent with the whole criterion of patentability.

23           In order to receive a patent, the entities that  
24 have engineered the seed must prove that the product is  
25 significantly different and sufficiently transformed in

1 order to be patented as an original creation. Nor are they  
2 near hybrids as they cross species barriers. But what is  
3 wrong with making plants tolerant to herbicides, resistant  
4 to insects, fungus or viruses?

5           What is wrong with fruits and vegetables that will  
6 not ripen or bruise before being sold? What is wrong with  
7 vaccines in bananas and high vitamin-A concentrations in  
8 rice and rape seed, giant salmon growing so fast that you  
9 can almost watch, or cows with oversized udders injected  
10 with recombinant growth hormone so as produce many times the  
11 amount of milk than non-treated cows and then highly dosed  
12 with antibiotics to treat their mastitis and other  
13 infections?

14           What is wrong with envisioning future plants and  
15 animals as tailor-made commodities. Even if all of these  
16 benefits were actually achievable and safe, society would  
17 have to question the ethics, the democratic process, the  
18 monopolies created, the patenting of life, the cost to the  
19 environment, the impact on the third world and on  
20 biodiversity.

21           Or we could simply ask what is wrong with food and  
22 nature as we know it? I am going to leave a little bit out  
23 in the interest of time. For the consumer, herbicide-  
24 tolerant plants pose another danger. Plants grown in the  
25 presence of weed killers can suffer from stress and react by

1 over- or underproducing certain proteins or other  
2 substances.

3 Glycosate-tolerant soybeans have been found to  
4 produce higher levels of plant estrogens when grown in the  
5 presence of that herbicide, thus presenting a potentially  
6 severe health risk to children. As for plants with built-in  
7 insecticides--thank you.

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

9 DR. BARACH: Good afternoon. I am Dr. Jeffrey  
10 Barach with the National Food Processors Association. NFPA  
11 serves as the scientific and technical trade association for  
12 the \$460 billion U.S. food-processing industry. Today, I  
13 would like to make several comments regarding foods derived  
14 using modern biotechnology and to affirmatively answer these  
15 two questions.

16 Number one; could the FDA voluntary consultation  
17 process be made more formal and transparent? Yes; we think  
18 it could. This would help with possible consumer safety  
19 concerns in both the U.S. and abroad. Number two; are  
20 criteria required to insure voluntary labeling statements  
21 are truthful and nonmisleading? Yes; we think well-defined  
22 criteria are very important to the integrity of this growing  
23 niche market.

24 As in the past, NFPA member companies remain fully  
25 supportive of today's agricultural developments and those

1 anticipated future biotech food products that will offer  
2 remarkable nutrition and health benefits directly to  
3 consumers.

4           As well as the technology, we support the  
5 consultation oversight process for safety assessment of  
6 biotech foods. The process has worked and continues to work  
7 well. Could this process be made more formal and  
8 transparent? Yes. Although we believe the current  
9 voluntary consultation process is already, essentially, a  
10 mandatory one, it may provide added confidence to the system  
11 to make it a more formal process.

12           We also strongly support the science-based FDA  
13 policy on labeling of biotech foods and promote the use of  
14 voluntary labeling statements provided that such statements  
15 are truthful, nonmisleading and disclose the necessary  
16 required material facts.

17           To this end, we would recommend that when  
18 voluntary statements are used, such as biotech-free, three  
19 criteria should be met. These include quantitation,  
20 certification and putting claims in contact with qualifying  
21 statements.

22           In conclusion, NFPA and its member companies  
23 strongly support the FDA's regulatory oversight of biotech  
24 foods. We believe our suggestions will improve the process  
25 as it develops into the next century.