1 markers, which could be — which could confer antibiotic
2 resistance. And you're not introducing new types of
3 promoters, which could have their own effects, as well.
4 So there are, there are several big differences
5 there. And I think that has to be our starting point
6 instead of just saying, well, it's just like moving genes
7 around.
8 You know, I'm going to take another example that
9 maybe is easy to relate to. You could say, well, we've
10 been moving mail around; we've been moving information
11 around for years. But the internet produces new types,
12 new ways, of moving information around. It's going to
13 change society. You can say we've been moving money
14 around for years, but it depends on how you move the money
15 around. If you're moving the money around electronically
16 with computers, it can be very different from an armored
17 car, or normal banking procedures. And, if you're moving
18 money around in campaign contributions, reading in the *New*
19 *York Times* Sunday, moving money around in campaign
20 contributions can be very different from moving it around
21 in ways that help people to build houses. So it depends
22 an awful lot on the context.
23 MS. COPP: Dr. Huttner.
24 DR. HUTTNER: What's clear, scientifically, is
25 when you move genes around, whether between sexually

1 compatible species, or unrelated species, once they're in
2 the new cell, they're subjected to the same biochemical
3 processes of genetics that they had been when they were in
4 the original donor cell. There's no difference there.
5 And, in fact, plant breeders have, for a very long time,
6 encountered unexpected and unwanted outcomes using
7 traditional breeding techniques. Often metabolic
8 processes were introduced that they didn't want, or they
9 disrupted metabolic processes that they did want. What
10 Professor Qualset said, very clearly, is that, through
11 that experience, they've developed extensive systems to
12 evaluate these plants over time and to eliminate those
13 that have traits, or metabolic changes, that are not
14 beneficial. That same system can be applied to the new
15 genetically engineered plant.
16 In addition to that, the Food and Drug
17 Administration's 1992 Policy has added another safeguard.
18 And that's if you introduce something into a food that
19 does not have a history of safe use, it's going to be very
20 stringently regulated as if it was a chemical food
21 additive. That's important to recognize. It's not as if
22 we have no safeguards for dealing with these novel kinds
23 of combinations that can be made.
24 COMMISSIONER HOLSTON: Is there anyone on the
25 panel that would like to respond?

1 DR. QUALSET: Yes.
2 COMMISSIONER HOLSTON: Dr. Qualset.
3 DR. QUALSET: One quick comment basically
4 supporting what Susanne has said. That the hypothetical
5 and real situations, that Dr. Regal points out, those are
6 the first steps. You see those at the first step in the
7 laboratory where you see unusual biochemistry, for
8 example, or morphology. Those aren't the things that are
9 going out to the public. Those are the first steps. We
10 only take things further and further when they have what
11 seems to be useful and meeting our targeted goals. So we
12 will never understand all the biology of mutant forms and
13 gross things that happen.
14 I'm saying we have to remember we're moving out
15 to the consumer. We're moving from the lab to testing out
16 in the field, and we're only working with those things
17 that seem to be beneficial. If there is serious
18 disruption in the physiology and metabolism, that will be
19 known, be shown, as a defect. And we will find it, then,
20 as low yielding, or some defect, and it will disgarded.
21 When I was breeding wheat plants, we grew
22 100,000 lines a year. We saved four or five that really
23 made it. You know, so we're in traditional breeding there
24 is a huge amount of selection for those that don't meet up
25 to the standards. So there's just another angle.

1 COMMISSIONER HOLSTON: Dr. Fagan.
2 DR. FAGAN: Just a couple comments.
3 Dr. Qualset just said that, if there is a
4 serious disruption, you'll know it. My question to him
5 is: How? Are you going to use X-ray vision, or — what?
6 You can't tell if a new toxin has been generated.
7 Another point that I think needs to be corrected
8 scientifically is that Dr. Huttner said that, when you put
9 — once you get a gene in, it's going to be subjected to
10 the same biochemical processes that were there in the
11 original organism. Now that's completely inaccurate
12 because even different cells in an organism will have
13 different regulatory proteins that interact with the gene
14 so that that gene, present in a liver cell, will function
15 very differently from a brain cell. Similarly, you take a
16 gene from agrobacterium, and you put it into a soy bean
17 plant, and the regulatory proteins that are present are
18 going to be a completely different spectrum. There's no
19 way to predict what kinds of interactions will be there.
20 A sequence that might have no regulatory function in the
21 agrobacterium might happen to be present in that gene when
22 it's put into soy, and there could be a protein present
23 that could interact with it to cause something completely
24 unexpected: rearrangements, increased, decreased
25 expression, a whole range of things.

1 I spent 20 years doing that kind of work. I
2 know the range of unpredictability that can come up when
3 you put a new gene in a new genetic background. It
4 happens everyday.
5 DR. QUALSET: But, still, at the end, you don't
6 keep the thing that isn't working.
7 DR. FAGAN: The question is: How do you know if
8 it's working or not.
9 COMMISSIONER HOLSTON: Okay.
10 DR. FAGAN: You can look at see if it grows
11 faster, or if it's resistant to —
12 COMMISSIONER HOLSTON: I'm afraid I'm going to
13 have to stop the debate.
14 DR. FAGAN: How would you know if you haven't
15 done the test.
16 COMMISSIONER HOLSTON: Are there other members
17 of the panel who have questions? Dr. Mitchell.
18 DR. MITCHELL: Yes. It's the same line of
19 questioning. I'd like to ask Dr. Regal if he could
20 characterize tests, or a series of tests, that would
21 satisfy the concerns that you're describing. We heard Dr.
22 Fagan describe one that sounds a lot like the testing
23 model for industrial chemicals. What do you have in mind?
24 DR. REGAL: You know, really, it wouldn't be my
25 field. That's a highly technical field, how you test

1 toxicologically, and so on. What I want to see are
2 scientists who can discuss these issues in depth, and who
3 are not simply defending the industry, who are aware of
4 what the problems are, and who are working on —
5 [Applause.]
6 COMMISSIONER HOLSTON: Excuse me. Could we
7 please allow the speaker to speak.
8 DR. REGAL: I want to see a literature that
9 moves forward, that discusses these and moves forward,
10 instead of, you know, trying to whitewash things. I want
11 to see research programs that we all are involved in
12 working out and push us toward better and better tests.
13 That's what I want to see. I'm not — I can't give you a
14 quick answer about this test or that test. These things,
15 they require a lot of thought and discussion.
16 COMMISSIONER HOLSTON: Panelists?
17 DR. MARYANSKI: I guess one of the things I
18 wonder about is how we will — you know, we are always
19 looking for ways to improve the kind of testing the
20 companies do. In fact, I suspect the companies would like
21 that, too.
22 It's a little puzzling when we think about these
23 unexpected effects, or long-term effects, in terms of
24 food. If we think about what are the effects that are
25 generated by simply consuming a particular food over the

1 course of one's lifetime, what do we know about that?
2 In other words, for any of the testing that we
3 do, we have to have something to compare. And, so, when
4 we start asking the questions about familiarity with
5 proteins, or toxins in the food, or vitamins, we have to
6 have some baseline. And I think that I wonder about how
7 we will be able to understand information that is
8 generated and be able to interpret it given what our
9 current state of knowledge is about foods generally and
10 effects on, for example, the nervous system, immune
11 system, and so forth, of any particular food. How we will
12 we — what kind of ways are there to approach that?
13 DR. FAGAN: I could get us started.
14 Let's — I think what you're getting at, Dr.
15 Maryanski, is the challenges of evaluating foods when we
16 don't really have existing paradigms for doing the tests.
17 The early studies, with the Flavr Savr Tomato, and some of
18 these things, tried to use classical toxicological
19 approaches, where you give very large doses to accelerate
20 the appearance of harmful effects. But because, with
21 foods, you have such a range of products there, or of
22 materials there, you ended up with toxicological effects
23 from things other than the elements in the food that you
24 were interested in. So, obviously, we can't use the
25 classical toxicological approach. But there are

1 approaches that can be developed, and this is the kind of
2 research that Dr. Regal was talking about, that we need to
3 develop these models.
4 Let me suggest a model that might work.
5 The GMOs that are developed here in the U.S. are
6 going all over the world. When genetically modified cry9C
7 containing protein, corn, goes to South Africa, it won't
8 be just a little part of the people's diet. When it goes
9 into Soweto or into Alexander, or some of these other
10 townships, it will be the major portion of the people's
11 diet. That means 80 to 90 percent of the diet will be
12 corn. That's how it is in those places. They're
13 essentially on a mono diet: 80 percent of the diet is
14 corn. Now, they get a little veggies and a little other
15 things with it, but that's what they eat.
16 Why not set up a model where we take that as a
17 worse-case scenario, and let's feed people these materials
18 for a period of time, where, you know, they still have 20,
19 15 - 20 percent of their diet to cover the protein, the
20 vitamins, the other things that they need so there won't
21 be malnutrition problems; but, yet, they'll have a higher
22 level of exposure to the material of interest. Put them
23 on that diet for awhile. Have to pay them quite a lot to
24 do that, I think. But you would learn some things. And
25 we then could really stand behind our claim that, if it's

1 been tested by the U.S. Food and Drug Administration, and
2 okay-ed by them, it's safe for South Africa, and it's safe
3 for Indonesia, and it's safe for the Philippines. That
4 would be a start.
5 COMMISSIONER HOLSTON: Are there any other
6 responses from the panel?
7 [No response.]
8 All right. Melinda.
9 COMMISSIONER PLAISIER: One of the things I
10 think it seems we've have heard in some of the other
11 forums, and I also heard this morning, was a need for
12 greater transparency and information to consumers and the
13 general public. And I'd like to direct this, first, to
14 Dr. Huttner, and, then, of course, anyone else who would
15 like to respond.
16 One of the points I heard you make, Dr. Huttner,
17 was that we have real polarization of views on this issue;
18 and, then, in between, we've got an information gap. And
19 I heard you also say that FDA has an important role that
20 we can play. I'd like you to talk in the context of
21 safety. I mean, obviously, this is a question relevant to
22 the labeling, which we'll be doing late this afternoon,
23 but in the context of safety review, what role do you
24 think the FDA has to play? How can we help fill that gap?
25 What do you think we can do?

1 DR. HUTTNER: The most important thing is to
2 help people overcome the sense that this technology and
3 these products are unlike anything that they've ever seen
4 before; and, so, they have no means, through their own
5 experience, to judge safety issues. So, as has often been
6 characterized in the press, their being used as guinea
7 pigs, or at least they feel like their being used as
8 guinea pigs. We have to empower them to be able to
9 consider these issues of genetic modification of food.
10 And the first step is to help them understand that genetic
11 modification of food has had a very long history, and that
12 each of us does have a good deal of experience with
13 genetically modified foods.
14 We also need to explain to them what roles
15 non-government organizations have played, especially in
16 the private sector, in determining the safety of products
17 before they get to the marketplace; and, then, what role
18 the federal agencies have in enforcing the Food, Drug and
19 Cosmetic Act should a food safety problem arise. I think
20 that that's important fundamental information that they
21 need before they start to address biotechnology foods.
22 Now this is something that's not going to be a
23 simple undertaking for the Food and Drug Administration.
24 But I encourage you to take it seriously because as
25 Gaskell, et al, found in their paper that was published in

1 *Science Magazine* in July, this past summer, that was
2 looking at the attitudes of American and European
3 consumers, U.S. consumers have remarkably confidence in
4 your agency. You're in a position of influence. I think
5 that it's a wonderful opportunity for you to provide
6 information to them, sound and accurate information on the
7 issues.
8 Now, after telling you that I think it's your
9 job, I'll say that we're willing and happy at the
10 University of California to help you in any way that we
11 can. We have a number of outstanding biotechnology
12 programs that have, at their core, public education
13 efforts. One in particular is at UC-Davis, run by Martina
14 McGloughlin, who is here today. Another is overseen by
15 Peggy Lemaux, who is the cooperative extension specialist
16 for biotechnology in California and has access to all the
17 farm advisers and home economists in the entire state of
18 California, and can provide you an excellent model for
19 communication to people out in communities, who are
20 influential and trusted and excellent communicators, to
21 allow you to get tremendous amplification. So we'd like
22 to work with you.
23 We also have organizations that interface with
24 the private sector, like the Bay Area Bio Science Center.
25 Dr. Sue Markland Day is here today. All of these

1 organizations in California could help you develop a model
2 for communication. We could help you to work with the
3 community, as we have in the past, to try to understand
4 what they're information needs are so we just don't send
5 things out and assume that it answers their questions.
6 First, we ask them first what they want; and, then, try to
7 best address those issues. Then, maybe after testing the
8 water out here, you might have a model that you could use
9 nationally.
10 [Applause.]
11 COMMISSIONER HOLSTON: Do we have anymore
12 questions from our panel here?
13 MR. LAKE: I have one more.
14 COMMISSIONER HOLSTON: All right.
15 MR. LAKE: I'd like to address a question to Dr.
16 Hefle.
17 One of the consistent concerns that we heard in
18 the hearing to this point really is about the potential
19 for unexpected allergens. So I'd like to probe your
20 expertise a little bit in that area.
21 One of the concerns that we've heard is that
22 there is the potential for something that is not now a
23 known allergen to show up, you know, in some future
24 product that might cause allergies. Do you have any
25 thoughts on anything that we could or should do in the

1 future that might lessen the likelihood of that?

2 DR. HEFLE: I think, right now, we're doing the
3 best we can do. Everyday, we eat new foods that our
4 bodies haven't seen before, especially with this — the
5 food producers exporting to the world, we're eating foods
6 we never ate before. Early in the '80s, before we
7 imported a lot of kiwis, or grew them ourselves in the
8 United States, there were no reports of allergy in the
9 literature in the United States to kiwi. But we imported
10 it and started eating it and, sure enough, people became
11 allergic to kiwi. Now, should we regulate kiwi like we
12 regulate genetically modified organisms? So we're eating
13 new proteins everyday.

14 I think the assessment that's in place for
15 proteins that have no allergenic history is appropriate
16 and the best we can do right now with the knowledge that
17 we have. We're learning new things everyday. The
18 developers do do giant comparisons of these proteins that
19 they're using with any known toxin or allergen that's in
20 the literature to date, up to date. They're updating
21 these everyday. And we do the digestibility studies,
22 also.

23 Now I think that's the best we can do right now.
24 It's very difficult to assess something that's going to
25 become an allergen. We just don't know until it does.

1 People are very individualistic. You may have an allergy
2 and someone else doesn't. There's a lot of issues there.
3 So I think, right now, I don't know of any
4 technology that would help us, or any testing that would
5 help us, additionally predict these things. If a
6 validated animal model would become available — and there
7 is promising research along these lines — it must be a
8 validated animal model, however, that would assist in the
9 prediction of possible allergenicity. That's the only
10 technology that I'm aware now that holds promise for
11 helping with that issue.
12 I am still confident in that, I mean, all of the
13 crops, right now, have no allergenic concerns with them.
14 These were novel proteins that do not have allergenic
15 history. I think that speaks for itself right there. We
16 have no increased allergy concerns.
17 COMMISSIONER HOLSTON: Dr. Regal.
18 DR. REGAL: Can I make a comment? This is
19 obviously a really difficult problem. But I just want to
20 make a comment.
21 I'm not comfortable with comparing these
22 genetically engineered organisms to kiwis. If you've ever
23 struggles with allergies yourself, you know, you find a
24 food that you can eat, and you find — you know that you
25 can avoid other things. So suppose you've found that you

1 can eat corn, you know. Well, you'd never suspect, if
2 suddenly you're allergic to corn, one batch of corn and
3 not another batch, you can't control yourself. You can't
4 control your life anymore. And that's very different from
5 finding that some exotic fruit from China is something
6 you're allergic to it because it's basically hidden in the
7 food, a food that you thought was perfectly safe before.
8 And, so, imagine the agony a person would go through, who
9 has allergies, trying to figure out what the source of
10 their problem is.
11 So I'm not quite comfortable with that problem.
12 But I, you know, it's a difficult issue, and maybe they
13 are — you know, they're working at it.
14 COMMISSIONER HOLSTON: Thank you.
15 Any other panelist? Jim.
16 DR. MARYANSKI: Thank you, Sharon.
17 I'd just like to follow-up because, with the
18 example of kiwi, of course, you're eating a fruit. You
19 got a whole food there. You're essentially exposed to a
20 lot of protein. I know that, you know, there isn't hard
21 and fast rules we can make about food allergy in any area.
22 But it seems to me there might be a difference between the
23 kinds of foods that are being produced where, at this
24 point of the technology, the substance is an enzyme. It
25 is present at very low levels of the food.

1 I would just like to hear from Dr. Hefle, and
2 others, whether in fact that is something that the
3 experts, who are knowledgeable about food allergies, think
4 that's something that's important or not important?
5 DR. HEFLE: Yeah. We think that exposure levels
6 are important. There are threshold levels for food
7 allergens. Unfortunately, we don't know what those
8 numbers are. We know that it's not zero, that there is
9 subclinical — someone can eat something and there's a
10 subclinical thresholds.
11 So expression level is very important, and it's
12 my understanding that most of the products on the market
13 today have very low levels of expressed protein in them,
14 or the proteins are expressed in a different part of the
15 plant than is actually eaten by the consumer. So exposure
16 level is something that's important. Exposure levels,
17 when people become allergic to foods, they're usually
18 exposed at very high levels for a significant amount of
19 time. That's for the classic food allergies, like peanut
20 and soy bean, and things like that.
21 So expression levels are important to us. We do
22 look at that. These are expressed right now in the
23 products we have at very low levels. I would not
24 anticipate that they would cause a problem at the levels
25 that are produced now.

1 COMMISSIONER HOLSTON: I'm looking at my panel,
2 and I'm seeing if anyone has any other questions?
3 [No response.]
4 If not, I would like to say, first of all, this
5 first session has been as stimulating as we had hoped it
6 would be. And I want to thank all of our invited
7 panelists for your very thoughtful comments. These are
8 certainly not easy issues, but the Food and Drug
9 Administration very much appreciates the input that we've
10 heard this morning, as we try to grapple with these issues
11 from this point forward. We had hoped to hear a variety
12 of views and you certainly didn't disappoint us in that
13 regard. And we are going to consider your views with the
14 ones that we also heard in Chicago and the ones we heard
15 in Washington, D. C., and, with the other information that
16 is going to be submitted for the public docket.
17 We are now going to break for lunch. After
18 lunch, we will be discussing labeling and other issues.
19 We have an hour for lunch; but, since we're just about
20 five minutes early, we will stick to our original
21 schedule, and that is: We will reconvene and start the
22 next part of our session promptly at 1:00 o'clock.
23 Thank you very much.
24 (Whereupon, at 11:55 a.m., the meeting was
25 adjourned, to reconvene at 1:00 p.m.)

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

2 1:00 p.m.

3 COMMISSIONER HOLSTON: All right, everybody. We
4 are at the time for starting the next part of our program.
5 I want to thank those of you who are here for returning
6 promptly so that we can get underway and have as much time
7 as possible for the presentations later on in the
8 afternoon.

9 To begin this session, Bob Lake, who heads our
10 Office of Regulations and Policy, for the Center for Food
11 Safety and Applied Nutrition, is going to describe FDA's
12 current policy on labeling and public information related
13 to bioengineered food.

14 Bob.

15 SESSION 3

16 FDA POLICY: LABELING

17 MR. LAKE: I will not take nearly as long as my
18 colleague this morning. He had to be more thorough
19 because he had more technical stuff to do, and I just
20 wanted to show two slides, actually.

21 One of the things that Dr. Maryanski didn't
22 mention this morning, that he asked me to mention right up
23 front, is that all of the information that we receive on
24 safety is publicly available information. It's available
25 under the Freedom of Information Act. We are thinking

1 about making it available in a more user-friendly sort of
2 way.
3 That's part of what we'll be talking about,
4 hopefully, in this afternoon's session, which is: Making
5 information available, either through labeling or other
6 means. Part of that is how, you know, input from you on
7 how FDA can processes more transparent, and make the
8 information that we have more readily available.
9 The issue of food labeling, which we know is a
10 topic of great interest to many of you, and many others,
11 is like safety, governed by the Food, Drug and Cosmetic
12 Act. The Act basically says that labels on foods, label
13 statements, cannot be misleading, cannot be either false
14 or misleading. So that's the overall guiding principle.
15 Now the Act does require a number of different
16 kinds of additional information, by statute and by
17 regulation, including ingredient statements, the
18 nutritional labeling panel that we implemented at the
19 beginning of this decade.
20 Also, a very basic thing that has always been
21 required on the label of a food is its common or usual
22 name. Simply, you know, put, it's, you know, identifying
23 what the food is. And that actually gets into one element
24 of existing labeling policy.
25 As Dr. Maryanski pointed out this morning, foods

1 that have been modified to the point that it is really no
2 longer appropriate to call them by their traditional name
3 can be required to bear a modified name to identify those
4 foods. And the modified soy that he mentioned is such a
5 food. We've done that a couple of times with regard to
6 the identity statement. And that's one component of
7 existing FDA labeling policy.
8 The Act also permits FDA to make other
9 requirements if there is a fact, a material fact. Well,
10 the material fact has to be either related to other
11 representations on the food label, or consequences of use.
12 And it's really this area of consequences of use that is
13 the part that is perhaps of greatest focus in the
14 discussions we're having here.
15 Also, the thing I would emphasize, the statute
16 does permit voluntary labeling, determined by those who do
17 the labels, so long as the information is truthful and not
18 misleading.
19 Next slide, please.
20 Now the other thing that we would like to hear
21 something about today is not just labeling, but other
22 means of making information available to the public. The
23 World Wide Web, 1-800 numbers, are a couple of ideas that
24 have come to mind. But we also would be interested if
25 anyone has other possible suggestions about ways of making

1 information available. And, of course, these are not
2 mutually exclusive. They can be used in combination, but
3 we would be interested in thoughts either from our panel
4 or from the speakers we have this afternoon on that.
5 So, with that, I'm going to stop and we'll get
6 on with this afternoon's panel.
7 Thank you very much.
8 [Applause.]
9 COMMISSIONER HOLSTON: Okay. Thank you very
10 much, Bob.
11 SESSION 4
12 PUBLIC INFORMATION AND LABELING
13 COMMISSIONER HOLSTON: I will now turn the floor
14 over to our panel on Public Information and Labeling.
15 Again, I will ask each member of the panel to give brief
16 opening remarks, and then discussion will follow among the
17 panel members, with questions from our FDA panel.
18 First, let me review the questions that we have
19 presented to our second panel:
20 No. 1 Should FDA's policy requiring labeling
21 for significant changes, including changes in nutrients or
22 the introduction of allergens be maintained or modified?
23 Should FDA maintain or revise its policy that the name of
24 the new food be changed when the common or usual name for
25 the traditional counterpart no longer applies? Have these

1 policies, regarding the labeling of these foods, served
2 the public?
3 No. 2 Should additional information be made
4 available to the public about foods derived from
5 bioengineered plants? If so, what information? Who
6 should be responsible for communicating such information?
7 No. 3 How should additional information be made
8 available to the public, for example: on the internet,
9 through food information phone lines, on food labels, or
10 by other means?
11 I would know like to introduce the panelists for
12 our second discussion.
13 Dr. Thomas Hoban is a professor with the
14 Department of Sociology and Anthropology at North Carolina
15 State University.
16 Andrew Kimbrell is the Executive Director of the
17 International Center for Technology Assessment.
18 Dr. Rhona Applebaum is Executive Vice President,
19 Scientific and Regulatory Affairs, for the National Food
20 Processors Association.
21 Susan Haeger is the Chief Executive Officer and
22 President of Citizens for Health.
23 Diane Joy Goodman is with the Farm Box Project
24 Consulting Group.
25 And David Bossman is the President/Treasurer and

1 Chief Executive Officer with the American Feed Industries
2 Association.
3 So, without further ado, I would now like to
4 invite Dr. Hoban to open to open this panel.
5 Dr. Hoban, please.
6 PANEL DISCUSSION
7 DR. HOBAN: Well, thank you very much. Is this
8 mic — it sounds like it's on. Very good.
9 Well, I am Thomas Hoban, as you heard, and I've
10 been studying the consumer perceptions, consumer
11 knowledge, about biotechnology for the past decade. And I
12 want to commend the FDA for holding these meetings. I was
13 fortunate to have a chance to give a short, two-minute
14 presentation in Washington, and glad you've invited me
15 back to hear a longer version of it.
16 Well, as you're certainly aware — and all you
17 had to do was to go outside and take a look — supporters
18 and critics of biotechnology are really clamoring to draw
19 attention to their positions. The consumer, however,
20 should be your most important consideration.
21 Those who claim to speak for the consumers
22 sometimes may not, in fact, will be serving in their true
23 interest. Because, despite rhetoric claiming the
24 consumers want all products of biotechnology labeled,
25 research really reveals some different consumer views on

1 this particular topic.

2 To talk about labeling issues briefly, labeling
3 questions on surveys are very complex and very ambiguous.
4 What I conclude from my own research and all the other
5 surveys that I've reviewed is that how questions are asked
6 directly effects how consumers respond. Let me highlight
7 this complexity with two basic examples:

8 On one hand, opinion polls do indicate that a
9 majority of consumers feel foods developed through
10 biotechnology should be labeled. However, almost as many
11 want to know the country of origin for the food. In fact,
12 an even much larger percentage feel that food labels
13 should explain which pesticides were used in the
14 production of the food. So it's very hard to set
15 priorities for limited label space when everything is very
16 important to everybody.

17 A more realistic approach to take is to provide
18 a meaningful context to elicit consumer views. In
19 research that I developed with the Interantional Food
20 Information Council, also known as IFIC, a question
21 described the current FDA policy, which was, in fact, not
22 the to label foods developed through biotechnology that
23 are basically identical to traditional foods. We'd
24 explained the cases in which they would be labeled. And,
25 in fact, when that survey was done three times over the

1 last two years, consistently find approximately
2 three-quarters of the U.S. consumer say they support the
3 current FDA policy. So, clearly, it's a little bit
4 different, probably 180 degrees different, from some of
5 the other surveys.
6 Well, as a survey specialist, somebody who has
7 been doing this for over 15 years, I hate to admit it, but
8 sometimes we do ask people to answer questions
9 spontaneously over the phone when they've not thought
10 much, if at all, about the topic. So such results, as
11 telephone surveys alone, do not provide a sufficient basis
12 for important public policy decisions. It's much more
13 valid to use focus groups, or other techniques, that tend
14 to engage consumers in much more thoughtful dialogue.
15 Let me quickly emphasize and summarize some of
16 the findings from focus groups that I've done myself for
17 USDA, as well as others, that I witnessed and reviewed.
18 One of the first things we learn is that the
19 consumers really expect the label only if the food has
20 been changed in some significant way. We explore that
21 example with the case of the widely used cheese
22 ingredient, which was mentioned this morning, caymosin,
23 developed through biotechnology, which, as you know, has
24 been in cheese production for almost a decade.
25 Most of the consumers we interviewed felt there

1 was no need for special labels, since, in fact, the cheese
2 was no different in taste, nutrition, or safety. And, in
3 fact, if you look at the cheese packages that are
4 available there is no special designation of it being from
5 products of biotechnology.
6 The other thing we found that was quite
7 important is that consumers see much less need for labels
8 on processed foods then they do on the fresh food or
9 vegetable. We used tomatoes as an example here, and
10 people would say that the Flavr Savr Tomato — that was
11 the model we used — would be probably beneficial to know
12 about, because they perceived there to be some beneficial
13 difference to it. But few even recognized that food
14 processors typically blend together different tomato
15 varieties to get the desired taste of consistency for
16 ketchup, or for frozen pizza. In fact, most consumers we
17 talked to did not particularly care how the ingredients in
18 processed foods were developed.
19 The next point we found was that most consumers
20 do not want to pay higher costs for food in order to have
21 the testing, or to keep the commodity segregated, as we
22 heard about this morning.
23 So care must be taken with any initiative about
24 labeling because cost will ultimately be involved, and
25 would ultimately be passed on to consumers, which would

1 also impose difficulties, logistically, on all parts of
2 the food-value chain from the farm to the table.
3 But, finally, I think, more importantly, when we
4 look at what consumers mainly use labels for — and this
5 research has been reviewed by USDA and a number of others
6 — we find that people mainly look at labels for fat
7 content, sugar content, salt content. Those items that
8 are of most concern to them from a health, from a
9 nutritional standpoint. That was the basis for your food
10 facts labels, and so on. So I think you've got a good
11 precedent there.
12 Many consumers, in fact, expressed a lot of
13 frustration with conflicting information that they read in
14 the media and elsewhere. They seem overwhelmed almost by
15 the variety of food already available. Most consumers, in
16 light of this, tells us their scarcest resource is time,
17 and complex labeling, related to biotechnology, would
18 significantly increase the time and mental energy that a
19 consumer must spend shopping for food.
20 Well, over the past decade, my research, as well
21 as a lot of that conducted by others, have found a clear
22 majority of U.S. consumers are quite positive and remain
23 quite positive about biotechnology.
24 We also recognize, though, that a number of
25 people have unanswered questions. So one effective way to

1 allow for informed choice would be to have a system of
2 voluntary labeling for foods not produced through
3 biotechnology. In that case, if the demand is real, the
4 market will become viable, as it seems to be happening now
5 with organic foods. In fact, it's, I think, a very good
6 position to put biotech-free foods in the category with
7 organic foods. In this case, a meaningful choice can be
8 provided to concerned consumers without imposing cost on
9 or denying benefits to the majority of consumers who
10 remain positive about biotechnology.
11 We clearly need more directed research to
12 determine what consumers truly expect and need on a food
13 label. It will also be vitally important to test
14 alternative wording, to look at the placement of the
15 information, to find out that it's truthful and not
16 misleading.
17 I do want to address the second point that the
18 committee is interested in hearing about, and that's the
19 education and information issues.
20 One way or another, education is vital for
21 consumer choice; but labeling is not the same thing as
22 education. Consumers truly want and they truly deserve
23 more information about biotechnology. In fact, without a
24 major commitment to education, any form of labeling
25 initiative will likely do nothing but confuse and alarm

1 most consumers. So let me quickly outline an effective
2 education program.
3 One of the first questions you want to know is
4 what the consumers want to know. We've done this in many
5 focus groups and surveys over the years.. One of the first
6 things they're interested in learning about is why is
7 biotechnology being used? What are the benefits? What's
8 in it for the consumer?
9 Next, they want an assurance that the products
10 have been certified as safe by an agency, such as your
11 own.
12 Finally, they're genuinely curious about it.
13 They really don't understand much about it and would like
14 to learn more about the topic.
15 Well, who should provide them with this
16 information? Any educational program would require an
17 ongoing partnership among government, industry, consumer
18 groups, universities, and others. U.S. consumers have
19 consistently told us that their greatest trust in
20 information is from third-party groups, university
21 scientists, and even your own agency. The nation's
22 land-grant universities, I might put out, and cooperative
23 extension programs are also ready and eager to help in
24 this educational effort.
25 Finally, how should we provide consumers with

1 the information they want about biotechnology? Toll free
2 numbers, internet sites hosted by third parties, those are
3 all viable alternatives, good ideas, as would be in-store
4 brochures, and so on. In fact, the FDA, or another group,
5 should maintain an information clearing house that
6 describes the products of biotechnology that have been
7 approved, including where those ingredients might be
8 found.
9 A quick final point here is as the FDA
10 considered the complex issues associated with
11 biotechnology, please keep in mind the real consumer
12 interest when it comes to food. Again, surveys that have
13 been done over the past 20 years have consistently shown
14 that consumers want their food to be tasty, affordable,
15 safe, nutritious and convenient, in that order. How seeds
16 and other ingredients are produced is very, very low on
17 the list, if it even appears at all, and will likely not
18 be an issue for the vast majority of consumers. Providing
19 the variety of safe and affordable food that the U.S.
20 consumers have come to expect, while feeding a world
21 population, will require ongoing development and adoption
22 of new technologies. The continued application of
23 science-based regulation will insure safety and real
24 benefits for consumers.
25 So I conclude that maintaining the current

1 policy of FDA is in the best interest of the majority of
2 U.S. consumers.
3 Thank you very much.
4 COMMISSIONER HOLSTON: Thank you, Dr. Hoban.
5 [Applause.]
6 Now, Mr. Kimbrell.
7 MR. KIMBRELL: Thank you very much.
8 I am director of the International Center for
9 Technology Assessment, as well as the Center for Food
10 Safety, and one of the counsels of record for the lawsuit
11 that was filed against the FDA in May 1998 demanding the
12 testing and labeling of genetically engineered foods.
13 And, by the way, which is currently pending. Final
14 briefing was over in July. FDA inviting me here shows a
15 welcome and refreshing masochistic tendency on the part of
16 the agency, and I respect that.
17 I think, at first, I have to note, with all due
18 respect to Ms. Holston and Dr. Maryanski, that a very
19 crucial element to public information was missing from
20 this morning's otherwise interesting presentation, which
21 is: This is not the first time that the public has been
22 asked about how it feels about the testing and labeling of
23 genetically engineered foods. As a matter of fact, when
24 the 1992 policy was first published in the *Federal*
25 *Register Notice,* comment was solicited. Thousands of

1 people responded. Many of the scientists you've heard
2 from today, and in the other two meetings, responded.
3 Nobel Prize Laureates, health professionals, consumers by
4 the thousands.
5 The results — and these are FDA's results, not
6 mine; this is something we got through discovery in the
7 lawsuit — 80 percent, 80 percent, favored labeling and
8 safety testing; 2 percent, 2 percent, favored the FDA
9 policy. Two percent. Not surprisingly, and in my view in
10 gross violation of the Administrative Procedure Act, the
11 FDA never responded, never responded at all to those
12 comments. Never responded. No public information went
13 out. FDA decided to do what it had to do in private.
14 In 1993, the beginning of the Clinton
15 Administration, another federal notice went out asking for
16 comments very much like the questions we're being asked
17 today, all these years later. Thousands of us bothered to
18 comment, again, the scientists, professionals, many of
19 whom you've heard in the last 3 meetings. Once again,
20 absolute silence from the FDA. No response whatsoever.
21 So I find it alarming and I find it scandalous
22 that we find ourselves here, all these years later, now
23 that these foods are being consumed by millions of
24 Americans, ten of millions of acres being planted by these
25 foods, and we can still have a session, like we had this

1 morning, where there is basic scientific conflict I think
2 on both sides, probably well-reasoned and in good faith,
3 on whether this food is even safe. Because of the refusal
4 of FDA in timely fashion to obey the law and respond to
5 the public, that food has been released on the public.
6 And the anger you see outside, FDA has no one to blame but
7 themselves, for the actions that they did.
8 Now Dr. Huttner, and others, have talked about
9 the regulatory regime at FDA that will insure safety.
10 That people's concerns about labeling are unfounded. I
11 think it's very important to understand what FDA's real
12 position is. This is their position in court on exactly
13 what we have with genetic engineering. What do we have?
14 We have a regulation. Do we have something that is
15 binding? Is it going to insure anything? I will quote
16 directly. This is FDA'a direct position — all right? —
17 that they wrote in their brief before a federal court.
18 "The 1992 policy statement creates no binding
19 norms of any kind, nor does it make any
20 dispositive scientific findings."
21 No binding norms, no dispositive scientific
22 findings of any sort. So this is extraordinary that we
23 find ourselves in this hearing, this discussion — I
24 should say; it's not a formal hearing, not pursuant to any
25 *Federal Register Notice* this time. All these years later,

1 what we have regulating genetically engineered food is a
2 nonbinding policy that has made no scientific findings of
3 any sort.
4 So, please, I don't want to hear about a policy
5 based on sound science. I don't want to hear about a
6 policy based on sound regulation when this agency has gone
7 before a federal court and stated that there is no binding
8 regulations and that there are no dispositive scientific
9 findings.
10 Now as to the issue of labeling. Labeling is
11 actually — and I thought it was well summarized by — is
12 it Dr. Lake? I don't want to mis —
13 MR. LAKE: Mr. Lake.
14 MR. KIMBRELL: Mr. Lake, okay, I thought
15 actually had summarized it quite well. The issue here is:
16 Are the changes that genetic engineering accomplishes in
17 food, are they material? All right? This is the key
18 legal issue. Material fact is defined in the legislative
19 history as what a reasonable person would expect to know
20 about the food that they are purchasing. What a
21 reasonable person would expect to know. All right?
22 The FDA, Dr. Maryanski, have decided that all
23 those 80 percent, and all the polls — and with all due
24 respect to Dr. Hoban, I think we're getting 95 percent of
25 polls saying that they want the foods labeled; that's what

1 the people want -- they are saying that's unreasonable
2 because these foods are essentially the same. All right?
3 The substantial equivalence. Why would you want to label
4 something that's the same? That's the argument, right?
5 Well, in our discovery, we found that that was
6 not the view of the scientists, nor even the compliance
7 officer that reported back to Dr. Maryanski when he
8 submitted the 1992 policy for their approval. I'm going
9 to quote directly from Linda Call, the FDA's Office for
10 Compliance. Ms. Call is obviously a very witty woman. I
11 won't include all of the jibes that she threw back at Dr.
12 Maryanski, but there are some here that are legally
13 extremely important. She said:
14 "I believe in at least two situation, relative
15 to this policy, it is trying to fit a square
16 peg into a round hole. The first square peg
17 into a round hole is the document that is
18 trying to force an ultimate conclusion that
19 there is no difference between foods modified
20 by genetic engineering and foods modified by
21 traditional breeding practices. The processes
22 of genetic engineering are different and
23 according to the technical experts in this
24 agency (the FDA) they lead to different risks."
25 This is the compliance officer at the FDA. It's

1 not emotional consumers, and this is not people on
2 demonstration. This is the compliance officer, the person
3 whose job it is to make sure that this policy complies
4 with the law. And who is she citing? The technical
5 experts in the agency. So when we're talking about sound
6 science, let's remember there's the FDA's own technical
7 expert that said these foods are different, they present
8 different risks, and they are not substantial equivalents.
9 So, once you get rid of this charade of substantial
10 equivalence, as exposed by FDA's own scientist, then we
11 get into what does, what does constitute a material fact?
12 It was said at the beginning of this
13 presentation that there has to be a significant change to
14 the food. Incorrect, not part of the law, not part of
15 FDA's regulations. In its regulation requiring the
16 labeling of irradiated foods, FDA said if there is
17 sufficient public demand, that even nonsignificant, even
18 nonsignificant, organoleptic — that is, material changes
19 to the food — should require labeling. And, indeed, that
20 was their holding with irradiated foods.
21 So you have two very basic categories. You have
22 performance characteristics and you have changes in
23 flavor, taste, texture. Now, if you look through the
24 gamut of genetically engineered foods — and I thought Dr.
25 Maryansky did a very good job of this earlier today; he

1 described exactly what performance characteristics were
2 changed, right? — we've got tomatoes that ripen later —
3 right? — a whole group of them. We've got herbicide-
4 resistant crops. We've got BT crops performance
5 characteristics both in the field. And, by the way, BT
6 potatoes, for example, there's less solids in them. These
7 Flavr Savr Tomato, they claim that there's flavor changes.
8 If you do what I've done and look at the patents
9 for everyone of these foods, there are only two open in
10 saying we're different, we're novel. We're creating
11 things that are absolutely impossible through traditional
12 breeding. So the processes we're using should be
13 patentable, and they have been, and the foods themselves
14 should be patentable, and they are.
15 Now, if FDA does not agree with that, perhaps it
16 should join others and file suit with the Patent Office to
17 rescind all of the patents on these foods. If they are
18 not truly novel, if the processes do not bring in
19 substantive changes, then they should not be patented, and
20 their patents are invalid, or would be invalid.
21 Finally, I think it's important to say that the
22 very nature of genetic engineering, according to FDA's own
23 scientist, creates important issues that require labeling.
24 In the response by the Division of Food, Chemistry and
25 Technology to Dr. Maryanski — who was aware of this,

1 again, in 1992 — this is what they said, and it's very
2 important: "The insertion ..." — remember before about
3 that insertion — right? — that Dr. Regal and Dr. Fagan,
4 and others talked about, and Dr. Huttner, that there's the
5 insertion of the gene, this mutagenesis of insertion?
6 This is what they're talking about:
7 "The insertion of DNA into the plant genome may
8 result in various desirable or undesirable
9 changes."
10 All right? And they stated what these
11 undesirable effects could be.
12 "These undesirable effects, such as increased
13 levels of naturally occurring toxicants,
14 appearances of new, not previously identified
15 toxicants, increased capability of
16 concentrating toxic substances from the
17 environment, pesticides or heavy metals, and
18 undesirable alterations in the levels of
19 nutrients may escape breeders attention,
20 unless genetically engineered plants are
21 evaluated specifically for these changes."
22 Toxicants, new toxicants, unknown toxicants —
23 right? — just what they were talking about today.
24 "Such evaluations should be performed on a
25 case-by-case basis. That is every

1 transformance should be evaluated before it
2 enters the market. Unrecognized toxic
3 substances may unexpectedly occur in
4 transgenic plants."
5 So they recommend long-term toxicological tests
6 and they recommend that these be labeled.
7 So that's what the scientists, that's the sound
8 science inside the agency. That's what they said. What
9 happened between sound science? They're different, they
10 contain risks, and significant performance changes. And
11 the policy and why that was kept quiet from the public for
12 7 years? These are questions I cannot answer right now.
13 But if you're going to be talking about public
14 information, clearly, there's a huge gap between what the
15 scientists have said, a huge gap with what the agency has
16 said, and what actually occurred. And I don't think
17 there's any discussion about the labeling of genetically
18 engineered foods. The law absolutely requires it. These
19 are material changes, performance changes. The public, by
20 a tremendous majority, wants these. And for 7 years, this
21 agency, with no scientific basis, by their own admission,
22 and no binding regulation, has deprived millions of
23 Americans of the right to choose. And that is regulatory
24 disgrace.
25 [Applause.]

1 COMMISSIONER HOLSTON: Thank you, Mr. Kimbrell.
2 Dr. Applebaum.
3 DR. APPLEBAUM: Good afternoon.
4 My name is Rhona Applebaum, and I serve as
5 executive vice president for Scientific and Regulatory
6 Affairs for the National Food Processors Association. Our
7 trade association serves as a scientific and technical
8 trade association for the food processing industry, and
9 our primary focus is on —
10 COMMISSIONER HOLSTON: Excuse me, Dr. Applebaum.
11 He says you're speaking too fast.
12 DR. APPLEBAUM: I'm sorry.
13 COMMISSIONER HOLSTON: Would you slow down just
14 a little bit.
15 DR. APPLEBAUM: I apologize. Okay.
16 And our principle focus is on issues related to
17 food science and food safety, and we appreciate very much
18 this opportunity to present our views.
19 I'm going to cover two principle issues, very
20 quickly, on the safety and then the remaining, my
21 remaining remarks will focus on why I'm here on the panel
22 today, and that's on labeling. First on the safety.
23 Consumers have a right to expect that all foods
24 on the market are safe to eat, whether those foods are
25 produced through traditional or conventional agriculture,

1 or the use of modern biotechnology. Food safety concerns
2 related to biotech-derived foods should be considered and
3 addressed no differently than other foods, with the common
4 goal of continuing to insure the safest food supply
5 possible.
6 In the case of biotech foods, the primary
7 oversight for safety of the food, quote, unquote, "to eat"
8 is through a consultation process with the FDA, a process
9 NFPA supports. Why do we support this process? Because
10 the process for overseeing the safety of food developed
11 through biotechnology is, with due respect to my colleague
12 on the panel, science-based, built on the principles of
13 risk assessment, and it works. It has worked, and it
14 works well. This is NFPA's view.
15 With that said, while we know that every biotech
16 company has submitted to this consultation process prior
17 to the marketing of new products from engineered plants,
18 the consultation process is voluntary. And this fact has
19 caused questions to be raised as to whether this is the
20 best approach to maintain consumer confidence.
21 Could this prior-to-market process be made more
22 formal and more transparent using already established
23 procedures, established for other FDA regulated food
24 products, and thereby insure, to the extent possible, that
25 consumer confidence -- something very important to the

1 food industry — is maintained?

2 Yes, it could.

3 NFPA has some specific ideas to improve the
4 formality and transparency of this consultation process.
5 First, we believe there needs to be a mandatory food
6 safety consultation. FDA should require that biotech
7 companies consult with them prior to introducing a biotech
8 food into the market. We believe this step would boost
9 public confidence in the safety review, a process, as we
10 heard this morning from Dr. Maryanski, that is thorough,
11 rigorous and scientifically based.

12 Second, at the conclusion of the consultation
13 process, at a specified time before the food is introduced
14 into interstate commerce, the biotech company should file
15 with FDA summary documentation to support the
16 determination of safety for the biotech food. And this
17 documentation should be made publicly available. NFPA
18 believes it is important for the summary information to be
19 publicly available so that anyone interested can examine
20 it, and so the general public can develop a high level, a
21 higher level, of understanding, a higher level of
22 confidence, and a higher level of comfort regarding the
23 safety of biotech foods.

24 We therefore agree with what Dr. Huttner stated
25 earlier this morning, that there is a serious information

1 gap. But we also agree with Dr. Regal, that rhetoric is
2 dangerous. To correct this serious information gap, we
3 need factual information in order to prevent the fears,
4 the fears that rhetoric produces. So to the extent that
5 we would like to see hyperbole and hypothetical risks
6 diminished, we do need factual information, we do need to
7 close this serious information gap.
8 Concerns over information that is trade secret,
9 or otherwise confidential commercial information, this has
10 already been addressed appropriately in FDA's general
11 regulations.
12 Now for labeling.
13 NFPA, and its member companies, strongly support
14 the current FDA policy on labeling requirements for
15 biotech foods. We believe it is essential that mandatory
16 labeling be reserved for information that is material,
17 that is information that goes to the safety, to health,
18 the composition or the nutritional value of the food.
19 NFPA further supports the use of voluntary
20 labeling of foods to indicate the presence or the absence
21 of bioengineered ingredients. NFPA has long supported
22 voluntary label statements provided such statements are
23 truthful, non-misleading, and disclose the necessary
24 material facts. Such label statements could include
25 biotech-free, or similar terminology, or contains biotech

1 ingredients.

2 In order to support any voluntary statements,
3 NFPA believes that three criteria are necessary. First, a
4 quantitatively-based threshold should be established
5 especially for any, quote-unquote, "free claim." Such a
6 threshold should be strict, but technologically feasible.
7 Just as a fat-free claim does not mean absolute zero fat
8 content, the threshold for biotech-free does not have to
9 be set at absolute zero. A reasonable threshold is
10 probably some small percentage. In this matter, consumers
11 understanding, in qualitative, of the meaning of "free"
12 needs to be given some consideration. The industry and
13 consumers could and should assist FDA in such efforts.

14 Second, every claim needs to be substantiated.
15 For a biotech-free claim, the ability to substantiate
16 identity preservation and other trace-back procedures
17 would be vital components. Provisions could be made on
18 the enforcement side for processors that make claims to
19 provide substantiation to FDA upon written request, just
20 like the substantiation provisions in the recent soy
21 protein coronary heart disease health claim provisions
22 that NFPA strongly advocated. In other words, FDA has the
23 authority to require substantiation.

24 Finally, most biotech-related claims will need
25 supplementary statements that place the claim in its

1 proper context. NFPA believes supplementary statements
2 are absolutely necessary to prevent such claims from being
3 misleading. NFPA believes that FDA's policy regarding
4 claims on milk from cows treated with RBST served as the
5 best model. In that policy, FDA made clear that
6 supplemental statements must include a representation that
7 no significant difference has been shown between milk
8 treated from cows and milk from untreated cows. In a
9 similar vein, for a biotech-free claim, a supplemental
10 statement should note that there are no significant
11 differences between biotech-derived and biotech-free
12 versions of the same food — the food, not the plant. No
13 significant difference has been shown between biotech-free
14 and biotech-derived products, or no significant health or
15 safety differences have been shown between biotech-free
16 and biotech-derived products are two possible accompanying
17 statements that may be considered.
18 NFPA and its members companies believe strongly
19 in the regulatory process FDA applies in assessing the
20 safety of biotech foods. It is a science-based process
21 built on the principles of risk assessment. And we urge
22 FDA to continue its strong science-based focus on placing
23 their resources on real safety issues, not hypothetical
24 risks. Only two questions require answers:
25 1. Could the review process be made more formal

1 and transparent? We believe, yes; it can and it should
2 be.
3 2. Are criteria required to insure voluntary
4 label statements are truthful and non-misleading? Again,
5 our position is yes.
6 Today, NFPA has advanced some ideas to help
7 reach those answers. The government should require no
8 more and consumers deserve no less.
9 Thank you for the opportunity to comment.
10 COMMISSIONER HOLSTON: Thank you, Dr. Applebaum.
11 [Applause.]
12 Ms. Haeger.
13 MS. HAEGER: Thank you.
14 I'm Susan Haeger, with Citizens for Health. We
15 are a consumer advocacy group that has chapters in all 50
16 states, volunteer chapters nationwide, of individuals who
17 are concerned about natural health issues. Our work and
18 our mission is to insure consumer access, information and
19 choice for natural health care products and therapies.
20 We have come to this issue because our
21 constituency has had tremendous questions about the
22 presence of genetically engineered materials in their
23 food. And through our investigation and discussion with
24 scientists, what we have seen is that genetic engineering
25 is a method of altering or making new organisms through

1 techniques that change the molecular or cell biology of
2 the plant by means that are not possible in nature. And I
3 think this has been a highly contested definition of GE
4 foods, and we hear, on the one side, that it's just an
5 extension of traditional breeding practices; and, on the
6 other side, that, in fact, there are material changes.
7 And, yet, there is no program in place to fully answer
8 this question for the consumers that have the concern.
9 We have many scientific studies being done,
10 which show that there are probable causes of concern in
11 both health and environmental areas. And, yet, many of
12 those emerging scientific studies are being set aside
13 because, supposedly, they are not thorough enough, or
14 they're not complete enough. But I think they raise flags
15 that consumers expect the FDA to be looking seriously at
16 and answering, and not simply setting aside.
17 We have had a growing numbers of consumers and
18 natural product retailers contacting us about the
19 prevalence of genetically engineered material in the food
20 supply. And I have seen that, week by week, this issue
21 has gained more attention as FDA has done an excellent job
22 of opening up this public discussion that these questions
23 are increasing.
24 The growth of preventative health care,
25 including the use of dietary supplements, the

1 establishment of the National Center for Complimentary
2 Alternative Medicine, the USDA's recent decision to
3 respond to public objections to its originally proposed
4 organic standards, are examples of how consumers create
5 market trends and resulting social changes that can change
6 public policy. But the American public cannot make
7 choices about genetically engineered foods without it
8 being labeled. And this segment of the public, which is
9 voting with its dollars, must be taken into account as
10 this debate is going forward. I think it's very important
11 to understand that consumers are making decisions about
12 the products they buy based on the way on which those
13 products are produced. We have now a healthy living
14 marketplace, which is estimated at $230 billion, that is
15 the segment of the public which is concerned about organic
16 food, natural food, natural dyes, environmentally
17 sensitive building, making certain that the products that
18 they're buying represent healthy living, both for
19 themselves and for the planet which they inhabit. These
20 consumer concerns should not be set aside.
21 We are committed to providing consumer choice
22 and pursuing mandatory labeling of genetically engineered
23 foods because we believe that the debate in the scientific
24 community that is going today shows that there is a
25 technical difference, there is a genetic difference, and

1 there is a difference in the scope of the impact of these
2 foods. And, when we talk about bridging the information
3 gap, I think the FDA will do both itself, as an agency, a
4 disservice and the American public a disservice by simply
5 putting forward the views of the biotech industry and not
6 seriously considering the concerns that have been raised
7 by experts and by scientists outside of the industry
8 itself.
9 We have also heard a lot about how consumers
10 really don't have to have labeling unless there is some
11 significant change shown to the product while the
12 scientific debate is going on about whether or not there
13 are changes. The easiest way to address it is to simply
14 label it, for people to make a decision for themselves.
15 And I think that the putting of the information on the
16 label tends to reduce people's fears and people's risks.
17 As we try to bridge this information gap, as Dr.
18 Applebaum has said, I think it's very important that we
19 provide a way for the individuals who are concerned not
20 bear the complete burden. I mean, what we're talking
21 about now is if there is only voluntary labeling, there's
22 only a voluntary information process, then the individuals
23 who are concerned about this are the ones who are going to
24 have to bear the burden. I think it should be borne by
25 those who have developed these technologies and not by

1 those who are now put at-risk.

2 Since FDA does not require mandatory labeling,
3 consumers don't have adequate knowledge to make informed
4 choices. And I think especially the fact that there is no
5 mandatory pre-market safety testing, and that these foods
6 are generally considered to be generally regarded as safe
7 or GRAS, there is enough scientific debate going on that
8 the agency needs to look closely at whether or not, in
9 fact, these foods can be considered GRAS simply on the
10 basis of getting voluntary submitted information from the
11 companies that are developing them.

12 Some biotech supporters are advocating making
13 the process of consultation mandatory, as Dr. Applebaum
14 has said. We don't believe that measure goes far enough
15 because the initiation and depth of the process to
16 determine whether a genetically engineered food is GRAS
17 depends on the discretion of the biotechnology companies,
18 whose products are involved. Products can be marketed now
19 whether or not FDA reviews the submitted information, and
20 we believe that the agency needs to be taking an
21 independent view of the information which has been — is
22 being put forward.

23 Additionally, I think there are concerns that
24 have been raised by our members about the regulatory
25 structure for genetically engineered foods being

1 fragmented. And I think this is something that FDA needs
2 to look closely at. The USDA approved the release of
3 genetically engineered plants into the environment and
4 approves crops for production. FDA oversees food safety
5 but not pesticides expressed in food, and the EPA
6 regulates pesticides expressed through genetic engineering
7 but not food. So there is a lack, from the public's
8 perspective, of complete agency coordination and looking
9 at the effects that these foods have. For instance: Corn
10 that is genetically engineered contains a BT pesticide.
11 It's commercially sold as a food product without
12 pre-market mandatory, independent pre-market safety
13 testing, even though no food product containing BT has
14 ever been ingested by humans before.
15 We're seriously concerned about the flaws in
16 FDA's pre-market screening and labeling processes and the
17 fragmented regulatory structure; and, therefore, we have
18 become involved and are supporting the mandatory labeling
19 legislation, which has been put forward in Congress. I
20 think the agency has an opportunity to address these
21 issues and to avoid this type of movement that's going to
22 take place in the public, and cause a lack of confidence
23 in the agency's regulation of the food supply, by clearly
24 addressing the need for the labeling and also for the
25 mandatory pre-market safety testing.

1 We're also concerned about the rapid
2 proliferation of largely unregulated genetically
3 engineered crops, as they pose a risk for organics. There
4 has been a 23 percent growth in the organic market every
5 year. It's going to — it's estimated to hit $10 billion
6 by the year 2000. And the polluting of organic crops is
7 of tremendous concern. It's virtually impossible for
8 farmers, whose fields are near genetically engineered
9 crops, to insure that their crops are free of genetically
10 engineered material. This is especially true with corn.
11 It's a wind-pollinated crop. And economically, this has
12 been having impact. We found Terra Prima, for instance, a
13 certified organic producer, had to destroy 87,000 bags of
14 chips that tested positive for genetically modified
15 organisms and they could not be sold as organic. This is
16 something that the organic community is grappling with.
17 And, yet, no one, when these products came to market,
18 looked at the impact that they could have on the organic
19 community, on the agriculture system that organic is
20 engaged in, and I think those questions should be answered
21 before these crops are allowed to proliferate.
22 We find that natural food sales are the fastest
23 growing segment of the retail market. And the new science
24 on the health and environmental implications of
25 genetically engineered foods that is emerging shows that

1 there are mounting concerns about disrupting the
2 ecosystems that may cause damage to the soil and other
3 plant and animal species. However, FDA's policies on
4 genetically engineered food, despite scientific and
5 consumer concerns, have allowed the introduction of these
6 genetically engineered foods and crops to proceed and to
7 out pace the science. And this morning's panel, and the
8 scientific panels you've had in Washington and in Chicago,
9 show that there are many scientists who do not agree that
10 there are no significant health and environmental
11 concerns.
12 Supporters of biotechnology contend that genetic
13 engineering is simply an extension of traditional
14 breeding. FDA scientists that we have heard from, and Mr.
15 Kimbrell, have disagreed with that. It's in the public
16 record. I think it's very important that, as this
17 information comes to light and the public begins to review
18 it, the agency clearly respond and give an explanation as
19 to why these issues have not been addressed before and why
20 the public comments that's been in before have not been
21 addressed.
22 So, again, I think that, from our perspective,
23 it's very important that there be mandatory labeling, that
24 there is an opportunity for consumers to make a choice,
25 and that there be mandatory pre-market safety testing that

1 is not simply company initiated and is looked at
2 independently by the agency. I would suggest that, as a
3 means of addressing these concerns, there have been
4 precedent, such as the FDA Council on Food Safety, and the
5 Keystone Project that was developed some years ago around
6 food labeling questions, that brought industry, academics,
7 scientists, consumers and the agency together to discuss
8 the concerns and to develop a policy for addressing
9 labeling. And I think that that would be very productive
10 because there is tremendous perspective in the public that
11 the agency has made all of these decisions in consultation
12 with industry without communication to the public directly
13 and without dialogue.
14 Thank you.
15 COMMISSIONER HOLSTON: Thank you.
16 [Applause.]
17 Ms. Goodman.
18 MS. GOODMAN: My name is Diane Joy Goodman, and
19 I'm a consultant to the organic agriculture and food
20 processing industry. And I'd like to thank the FDA for
21 inviting me to speak here today.
22 I've been involved with food, which is the focus
23 of my personal, professional and public life for over 25
24 years, the last 10 exclusively in the organic industry. I
25 have run restaurants, I've marketed fresh produce at large

1 distribution terminals, as well as farmers' markets. I've
2 live on farms and I've worked in the field. Currently,
3 I'm the chairman of the California Organic Food Advisory
4 Board of the California Department of Food and
5 Agriculture. And I sit on task forces, with the National
6 Organic Standards Board.
7 As a consultant, I advise entering and existing
8 businesses, particularly in the areas of government
9 affairs, marketing and communication. My clients come to
10 me to learn how government and industry regulations will
11 impact their production and marketing practices, and how
12 best to educate themselves, their companies, their
13 suppliers, and their customers about the organic industry
14 — especially about what sets them apart from conventional
15 agriculture and processing.
16 My comments today are going to focus on the
17 needs of the organic industry and the public's expectation
18 of the organic label, and why labeling at all product
19 levels, from seed to supermarket, is necessary to the
20 organic industry.
21 The National Organic Standards Board, the NOSB,
22 established by the Federal Organic Food Production Act of
23 1990, defines organic production as — and I quote part of
24 this — "... the use of materials and practices that
25 enhance the ecological balance of natural systems." The

1 NOSB has further recommended that genetically engineered
2 organisms, and their derivatives, be prohibited in organic
3 production and handling systems. USDA Secretary Dan
4 Glickman stated, in response to the overwhelming, 280,000
5 public comments to the first proposed rule for the
6 National Organic Program that, and I quote, "Biotechnology
7 does not fit current organic practices, nor meet current
8 consumer expectations about organics, as the comments made
9 clear."
10 The organic industry is based on the premise
11 that food can be raised and produced in the manner that
12 replicates nature. Genetic engineering, specifically the
13 technology of recombinant DNA, the movement of genetic
14 material from one species into the genetic code of an
15 unrelated species, would never occur in nature. It is not
16 comparable to hybridization and traditional breeding
17 practices. The transference of genetic traits between
18 species, not varieties but species, does not occur in
19 nature. Organic farming has never needed genetic
20 modification, and I cannot see that it ever will need it.
21 The National Organic Standards Board, as well as
22 the 44 public and private organic certification agencies
23 currently operating in this country, have determined that
24 this technology is a synthetic process. And synthetic
25 processes and products are only permitted in organic

1 agriculture and food processing if they meet strict human
2 health, environmental and toxicological criteria. Even
3 then, their use in the field is limited by application
4 rates and necessity, as documented by soil and plant
5 tissue testing.
6 In organic food manufacturing, ingredients
7 produced by synthetic process may only be included in no
8 more than 5 percent of the ingredients of a product, and
9 that is only if all criteria have been met and absolutely
10 no other alternative exists.
11 Organic food generated over $5 billion in sales
12 in 1998. The industry has grown at the rate of over 20
13 percent annually for the last 10 years, compared to
14 conventional grocery growth of rates of only 3 to 5
15 percent. American consumers are more aware than ever
16 before of the choices available to them in the
17 marketplace. Health, wellness, environmental conscience
18 are now deciding factors in the shopping habits of a
19 growing number of consumers. And many of these people are
20 choosing organic food because they can trust the label to
21 represent food that is grown and processed without the use
22 of materials that may be harmful to the soil, to the
23 water, to the air, to plants, animals, to their own or
24 their family's health.
25 On the farm, organic practices offer a new set

1 of tools to today's farmer looking for ways to reduce
2 chemical use in the field, and generally return of 20
3 percent, or better, premium in the market over
4 conventionally raised crops. Over and over in
5 conversations with long-time conventional farmers. who
6 have incorporated organic practices into part of their
7 operations, we hear the same success stories about the
8 decreasing pest pressure, both disease and insects. The
9 success is always attributed to the increased health of
10 the soil and, of course, to the resourcefulness of the
11 farmer.
12 Without labeling of genetically engineered
13 agricultural and food products, a potential liability is
14 created for the organic industry, who has made the public
15 commitment to keep organically grown food free of
16 genetically modified organisms. Without labeling, this
17 promise is becoming more difficult to keep. As far back
18 at the seed, organic farmers need to know that they seed
19 they buy is not genetically engineered, or that it does
20 not contain traits environmentally transferred to it.
21 Organic farmers need to know that livestock feed contains
22 no cotton seed meal that comes from genetically engineered
23 BT cotton. Organic manufacturers need to know that the
24 enzymes used in cheese making contain no caymosin. And
25 the organic customer needs to know that the soy milk, for

1 their infants, don't come from Roundup Ready Soy Beans.
2 Without labeling, GMOs may make their way into the organic
3 food chain and violate the public trust it has taken 20
4 years to build.
5 The chain of responsibility must start at the
6 genetic souce. Right now, the organic industry is
7 struggling to determine policy about how to test for the
8 presence of GMOs in minor ingredients, in manure use for
9 compost, and in additives to livestock feed and vaccines.
10 The certification agencies are baffled at how to manage
11 genetic drift from pollen from BT corn that may be carried
12 over miles when traditionally sufficient zones have never
13 exceeded 25 feet. I believe the responsibility of proof
14 is misplaced on the organic industry, and that it presents
15 undue obstacles for the potentially stunning opportunity
16 of growth the organic industry has in the future for
17 farmers and for the public.
18 Manufacturers who market genetically engineered
19 products must be willing to inform their customers about
20 the unique technology that went into production. If these
21 products are proven to be safe over time, and with
22 long-term testing and development to insure environmental,
23 as well as public safety, it's certainly possible that
24 they will. And after determining that safety is as
25 important as recovery of the financial investment gone

1 into bringing these products to market, labeling will be
2 enthusiastically and willingly used by the products'
3 manufacturers.
4 Genetically engineered food and its production
5 are still in trial phases, as is demonstrated by the
6 numerous new scientific revelations about its effect.
7 Every few weeks, a new study is published about these new
8 discoveries and the potential effect, whether it be on
9 Monarch Butterflies, to transference of pest resistance to
10 the soil, or to Brazil Nut allergies in soy beans.
11 The pharmaceutical industry, in the
12 pharmaceutical industry, a new drug is offered in trials
13 to patients that may benefit from it. But those people
14 choose to participate in the trial, and it takes place in
15 closed environments. Drugs are developed in laboratories
16 and used by people that make that choice.
17 Seeds, on the other hand, are planted outdoors
18 and released into the environment. Food produced by those
19 seeds is currently being eaten by people who don't know
20 they are participating in a trial. They don't have the
21 choice. Choice in the marketplace has always been an
22 essential element of American culture. Those people who
23 want to eat only kosher food look for kosher labels.
24 Vegetarians read labels to make sure there is no chicken
25 stock in their minestrone. And people with peanut

1 allergies read candy bar labels to stay alive. People who
2 want a drop a few pounds look for fat content. Isn't this
3 the reason we have nutritional labeling information? The
4 organic consumer seeks out the organic label the same way,
5 and is entitled to trust what that label has come to
6 represent.
7 In specific response to the questions put
8 forward in the *Federal Register Notice,* of October 25,
9 1991, requesting information regarding labeling of
10 genetically engineered food, yes; the current FDA policy
11 should be modified to address environmental safety, as
12 well as food safety. The name of the food should be a new
13 name that clearly states it is the product of genetic
14 engineering. And, no; these policies have not served the
15 public well or wouldn't even be here.
16 Furthermore, labels should clearly state in
17 language similar to that recommended in legislation
18 recently introduced into the House of Representatives by
19 Congressman Dennis Kasinich of Ohio, and I quote:
20 "United States Government Notice. This product
21 contains a genetically engineered material, or
22 was produced with genetically engineered
23 material."
24 To close. In response to the question of how to
25 make information available to the public, yes; you do use

1 the internet and food information phone lines and food
2 labels. The larger question is what information to make
3 available.
4 I think the information needs to be broader than
5 about promotion and marketing, and it needs to be more
6 than about its safety. It needs to be about its potential
7 unknown risks. Yes, please do it. Also use other means.
8 Use longer environmental-criteria-based testing. Use
9 greater percautions in protecting the health of the
10 public. Respect the American consumer's right to be
11 informed and make marketplace choices. Be transparent, be
12 honest, and please be as concerned about this as I am.
13 Thank you.
14 COMMISSIONER HOLSTON: Thank you.
15 [Applause.]
16 Dr. Bossman.
17 MR. BOSSMAN: I'll keep it brief, and not
18 doctor.
19 My name is David Bossman, and I'm president of
20 the American Feed Industries Association in Arlington,
21 Virginia. AFIA is the national trade association
22 representing the manufacturers and more than 75 percent of
23 the commercial livestock, poultry and pet food sold
24 annually in the United States. Our industry is the single
25 largest purchaser of grain, oil, seeds and byproducts in

1 the U.S. Nearly 65 percent of the nation's corn, and
2 almost all of its soy bean mean are used in the feed
3 industry.
4 We all have to very proud of what we're doing
5 here today and that we're a part of the United States
6 where we can discuss, demonstrate, debate and litigate an
7 issue that carries so much passion from all sides.
8 I've attended all three of the FDA public
9 hearings on biotechnology and am aware of the
10 controversies surrounding not only the use of
11 biotechnology, but the debate over whether the product
12 should be mandatorially labled if they contain ingredients
13 derived from biotechnology. I certainly don't have to
14 remind the agency that standards for determining federal
15 labeling on any regulated product must be based on science
16 and not on public opinion polls.
17 AFIA supports FDA's current labeling policy and
18 opposed blanket mandatory labeling. If genetically
19 modified feed ingredients, and products which contain
20 them, are not materially different from the conventional
21 counterparts, if they're just as safe, of equal quality,
22 and have the same functional characteristics, then
23 mandatory labeling is not justified.
24 We view reasonable labeling regulation as
25 critical to enhancing consumer confidence in the food they

1 buy. However, to be consumer-friendly, labeling must,
2 above all, provide useful information for the purchasing
3 decision. Requiring labeling in the case of material
4 differences between genetically engineered and
5 conventional products makes sense. It makes sense to
6 label if there is a demonstrated safety risk. It makes
7 sense to label if we are effectively creating a new plant
8 variety. It makes no sense to label based on a production
9 method when there is no material difference between the
10 conventional and the genetically engineered foods or feed,
11 since such arbitrary labeling really provides no benefit
12 to the consumer.
13 FDA has resisted such labeling requirements
14 demonstrated in the original BST approval. Avoiding this
15 policy will also keep the — will be keeping the agency's
16 longstanding policy against regulating based on
17 theoretical risks.
18 Voluntary labeling means the marketplace, not
19 the government, who will determine what foods consumers —
20 what information consumers value when it comes to
21 genetically engineered foods or feed. Labeling is one of
22 the many ways that impart knowledge. All the means that
23 you mentioned, the 800 number, the internet, and product
24 production, are all appropriate and necessary.
25 From a food safety perspective, FDA policy on

1 biotechnology must not only insure that the information
2 provided on the label is accurate and valuable, but that
3 the product inside the package is safe. Food safety and
4 consumer confidence is the top priority of the feed
5 industry. There can be no higher goal for industry or for
6 government.
7 Our industry supports sound-science-based
8 production systems. We support balanced government
9 regulation that fulfills the agency's mandate to protect
10 public health and a benefit to the food production. The
11 two goals are not mutually exclusive. We strongly oppose
12 regulation based on theoretical risk.
13 The consultation system, initiated as part of
14 the agency's 1992 policy, under which companies
15 voluntarily share with FDA information about the safety
16 and nutritional labeling, appears to be successful.
17 However, we do support a move to formalize those
18 requirements of those consultations and make that more
19 transparent.
20 The industry's priority and the government's
21 mandate to insure the food supply is safe is paramount.
22 Only compelling science can be used on the basis for
23 regulation of biotechnology. The promises of
24 biotechnology are known and achievable. The risks are
25 easily managed because they are minor.

1 Also important is the need to educate consumers
2 about that technology and how it will transform the food
3 production. Consumers need to hear the story of
4 technology, its promises, it's limits. Consumers need
5 facts not horror stories. They need to hear from the
6 government and they need to hear from it industry.
7 We in the U.S. and most of Europe are part of
8 the earth's wealthy and well-fed few. Five billion of the
9 six billion people in this world are less fortunate. In
10 the next 40 years, we must produce as much food that has
11 already been produced in the history of the world.
12 Because we born here in the United States are clearly
13 apart of that lucky gene club that has all the food we
14 need, we have a responsibility. We have a responsibility
15 to use all the available technology to produce an abundant
16 and wholesome food supply, not just for us, but for the
17 world.
18 We understand FDA's role is not to be an
19 industry cheerleader. However, the agency must publicly
20 explain the effectiveness of your regulatory process that
21 assures continued safety of biotech-developed foods and
22 feed ingredients.
23 Thank you.
24 COMMISSIONER HOLSTON: Thank you very much.
25 [Applause.]

1 PANEL ANSWERS FDA QUESTIONS

2 COMMISSIONER HOLSTON: All right. Thank you all
3 very much for your comments. And we are now going to turn
4 this part of the program over to the FDA panel to pose
5 questions to you, either individually or to the entire
6 group.

7 So, I'm going to ask who would like to be the
8 first? All right. Melinda Plaisier.

9 COMMISSIONER PLAISIER: This is really to
10 everyone. I'm still trying to sort of get my arms around
11 this broader issue. I've heard a lot of things today.
12 This morning I heard that we have a gap, a lack of
13 information, that we need to better educate and provide
14 information to consumers. That we need to continue to
15 uncover the science of this new technology. And then I
16 hear from this panel a call for labeling.

17 What I'm trying to figure out and what I'd like
18 to hear from you is: How do you filter this down? How do
19 you decide what information to provide consumers? What
20 information would you envision going on the label? As we
21 heard this morning, you know, tomatoes started as a
22 bitter berry, and corn came from a grass. How would you
23 label that? What kind of information do you think is
24 important to provide consumers, and how would you go about
25 doing that?

1 MS. GOODMAN: I think that, to start with, I
2 think FDA would need to be willing to give both sides of
3 the story on the label. That may mean putting something
4 on the label about the genes that have been included.
5 That the product has been genetically modified, and here's
6 how it's been modified. This particular gene has been
7 inserted into the genetic code of this particular product.
8 This gene comes from something else. Of course, it
9 couldn't be this wordy, but the gene comes from something
10 that is not corn; it comes from a bacteria. And, then, to
11 present what you know about its safety, and some form of
12 disclaimer that you may not know at all. And I think that
13 that would be at least a starting point in your thinking.
14 MR. KIMBRELL: I'd like to comment on that.
15 There's a — you know, whenever I speak about this — and
16 I'm sure this is true for people on the panel and people
17 at the FDA — one of the confusions people say: Well,
18 wait a minute! If it's not safe, then we should certainly
19 label it. All we know that this is not the issue. As was
20 explained earlier this morning, in the 1992 policy, FDA
21 said that these were probably food additives, all these
22 genes and promoters and antibiotic marker systems; but
23 that they were going to give them GRAS. They were going to
24 say that they were generally recognized as safe. That
25 would require scientific defenders. That's one issue.

1 Okay?

2 It's my view that giving a blanket
3 generally-recognized-as-safe to an entire class of foods,
4 rather than the individual way it's handled generally in
5 the additive things. Grossly negligent, but that's one
6 issue. We don't label unsafe foods. We take them off the
7 shelves. They're adulterated. They don't belong there.

8 Once a food, and once we were to have mandatory
9 toxicological testing of genetically engineered foods, and
10 many were to be, I'm sure would prove probably safe, then
11 the issue of labeling comes in. Then is there something
12 material about those foods that consumers have the right
13 know? The reasonable consumer would have the right to
14 know if their peformance changed, longer shelf life, more
15 viscosity, a difference in an oil or fatty composition,
16 many of the things we've already discussed. And in
17 virtually every food that I have seen so far, there is at
18 least some organoleptic change and/or some performance
19 changes, which is what the law requires if the agency also
20 believes that the public wants that kind of labeling —
21 and, clearly, it does.

22 So I think it's helpful to make a dichotomy
23 between the safety issues and the GRAS issue, and the
24 labeling issue. First, we got to decide if they're safe.
25 First, there has to be tests. Then, if they're safe, then

1 those who want to be more precautionary, who have
2 religous/ethical objections, who may be allergenic and
3 sensitive, then they have the right to know what's in
4 those foods. Two separate issues that need to be dealt
5 with separately.
6 DR. APPLEBAUM: I have just a couple of points.
7 In regards to the statement by Mr. Kimbrell, as it
8 relates, you know, not being allowed to have safe, unsafe
9 foods on the, on the market, just because, you know,
10 whether or not they carry a label or not, we only wish
11 that were the case. We have an incident, or an issue,
12 here in the United States with raw juice being sold and
13 not, and carrying a warning label on that. There's a
14 perfect example of a label for an unsafe product, but
15 that's a different issue. But I want to make that point
16 so Mr. Kimbrell wasn't, was made — it was clear to Mr.
17 Kimbrell that there is an example of that on, in the
18 marketplace.
19 On a different issue, and the question to your
20 point, Ms. Plaisier, as it relates to the issue you
21 raised. It gets down to what are you talking about. Are
22 you asking whether it's mandatory or voluntary? Let's use
23 that tomato as an example.
24 The early tomato being a toxic berry, and
25 today's tomato being, you know, a red, very nutritious

1 product. Let's just say that that early berry didn't
2 contain a toxin, but it contained a particular nutrient,
3 and the nutrient, today, through modern biotechnology, was
4 increased. So let's just say that toxicant is now a, a
5 very beneficial antioxidant, and the tomato, produced
6 today through modern biotechnology, that the antioxidant
7 was increased. It's that increased level of that
8 antioxidant that should be labeled, and that's FDA's
9 policy as it stands. And for that, we applaud that.
10 Because you are providing material information. You are
11 providing information that has to do with health,
12 nutrition and composition. And that is material.
13 As for whether or not to provide that
14 information voluntarily, yes; that information can today
15 be provided voluntarily, as long as it's truthful and
16 non-misleading. You have to be very careful, as the legal
17 shows, as to what constitutes misleading and what is,
18 indeed, truthful.
19 On a different issue, again, it has been raised
20 in terms of taste organoleptic differences. When it comes
21 to mandatory labeling and the statute reads that mandatory
22 labeling revolves — I'll leave it at that — material
23 fact. Material fact, by statute, has to be, is and has to
24 be, consequence-based information. You have to have some
25 type of a common denominator, or a denominator that is at

1 least objective. If you move to a paradigm where you have
2 a value or preference-based information, there will be no
3 end to that type of information that will be required on
4 the product label, or desired on the product label. Were
5 consumer interest alone sufficient to mandate information
6 on a product label, there would be no end to that type of
7 information. Right now, we're focused on a process, a
8 production method. There is materiality associated with
9 that process or the production method, unless there is a
10 significant change in the food. And what we have seen
11 today, in terms of the science that has been presented,
12 there is no discernible impact to the food that can be
13 identified. There's a lot of hypotheses. There's a lot
14 of hype, you know, theories abounding; but there is no
15 discernible impact.
16 So, in order to make your job easier, our job
17 easier, not only as representatives of industry, but also
18 as consumers, you have to have some common denominators
19 that are objective in order to make the issue as easy as
20 possible. If not, when you're dealing with value and
21 preference-based information, that's where the market
22 steps in.
23 Mention has been made to niche markets for
24 kosher and organic. Consumers have made an impact in
25 terms of those three niche markets. The same can be true

1 for GM-free and biotech-free, but it should be voluntary.
2 It should not be mandated by the government. Government
3 has no business in marketing and mandating certain market
4 segments.
5 Thank you.
6 DR. HOBAN: I'd like to just build on what was
7 just said there already, and kind of come back to sort of
8 some different rationale for labeling, which have been
9 used over the years.
10 I think the approach of FDA have been one of
11 sort of need to know, if you will. You will put
12 information on there that there is some need for that
13 consumer to know. And then we'll get into the whole area
14 that Rhona just talked about of the want to know. Things
15 we would like to know about our food. Then you might also
16 imagine a lot of cases in the future where there will be
17 the want to market, or want to sell the food, based on
18 some enhanced characteristics and desirable traits being
19 added in all these new next-generation biotech products.
20 But I do think it comes back to, when it's the
21 want-to-know situation, and where you said there's almost
22 an unlimited amount of things that people would want to
23 know about their food. And that was the point I made from
24 the USDA survey we did a few years back, when we asked for
25 15 minutes worth of question on biotechnology. Went ahead

1 and said: Now tell me if each of the following types of
2 information would be very important, somewhat important,
3 or not important to you to have on a food label. And we
4 did, in fact, find 85 percent said it would be important
5 to know if biotech was on the label; 95 percent wanted to
6 know what pesticides were used; 93 percent wanted to know
7 the type and amount of fat, the food additives, the
8 radiation. Those four all came in above biotech. The
9 other thing that came in was 81 percent wanting to know
10 the country of origin. So I do feel like, if we had
11 asked, did you want to know if it's produced in an
12 environmentally sound manner, you'd get 95 percent. I
13 mean, there's a lot of things consumers would want to know
14 about their food.
15 Now I thought it was very interesting, the
16 comments about the organic industry right now. Because I
17 would imagine, if I was in the organic industry, I would
18 see this whole issue as one of the greatest boons to the
19 business imaginable because of the fact that, for those
20 consumers who want to know and want to avoid the products
21 of modern biotechnology, I think this is an incredibly
22 efficient and effective niche for that to happen. And,
23 if there's been a growth rate of 23 percent, hey!, this
24 may cause an even greater increase in consumers' desire to
25 avoid certain products because they want to know, as she

1 was saying, the food is produced along a number of
2 desirable characteristics.
3 So, I guess that's where we're thinking that, if
4 there was a way that this could be described for people,
5 and you could put the products side by side in the store
6 and let an actual test be done — and there were those
7 done, if you think back a few years, in England, back
8 before, when there was still a consumer choice allowed in
9 England.
10 There was actually a tomato paste produced and
11 sold through Safeway Stores, and others, that was labeled
12 as a product of modern biotechnology. Then it went on to
13 explain how that resulted in less wastage of the tomato,
14 and things. It gave a little benefit statement. Then the
15 clincher was, it was a couple cents less a can and it
16 outsold the other tomato pastes very, very quickly. Now
17 that was, of course, pre all the publicity that's been
18 going on in the UK.
19 I think you'd find the same case here. It'd be
20 nice to see a true market test, where there would be a
21 GM-free product on the shelves right, next to one that's
22 already, you know, produced through conventional means,
23 and see, you know, given the differential costs that might
24 be associated. As I understand, organic does cost a bit
25 more. You know, see if the consumer will pay for it or

1 not, rather than seeing this proliferation. If you go to
2 the average supermarket, where now you may have 50 or 60
3 different kinds -- and I used spaghetti sauce as an
4 example. You've got it with basil, you got it with
5 garlic. You've got all these different kinds of choices
6 for the consumer right now. If you were to then double
7 those, so that some could be GM-free and some would not,
8 in the average supermarket, I think what you'd end up with
9 is them saying: Well, gosh! We're going to only have
10 room for 60, so we're going to scrap 30 of the ones we
11 already have anyhow.
12 So I think these kind of issues have to be
13 decided as compared to having a whole different
14 alternative channel of products available for that
15 consumer who wants to know, wants to avoid — and that's
16 what we're having here: not who wants to seek out, but
17 wants to avoid, just like people want to avoid pesticides,
18 want to avoid other kinds of things. I think that just
19 makes it more market oriented sense and will still give
20 the consumers — again, in the surveys we've done, we find
21 that people generally aren't as concerned about this as
22 they are other issues, like pesticides, fat content, and
23 things like that — in that market an opportunity to work.
24 COMMISSIONER HOLSTON: Ms. Haeger.
25 MS. HAEGER: I wanted to comment on several

1 things that have been said.

2 Dr. Applebaum talked about the fact that their
3 voluntary labeling is a solution because, then,
4 individuals can decide whether or not they wanted to
5 inform the public about what's in the product, and that
6 RBST was used as an example. RBST was finally allowed to
7 be labeled after a 7-year lawsuit. The original
8 regulation, by the FDA, did not allow manufacturers of
9 dairy products to label their products. It originally had
10 to be fought in a court of law whether or not that label
11 could go on products, telling consumers that it was free
12 of RBST. And, yet, the final label that came out that's
13 telling consumers where people can say that it has RBST,
14 it tells them that it's no different than any milk that's
15 produced with RBST; but it fails to tell consumers that
16 there's good, sound science out there that shows that
17 there's increased incidence of mastitis in cows. So what
18 kind of a really and truly informed decision is the
19 consumer getting to make in that particular instance?

20 I think, also, when we talk about niche markets
21 and organic and kosher, et cetera, and the fact that this
22 allows consumers to make a decision, I think it goes much
23 -- in this particular instance, it's very difficult.
24 Because, as we've discussed in organic alone, there is
25 contamination and there is cross-pollination. There are

1 other issues in transportation and contamination of other
2 materials with genetically-changed material, which then
3 changes the organic material. And until those kinds of
4 issues can be addressed — for instance, until all of the
5 ingredients and byproducts are segregated and a
6 manufacturer can know whether or not they're buying a
7 non-GMO-produced product, they can't label it non-GMO.
8 In the market today, it's very difficult. We
9 see a proliferation now of marketing claims being made
10 because people that it is a market advantage to say it's
11 non-GMO. But there's no standard there, and there's, in
12 many cases, companies that I know that very much want to
13 deliver non-GMO products to their customers but can't do
14 it because they're having such a difficult time finding
15 out if their original supply is GMO or non-GMO.
16 We know, today, that genetically engineered corn
17 is being processed into corn syrup, and because it doesn't
18 test for having genetic modification DNA in it, because
19 the DNA is so mutilated in the processing, it's being
20 shipped over to Europe and being sold as non-GMO corn
21 syrup when, in fact, it's derived from genetically
22 engineered corn. These are the kinds of things that
23 manufacturers and suppliers are confronting in the
24 marketplace, and it's very difficult, then, to bring a
25 product to market that consumers can make a choice about,

1 unless the agency is requiring those products to be
2 segregated and to be labeled.
3 Mr. Hoban talked about there's a lots that
4 consumers want to know. And I think that, in this
5 particular instance, consumers want to know because the
6 debate over whether or not there is material change in
7 these products and the types of impacts that have in the
8 long term in the environment and on human health have not
9 yet been resolved, and while those questions are open
10 consumers want to be able to make a choice about whether
11 or not they consume them. So I don't think the burden
12 should be put on manufacturers to develop products that
13 are non-GMO. Let those who are investing the dollars in
14 developing genetically modified products indicate to
15 consumers that that's what they are, and then let
16 consumers choose.
17 It fundamentally comes down to the fact that you
18 can do focus groups, and you can have consumers standing
19 there in the aisle looking at a non-GMO or GMO product;
20 but, if they don't understand, in the first place, what
21 the issue is, they're not going to be able to make a good
22 decision. And I think that's why we're seeing in America
23 today, now, that the issue is growing through the process
24 of these hearings, because people are getting themselves
25 educated. It's the process that's going on. It's while

1 this process is going on, I think it's very important to
2 include everyone who is impacted by it in the dialogue.
3 I think it fundamentally comes down to the fact
4 that these products have been made GRAS, and there's a lot
5 of questions outside of the biotech industry, and outside
6 of the FDA, that people feel aren't resolved; and,
7 therefore, the product should not be being considered as
8 GRAS right off the bat.
9 COMMISSIONER HOLSTON: Thank you. Bob.
10 MR. LAKE: I would like to ask a question that
11 follows up on some of the discussion we've just had. But,
12 before I do that, I need to correct an omission.
13 For some inexplicable reason, I failed to point
14 out in my little discussion up front that, under existing
15 FDA policy, we would require the labeling of an unexpected
16 allergen, should it shows up in a food. I just failed,
17 failed to say that explicitly.
18 Coming back to some of the discussion we were
19 just having, I heard concerns about the need for FDA to
20 set standards. I've heard concerns about contamination,
21 and even, you know, among organic growers who are trying
22 to stay away from genetically engineered organisms.
23 I guess one of the questions, you know, that I
24 would like to ask of this group, and I would like each
25 panelist to answer it — I've asked it in the two previous

1 meetings, as well — what would be your thoughts on what
2 the appropriate standard would be for genetically
3 modified-free on a food label, taking into consideration
4 the fact that there is apparently a growing amount of
5 unavoidable contamination?
6 Let me just start down at this end of the table,
7 and I would like to hear from each of you.
8 DR. HOBAN: Well, certainly, one of the lessons
9 that has been learned in pollution control — which we've
10 done a wonderful job of over the last 25/30 years —
11 certainly more could have been done. But it often — you
12 can get out the first 95 percent of the pollution for a
13 certain amount of money; and, then, getting that final
14 percent, that 5 percent out, is going to cost you as much
15 money as the first 95 percent, and some.
16 So I would think we do need to set the standard
17 at some point, and I don't have the number, a magic
18 number, out of the air that would be, I would say, cost
19 effective to the standpoint that it would still give a
20 consumer a sense that it was free of any GM materials;
21 but, in a sense, didn't drive the prices through the roof
22 by being unrealistically stringent and making sure there
23 was like 0.01 percent. I think the number that's been
24 thrown around is 2 to 3 percent, something along those
25 lines.

1 I would say FDA goes back and looks at some of
2 your other tolerance settings. You know, you got
3 tolerances for certain things. We don't need to get a lot
4 into the insect parts, and things like that. But there
5 are certain things in food that, if they're below a
6 certain below a certain level, they're not required to be
7 put on the label, and they're not required to be discussed
8 in any particular manner. So there's certain tolerances
9 for metals, et cetera. Not to put these in the same
10 category as biotech, but I'm just saying, in fact, we
11 can't achieve zero. There's no such thing.
12 I think the other thing that's important to talk
13 about in this whole debate, which we missed, is that there
14 is no zero risk to anything, either. Everything we do,
15 everything we eat, contains some sort of risk. So I think
16 at that point, you need to just use your best available
17 science and find something in consultation with consumers,
18 with the industry, that's going to have to carry out the
19 law.
20 Then I would again come back to something like
21 the case of caymosin, where you've already decided, and
22 the marketplace has already accepted the fact that that's
23 been a genetically engineered product that's been on the
24 market for for 8 or 9 years now, and we're not going to go
25 — we're going to go back and require that to be in some

1 way labeled differently.

2 MR. KIMBRELL: That's a very good question and a
3 very difficult one, and I know the organic community is
4 working on that question. It's one they're going to have
5 to resolve.

6 Just a quick comment before, when Ms. Applebaum
7 correctly said that there are products out there that are
8 not labeled, but are adulterated. And I think you
9 mentioned the E. coli.

10 DR. APPLEBAUM: Orange Juice.

11 MR. KIMBRELL: They are labeled but adulterated.
12 You mentioned the E.coli, apple juice. That's very true.
13 As a matter of fact, one of my lawsuits against the Center
14 for Food Safety recently was against the USDA for not
15 having mandatory cooking instructions on beef because of
16 the E.coli contamination. And we said it is mis-branded.
17 That beef is mis-branded because you're selling it without
18 saying how it has to be cooked in order to make it
19 healthy, to make it worthy of the brand that it currently
20 has. We won that lawsuit. It's on the label that you can
21 see.

22 So I certainly support you, and I agree with
23 you, that federal agencies sometimes guilt of not having
24 the right labels on, and that we need to remain ever
25 vigilant to make sure that they do the job so that public

1 safety and health is protected.

2 I think on the genetic pollution issue, we have
3 a very complicated, speaking as an administrative attorney
4 — admittedly, some people think of some of the lowest
5 forms of life on earth; but I think the work is
6 interesting — this is a major problem that you brought
7 up. Absolutely important problem. I'm not sure FDA is
8 the major agency that has to deal with it. We know that
9 EPA and USDA actually have better jurisdiction on this.
10 But the problem with the entire environmental movement —
11 which many of us have been struggling for — is that it is
12 based on a chemical pollution paradigm. All right?
13 Chemical pollution is a contamination model of pollution.
14 You put poisons in the water, you put poisons in the air,
15 you put poisons in the food, and we want to get rid of
16 those toxics — right? It's a contamination model.

17 We're dealing here with biological pollution.
18 Biological pollution is a disease model of pollution. You
19 have pollution by a living organism, or by genetic
20 components of a living organism. And one of the great
21 difficulties we've had, and the reason this has been so
22 litigious and such a difficult area, is that all of our
23 environmental laws, Clean Water Act, Clean Air Act, the
24 whole acronym bit, are based on chemical pollution. And
25 despite the best efforts of people of then-Representative

1 Gore and Senator Bacchus and Bob Castenmeyer, and many,
2 many fine legislators throughout the years, we've never
3 been able to pass a singly law on biological pollution,
4 never, over the last 15 years that they've been trying,
5 these fine legislators, because of the pressure from the
6 biotech industry. So we don't have any laws on the
7 biotech industries.
8 So what happens? We have to take all of these
9 issues and try and shove them back into regulatory
10 agencies — which, even despite my occasional rhetoric, I
11 have some sympathy for — who then have to regulate these
12 biological pollution issues under chemical pollution
13 statutes. So you have these weird things like where you
14 have to view an entire plant as a pesticide. Or USDA will
15 have to view a whole plant as a plant pest. These very
16 anomalies. Well, you have to do that because of the
17 resistance to a really good law on biological pollution
18 that we desperately require if we're going to deal with
19 this problem.
20 I recently had a meeting with Secretary
21 Glickman. He said that his major concern here is the
22 liability issue, regardless of the tolerance level that is
23 set up. Whether it's 0.1, as some have requested, or more
24 than that, you're going to have a biological pollution
25 issue. And he feels that the government has significant

1 liability in this. Because, if they allow a genetically
2 engineered crop out there, there will be the inevitable
3 genetic drift, this biological pollution, that the
4 government will be liable. And he, at that point, was
5 suggesting actually self-insurance by the government to
6 try and avoid this problem.
7 Once again, it's in your own 1992 policy. The
8 chickens are coming home to roost. I hope that's not a
9 double-entendre.
10 The biological pollution issue -- which,
11 unfortunately, the biotech industry has been able to stop
12 reasonable and important legislation going through -- is
13 now reaching the point where it's going to have tremendous
14 liability for the industry, and potentially for the
15 government. It's long past due that we address this
16 question, long past due.
17 [Applause.]
18 DR. APPLEBAUM: Your issues, Mr. Lake, in
19 regards to what type of criteria to use, in our comments,
20 we identified three criteria, that there needs to be some
21 type of a threshold. If you're looking for a number at
22 this point in time, we don't have a specific number. The
23 numbers are all across the board. Sometimes, from the EU,
24 it's 1 percent. Sometimes you hear a tenth of 1 percent.
25 Some people try to throw out zero. We know zero is

1 technologically unfeasible. You just won't be able to do
2 it.
3 At the same time, I think there are — there's
4 some work that needs to be done. The number is not just
5 going to pop out of the hat. There's going to have to be
6 some studies done to assess what that, what is technically
7 feasible from the potential for cross-contact, or the
8 issue of drift. So there isn't a number that we can
9 identify, I can identify, for you today. I think it's
10 something that's going to take a little bit more, more
11 research to get a hold on.
12 As it relates — and this is an issue that I
13 want to get back to Ms. Haeger. We, too, do not agree
14 that something should be identified as GM-free just
15 because you can't find it. If that were the case, we
16 would only put the one criterian for GM-free, that it be a
17 threshold, and either you meet that or you don't. You do
18 have to have substantiation. You do have to have identity
19 preservation and other trace-back to make sure that, if
20 you're dealing with a corn syrup, that corn syrup was not
21 derived from BT corn. To do anything else but would be
22 misleading to the consumer, and you can't do that. And
23 last but not least, of course, you have to have the
24 accompanying statements. Because, in today's environment,
25 there is a warning associated with biotech not due from a

1 scientific perspective. It is a fear that has been
2 generated due to a gap in the information. And to
3 require, or to allow for a GM-free, or contains GM type
4 label, without the accompanying statement, would just be a
5 disservice to the consumer. It would not be providing
6 them with the information they need to have a balance
7 assessment of what that, that truly does infer.
8 MS. HAEGER: This relates to your question about
9 a GM-free label. I agree that threshold levels are really
10 difficult to identify. Certainly the current testing
11 methodologies that are available will test down to
12 one-tenth of 1 percent. Most things, except for processed
13 ingredients, can be tested for that. However, as we see,
14 because of the difficulty with processed ingredients, in
15 many cases, people are being misled. I think, therefore,
16 the only competent way to do it is to see the shelf
17 tracking system that has similar system to the
18 certification that's done for organic.
19 I think, also, the established threshold for
20 genetically engineered foods must apply to individual
21 ingredients and not to the overall product only. I think
22 that's very important. I think consumers who are
23 concerned about avoiding genetically modified organisms in
24 their food want to know that on an ingredient basis,
25 versus on a general overall product basis.

1 And I think that the processes that are
2 developed for pre-market safety testing and for handling
3 liability issues are critical to this whole concern of
4 creating a GM-free label. Because, as we've heard about
5 in organic — and I think the organic community is only
6 beginning now to identify all of the issues for which
7 they've been impacted — is that we have all of these
8 genetically engineered crops that have been planted, and,
9 over the 4 years that there's been such a large
10 proliferation, it's only now that we're figuring out what
11 it's impact is on the organic community. There could be
12 other impacts that we're going to be figuring out two or
13 three years from now that have — that causes more serious
14 concern; and, therefore, I think that the liability issue
15 and the pre-market safety testing issues are going to have
16 to be addressed.
17 I also go back again to this point, which I've
18 made several times, but which I think is very important,
19 is that, when we talk about a GM-free label, I think it's
20 — at this moment, we're encouraging companies to develop
21 foods that are free of genetically modified organisms. We
22 don't think you can have a GM-free label. We actually
23 think that's a misleading label because you can't get
24 GM-free at this point. You can get to a certain
25 threshold.

1 But I think that, again, the burden of dealing
2 with this labeling, and informing the consumers when these
3 products are present, should be on the foods that are
4 genetically modified and not on creating this whole new
5 niche market now.
6 Natural health consumers, those who, you know,
7 who are buying in natural food stores and natural products
8 in traditional supermarkets, these people want to know
9 whether or not the food is genetically modified. And
10 we're talking now about having to create alternate system
11 to organic, which is now going to be a non-GMO system.
12 MS. GOODMAN: I'd like to respond to your
13 question. As was stated earlier on the panel, the range
14 of tolerances that are being considered by the organic
15 industry right now have not been formulated. They are in
16 discussion. The Organic Trade Association has a task
17 force that's looking at trying to determine tolerances
18 that are acceptable to the organic industry. And the
19 numbers of the EU of 1 percent, down to testing ability of
20 one-tenth of 1 percent, are all being considered, and
21 everywhere in between.
22 It brings up whole plethora of issues and the
23 minutiae becomes overwhelming of how far detailed do we
24 want to go, as an industry, to trace back where can
25 contamination occur. And, then, the question arises: Are

1 all products evaluated at the same level? Will there be
2 varying levels and varying tolerances for different uses
3 and different products?
4 The bigger question, for the organic industry,
5 is the cost of all of this testing. Right now, it is the
6 industry to bear the burden of proving the proof of the
7 truth of their label, that, in fact, there are no
8 genetically engineered organisms in organic products. The
9 organic industry is essentially looking for the needle in
10 the haystack, and it's exceptionally costly. Were
11 manufacturers to put this information on their labels at
12 all levels of the product chain, we'd only be bearing the
13 cost of labeling, which eliminates the mystery, as well.
14 And I really can't help but have this prompt this question
15 to me: If the confidence is there in the safety of these
16 products, why is there so much objection to labeling?
17 [Applause.]
18 MR. BOSSMAN: Obviously, if this was an easy
19 answer, it would have been made quite some time ago. In
20 the grain feed industry, for instance, the tolerance level
21 for foreign material is 3 percent. That's the starting
22 number. Now, as we just heard, there probably needs to be
23 multiple levels, and it would make some sense to have
24 multiple levels. If you have fresh produce, for instance,
25 where people are consuming it right off the vine, that

1 probably should have a different tolerance level, or a
2 different labeling level, if you will, than something that
3 has been processed. You can expand that to something that
4 has been further processed more than once, because the
5 levels would continue to drop.
6 As Dr. Baldwin said this morning, when you pass
7 products through livestock, it's an incredibly good
8 screening process, if you will, to take out anything that
9 humans can't eat or wouldn't want to eat, or may feel that
10 it's not safe to eat; but the meat, the eggs and the milk
11 that they get is certainly wholesome.
12 So there's a huge gap, I think, and, clearly,
13 it's one of those that you're struggling with. Is it
14 proper to just label it GMO of GMO-free? I'm not sure
15 that that's even proper. I suspect, in an year or so, we
16 will come back and the debate will be how do the companies
17 that develop the products that want to label, because of
18 the attributes that they gain out of the technology, how
19 are they allowed to label those products? Whatever you do
20 now certainly has to pass that test, as well.
21 If we use terms like "uses less pesticide," or
22 "produces less waste," they are very user-friendly terms,
23 and, clearly, they are apart of all of this. The
24 biotechnology firms aren't making these products just for
25 the sake of making these products. There is a need out

1 there that are satisfying. And I think we sometimes lose
2 sight of that.
3 Are there risks? Yes, but none of them as great
4 as what they are when we jump in our car and drive home
5 tonight.
6 COMMISSIONER HOLSTON: Thank you.
7 Panelists?
8 MS. COPP: I'd like to ask a question as a
9 follow-on to Mr. Lake's question. He assumed in his
10 question, I believe, that FDA would set the standard, if
11 they were such a standard for GMO-free, or whatever the
12 label might be. I'd like the panelists to address whether
13 there are other organizations that could also, independent
14 of the agency, set a standard. What are your thoughts on
15 that?
16 DR. HOBAN: I'd just might throw in one concept
17 that would be very important. It probably ought to be an
18 international standard at some point, given the fact that
19 the commerce does take place. I know you're all involved
20 with Codex, and things like that. I would imagine that
21 any standard that would and could be set ought to be in
22 harmony. Because that's much of the difficult we're
23 running into right now, which is: The depth of the ocean
24 between here and Europe.
25 MR. KIMBRELL: I think this problem is actually

1 rather easily solved, as Diane and Susan have suggested,
2 simply by putting the burden where legally it belongs,
3 which on those who are introducing genetically engineered
4 foods into the market to label. That's what the law
5 requires.
6 And I respectfully disagree with Mr. Hoban.
7 This is not like country of origin, or as FDA official
8 once said, like scab labor or union labor picking your
9 fruit. That was an irresponsible statement to make to the
10 press, which they did.
11 I have -- I mean, I don't want to go and bore
12 the audience with a list, but you all know these. I can
13 go down to the Calgene Flavr Savr Tomato, the DNA Plant
14 Technology ripening tomato, all the way to AgrEvo's
15 tolerant corn. Each one of these -- and by the way,
16 unlike the mild produced from BST, each one of these has
17 novel material changes, performance characteristic
18 changes, and organoleptic changes. That is texture, by
19 the way, shelf life, nutrient values, which have already
20 been determined to be requiring labeling, mandatory
21 labeling, by FDA. All right? Each one of these foods is
22 patented for that purpose.
23 So I think the whole discussion of voluntary
24 labeling is both legally incoherent and also tremendously
25 unjust to companies who are not trying to bring these

1 changes into the food system, and you're asking them to do
2 this, to actually try to find another body that might find
3 a label that find a label that would be suitable for them.
4 It's easy: Follow the law. Label these material changes.
5 Have the companies that are introducing this food in the
6 market, mandatory labeling. Very easy. It's your
7 solution.
8 [Applause.]
9 MS. COPP: Excuse me, Dr. Applebaum. I've been
10 asked to restate my question. My question is: If you
11 assume that there will be voluntary labeling of GMO-type,
12 free-type labeling, and that there needs to be a standard,
13 which I believe your organization has stated is the case,
14 who, besides FDA, could perform the function of setting
15 that standard?
16 DR. APPLEBAUM: And, again, I think that's an
17 excellent question. Also, it even goes further in terms
18 of establishing, perhaps -- it might already be
19 established -- a body to assess whether or not they're
20 meeting those criteria, once those criteria are set.
21 I think, in terms of a body of this nature, it
22 needs to be all stakeholders, not just the industry. Even
23 though the industry is very keen on allowing opportunity
24 to police itself. We know that raises a lot of issues,
25 you know, with that type of a statement. So we would like

1 to see something where all stakeholders a part of the
2 panel, or part of a council, if you will, consumers,
3 industry, academics, government, to the extent that
4 government could participate on such a panel, to have
5 these criteria established. Where the facts are presented
6 in terms of what the reality is, and identify, again,
7 going with the threshold, going with the substantiation,
8 as well as the accompanying statements.
9 Now, once those criteria are set, we can't
10 expect FDA to provide resources to determine whether or
11 not those criteria are being met. They have a greater job
12 in the enforcement.
13 So, in terms of looking at what's currently
14 available as a prototype, as a paradigm, the National
15 Advertising Council, for example, seems to work very well
16 as it relates to identifying whether or not advertising is
17 meeting — quote-unquote — "the letter of the law." If
18 it isn't, it's sent over to the FTC. These are all ideas
19 that we, I think, would welcome the opportunity to
20 brainstorm further with FDA on, as well as others, who are
21 interested in advancing this issue, as opposed to just
22 seeing it shelved for not particular benefit to humankind.
23 Thank you.
24 MS. HAEGER: I simply want to comment that it
25 concerns me that the agency might consider, in light of

1 the comments which have been made in the three panels,
2 including today's thus far, and other comments which have
3 been submitted and the questions which have been raised,
4 the idea of putting forward voluntary labeling before
5 these other issues around whether or not these products
6 are, in fact, GRAS, and whether or not, in fact, the
7 consultation process should not be a process of simply
8 getting information from industry, but should be a process
9 of looking at the information provided and independently
10 evaluating it, and determining if there's other criteria.
11 I mean, I heard on the science panel this morning, and
12 from other scientists that have presented previously, that
13 there is still a big debate in the scientific community as
14 to whether or not these products cause a concern in health
15 and environmental implications.
16 And, so, I think to simply set up a voluntary
17 labeling system at this juncture is not going to serve the
18 public. Because, for those people — and I'm one of those
19 people who wants to know whether or not I'm eating
20 genetically modified organism in my food. I have no
21 guarantee that, when I purchase food, that I'm fully
22 informed. Or else I am going to have to search out those
23 foods which have gone through this process and have been
24 voluntarily labeled, and I may or may not be able find
25 them when I need them.

1 So, I think that there's some fundamental issues
2 that have been brought up through these hearings that need
3 to be addressed by the agency before any voluntary
4 labeling or simply making the current consultation process
5 from voluntary to mandatory should be considered.
6 COMMISSIONER HOLSTON: Before you comment, I
7 would just like to say that we want to make certain that
8 we have adequate time for our oral presentations. So
9 we're getting very close to the end of this part of the
10 program.
11 Let me just ask my panel, who else has a
12 question that they would like to raise? Jim, Bert. Okay.
13 I just need to gauge how much time we have left.
14 Please go on.
15 MS. GOODMAN: I'll be very quick. I'm a
16 creative thinker, and I always think very positively.
17 And, when I hear this question, I start thinking: Okay.
18 Who else could be involved in this process? Well, USDA
19 should be involved in the process, and EPA should be
20 involved in the process. And then I realize that this
21 process is going to open up a Pandora's Box, but
22 essentially it's the wrong box.
23 I think GMO-free standards is looking at the
24 situation that needs to be addressed in a convoluted way.
25 If you go towards GMO-free labeling, then you're going to

1 need regulations. And after regulations, you're going to
2 need enforcement. And enforcement is going to require
3 testing. And enforcement is going require penalties. And
4 my question that that would promote would be: Will the
5 government be funding the cost, the cost of an entity
6 meeting those standards? Would this become a marketing
7 program that would be subsidized by the government so that
8 you could say your product is GMO-free? And I think it's
9 really the wrong box.
10 I think it needs to go back to the manufacturer
11 taking the liability and saying, yes; these things are in
12 our products. And, if the belief is there that they are
13 okay, and they are safe, then they can do their own
14 marketing and let the market decide whether or not they
15 want to purchase them.
16 [Applause.]
17 MR. BOSSMAN: There are a lot of groups that
18 would certainly help with the labeling; but, ultimately,
19 it's going to come down to FDA, EPA and USDA, or the
20 government approving, if you will, those labels. Clearly,
21 there's going to be lawsuits that follow, on one side or
22 the other, and it's got to come down to the government
23 approving the labels. But you can have a lot of help in
24 having people help you build them.
25 COMMISSIONER HOLSTON: Thank you very much.

1 And the last question from the FDA panel will
2 come from Dr. Bert Mitchell.
3 DR. MITCHELL: Just a quick question, then, for
4 Dr. Hoban. To the extent that you can here, and
5 preferably I think for the docket, would you elaborate on
6 the distinction you introduced there between education and
7 labeling, as far as the consumer is concerned?
8 MR. BOSSMAN: Well, very good.
9 Certainly, there is a distinction. Our feeling
10 is that any kind of labeling, if you want to make an
11 informed choice, you need to know what a term on the label
12 would mean. So if you look now at the nutrition facts
13 label, people get a lot of information on fat content,
14 salt content. Often, if their physician — they, in other
15 words, have a reason to care about that issue to start
16 with. And the education they gain is often sought out as
17 a result of some of us being a bit overweight and thinking
18 we should avoid fat, some of us being hypertensive and
19 want to avoid salt. So we actually go and seek out
20 information actively.
21 What we found with this particular issue of
22 biotechnology is almost the vast majority of things that
23 people have heard so far have come from the mass media.
24 They've heard a strory on the news. They've heard a
25 little bit about it. They really haven't delved to deeply