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FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

IMPLEMENTATION OF THE FOOD AND DRUG ADMINISTRATION  
MODERNIZATION ACT: PROVISIONS FOR USE IN  
FOOD LABELING OF HEALTH CLAIMS AND NUTRIENT CLAIMS  
BASED ON AUTHORITATIVE STATEMENTS

PUBLIC MEETING

Tuesday, May 11, 1999

8:35 a.m.

Jefferson Auditorium  
US. Department of Agriculture  
South Building  
1400 Independence Avenue, S.W.  
Washington, D.C.

MILLER REPORTING COMPANY, INC.  
507 C Street, N.E.  
Washington, D.C. 20002  
(202) 546-6666

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P R O C E E D I N G S

**WELCOME AND INTRODUCTION**

1  
2  
3 MR. LAKE: Good morning. We might as well go  
4 ahead and get started.

5 My name is Bob Lake. I'm with the Food and Drug  
6 Administration Center for Food Safety and Applied Nutrition.  
7 My new title, since we went through a slight realignment, is  
8 regulations and policy.

9 Let me first welcome each and every one of you.  
10 We have a long day and I would like to stick as closely to  
11 the schedule as possible, particularly the panelists that we  
12 have coming at 1:00, right after lunch. Their time--several  
13 of those people have time that is very tightly constrained,  
14 so in particular we want to be on time for that part of the  
15 program.

16 As you came in, there were cards on which you  
17 could write questions and I would encourage you to, if you  
18 have questions, to write them down on one of those cards and  
19 at three different times during the course of the meeting,  
20 we will take questions. The first time will be after--I'm  
21 going to give a little bit of an introduction here and then  
22 Dr. Christine Lewis will be giving a little bit of the  
23 framework for the rest of the day and we will take some  
24 questions at that time and before we have our morning break.

25 Again this meeting today is about the provisions

1 on authoritative statements relative to claims that is found  
2 in the FDA Modernization Act, and I'll say more about that.  
3 Indeed, the whole topic for the day will be about that.

4 Let me give you a few housekeeping things before  
5 we get into the meat of the program. I'm told that the  
6 ladies room, for those of you who wish to visit it during  
7 the day, that if you turn left after going out the back of  
8 the auditorium--no, I'm sorry; ladies room is to the right,  
9 down to wing 5 and then you go up wing 5, past the elevators  
10 and there will be the ladies room, water fountains and also  
11 telephones.

12 For the men, if you go out and turn left down to  
13 wing 6 and up wing 6 till you see water fountains, restroom  
14 and also some telephones there.

15 At the lunch break if you want to eat in the  
16 cafeteria, that will be available to you. You go to the  
17 right down to wing 3 and then down the steps.

18 Incidentally, as you're wandering in the building,  
19 if you wear the name tags that you picked up when you came  
20 in, that will allow you to come back into the complex.  
21 That's the security mechanism that they are using here.

22 This meeting is being hosted by the Food and Drug  
23 Administration but the folks at the Department of  
24 Agriculture have been kind enough to make this auditorium to  
25 us and to provide the service here and we very much

1 appreciate that.

2           The Food and Drug Administration Modernization  
3 Act, otherwise known as FDAMA, was signed into law in  
4 November of 1997. It provided for health claims and  
5 nutrient content claims based on authoritative statements  
6 from federal scientific bodies that had responsibility for  
7 nutrition research and also the National Academy of  
8 Sciences.

9           FDAMA became effective 90 days after passage.  
10 And, of course, it's a very large piece of legislation and  
11 has a lot of provisions in it. FDA, all parts of FDA, have  
12 been very busy since its enactment, figuring out how to  
13 implement the various provisions in it.

14           In many instances we've had to begin some  
15 implementation prior to actually having the opportunity to  
16 develop regulations and the authoritative statements are one  
17 of those situations. We first issued guidance relative to  
18 authoritative statements in May of 1998, about a year ago.

19           The first notification that the agency received  
20 for health claims based on authoritative statements was  
21 received in February 23 of 1998. It was a single  
22 notification but it contained nine different health claims  
23 based on various statements that were identified as being  
24 authoritative by the notifier.

25           FDA issued interim final rules to prohibit the

1 claims, which is one of the options. We actually have to  
2 respond in 120 days to prohibit or modify. If we take no  
3 action, the claim is allowed by operation of the statute.

4 In the case of these original nine health claims,  
5 we did publish interim final rules to prohibit them and  
6 these were published in June of 1998.

7 In the preamble to the first of these nine rules,  
8 the one concerning vitamins C and E, FDA spelled out a  
9 tentative approach on how we were going to deal with these  
10 notifications for--or claims based on authoritative  
11 statements. Since that time, we, of course, have gotten a  
12 lot of comment and it is because of the number and nature of  
13 the comments that we've gotten that we felt that we needed  
14 to have this meeting today to provide a public opportunity  
15 for considering some of the issues around how we should be  
16 dealing with authoritative statements in the future.

17 The agency at this point is very open on where we  
18 go in the future and we're looking forward to hearing the  
19 comments from the two panels that will be coming up here  
20 momentarily, as well as the other people from the audience.  
21 A number of people have asked to speak this afternoon and so  
22 we will be hearing those comments, as well.

23 I think at this point what I will do--well, let me  
24 briefly review the agenda and I'll tell Chris Lewis to start  
25 getting ready because she'll be up here momentarily. And

1 then, following her presentation, we will have an  
2 opportunity for questions, which can be about the further  
3 proceedings if you wish. I mean any questions about the  
4 arrangements or anything like that we will certainly take at  
5 that time.

6           Following that, we will have a break and then, at  
7 10:00, we have scheduled some remarks from Joe Levitt, the  
8 director of the Center for Food Safety and Applied  
9 Nutrition. He is, as many of you know, not new to the  
10 agency but new to CFSAN and coming into the whole area of  
11 health claims and authoritative statements with an open  
12 mind. So he will have some remarks.

13           Then, following that, we have a panel and we won't  
14 ask them to come up until after the break but this will--and  
15 the panelists know who they are, but it'll be the  
16 representatives from several segments of the industry.

17           Following that, there will be an additional  
18 opportunity for questions. Then we will break for lunch,  
19 and again you're on your own for lunch. The cafeteria is  
20 the closest thing, the one in the building, but there are  
21 other places outside if you wish. But again we will be  
22 promptly reconvening at 1:00 to listen to the scientific  
23 panel, which we're all anxious to hear from.

24           Once that is over, we will have a further  
25 opportunity for questions and then, following that, the



1 given us an alternative process or a fast track for nutrient  
2 content and health claims.

3 In short, the situation is more or less that under  
4 the NLEA petition process, a petition is submitted by an  
5 interested party. FDA conducts a review of the scientific  
6 basis, usually in conjunction with a PHS agency. This then  
7 goes through notice and comment rulemaking and, in the end,  
8 there's an authorized claim.

9 Under the FDAMA notification process, the  
10 scientific basis is established by the scientific body, not  
11 FDA, by the scientific body in an authoritative statement.  
12 A notification is submitted by an interested party and  
13 without prohibition on the part of FDA, the claim is  
14 authorized by the statute.

15 As Mr. Lake mentioned, last year we went through  
16 the process of reviewing our first notification under the  
17 FDAMA provisions. The kinds of issues that have been raised  
18 fall into four broad groupings.

19 First, can authoritative statements be generally  
20 characterized? What are the characteristics of  
21 authoritative statements? Second, what's FDA's role here?  
22 How should FDA interact with the scientific bodies? Third,  
23 what should be included in notifications? What are  
24 notifications to contain? And then last, how should we  
25 think about implementing regulations? At this point in time

1 we do not have implementing regulations, so this is an issue  
2 on the table.

3 For the moment, let's start our framework directly  
4 with some context on authoritative statements, and we have  
5 to keep in mind that authoritative statements are more or  
6 less the star of today's program.

7 We know from the legislation that authoritative  
8 statements are statements from federal scientific bodies or  
9 the National Academy of Sciences that, as described in the  
10 legislation, are currently in effect about a relationship  
11 between a diet or disease or, in the case of a nutrient  
12 claim, about a nutrient level. They're published and  
13 they're not made by employees in their individual capacity.

14 But the first question that's been raised by some  
15 is the question of whether all statements published by  
16 scientific bodies are authoritative. The legislation refers  
17 to authoritative statements, not just to statements, and FDA  
18 has tentatively proceeded with the assumption that not all  
19 published statements from these bodies are, in fact,  
20 authoritative statements.

21 Not all agree with this interpretation, so we ask  
22 the first question: Are all statements from federal  
23 scientific bodies and the Academy authoritative?

24 If, for the purposes of continuing and fleshing  
25 out the approach taken by FDA, we proceed in the direction

1 that not all statements are authoritative, the next question  
2 we have is what distinguishes an authoritative statement  
3 from another statement? As I mentioned before, we have  
4 these four characteristics from the legislation itself. And  
5 while they're helpful, they don't appear to sufficiently  
6 distinguish among the various statements to allow a  
7 conclusion as to what is an authoritative statement.

8           So in many ways, the pivotal question for us today  
9 is what are authoritative statements? Or perhaps more  
10 directly, how is it we know when we have an authoritative  
11 statement?

12           Before we actually tackle questions on  
13 authoritative statements themselves, I want to backtrack  
14 just a little and talk about the process relative to these  
15 FDAMA provisions. As you've heard from Mr. Lake, a  
16 notification concerning the use of an authoritative  
17 statement for a claim on a food is to be submitted to FDA  
18 120 days before the intent to use the claim. The  
19 notification is to include or to identify the authoritative  
20 statement and to provide the exact wording of the claim.

21           FDA can act to prohibit or modify the claim but in  
22 the absence of FDA action, the claim is authorized by  
23 statute.

24           It would seem, then, that the first step in this  
25 whole process is more or less a kind of routine check-in.

1 FDA would look to see if all the pieces are there. Is there  
2 an authoritative statement? Is the source identified? Is  
3 there wording for the claim? And does the notification  
4 contain a balanced presentation of the scientific  
5 literature? This was required by statute.

6 But the question is what happens next? From FDA's  
7 perspective, the scientific body is the best arbiter of  
8 whether its statement is authoritative. They are in the  
9 best position to determine when they have issued an  
10 authoritative statement.

11 But the reality of the situation is that FDA has  
12 the notification in hand and it needs to know whether the  
13 statement is an authoritative statement. Our questions to  
14 you are how should we handle this? How should we get this  
15 needed input?

16 After the passage of FDAMA, Secretary Shalala  
17 facilitated a channel of communication for FDA. Each  
18 federal scientific body was contacted and asked to provide a  
19 person with sufficient authority to speak for the agency;  
20 that is, to assist FDA in this effort. These persons formed  
21 the so-called Liaison Group on Authoritative Statements.  
22 And in this afternoon's panel, which consists of these  
23 members of the Liaison Group, you'll hear from them  
24 directly.

25 I just need to note as an aside that the

1 legislation refers to scientific bodies and identifies these  
2 as federal agencies and as the National Academy of Sciences.  
3 It does not further clarify who these federal agencies might  
4 be, although it gives as specific examples CDC and NIH.

5           The four federal agencies listed here are, at this  
6 time, the agency's best thinking as to the federal agencies  
7 that would constitute the scientific bodies under the FDAMA  
8 provisions. But, of course, this tentative conclusion is  
9 open for comment.

10           The channel of communication, this Liaison Group  
11 of Scientific Bodies, is a first step when we begin to think  
12 about what is the next step? And during this initial first  
13 step, FDA also considered the benefits or the utility in  
14 identifying general characteristics of authoritative  
15 statements. It was considered that such a listing could be  
16 helpful to notifiers in identifying or distinguishing  
17 authoritative statements from other statements, but it was  
18 also well recognized that a listing, if it were to be done,  
19 a listing of general characteristics, had to be developed  
20 with the Liaison Group members; that is, with the scientific  
21 bodies.

22           In the spring of 1998, the Liaison Group began to  
23 meet. The National Academy of Sciences, while a scientific  
24 body by legislation, is not a federal agency and therefore  
25 have not taken part in these Liaison Group meetings.

1 However, we at FDA did meet with them separately and kept  
2 them informed about the Liaison Group activities.

3 As I mentioned, you will hear from the Liaison  
4 Group members today, but I think it's fair to characterize  
5 these early discussions as open, with a great deal of give  
6 and take. The discussions were informal and the topics  
7 ranged from how to make this communication channel work to  
8 identifying general characteristics of authoritative  
9 statements.

10 Some have characterized this effort, these  
11 discussions within the Liaison Group, as helpful. Others  
12 have considered them to be inappropriate, misguided and even  
13 heavy-handed.

14 The approach used in these discussions was to turn  
15 to the legislative history for the FDAMA provisions to  
16 better understand and perhaps to clarify the nature of  
17 authoritative statements. Through this process three  
18 characteristics were added to the general list already  
19 provided specifically within the statute.

20 It was considered that a statement would have  
21 undergone a deliberative review. It was considered that a  
22 statement would not be about a relationship that was  
23 preliminary or inconclusive, and that the statement would  
24 reflect official policy.

25 Concerning deliberative review, both the Senate

1 and the House report highlighted a characteristic that they  
2 described as deliberative review. This characteristic was  
3 added to the list but it was not defined. Its definition,  
4 it was felt, was better left to each scientific body.

5           Secondly, the House report indicated that  
6 authoritative statements would have presumption of validity  
7 and that more scientifically sound nutrition information  
8 would be provided to consumers. On this basis, not  
9 preliminary or inclusive was added as the general  
10 characteristic of an authoritative statement. But again no  
11 definition was attempted.

12           Third, the legislative history indicates that  
13 authoritative statements should reflect consensus within  
14 federal scientific bodies and the statute identifies these  
15 statements as not coming from subdivisions of the federal  
16 scientific bodies, nor from individual employees. So the  
17 concept of official policy was added to the list but again  
18 without specific definition.

19           As I believe you will hear from some of the  
20 scientific bodies this afternoon, experience that they have  
21 had in considering this during the last year has given them  
22 some pause about this concept of official policy and it may  
23 need to be reconsidered as a characteristic of an  
24 authoritative statement.

25           These three added characteristics have been the

1 subject of a great deal of discussion. Our questions today:  
2 Are these characteristics helpful to notifiers and to  
3 others? Are they appropriate?

4 Some disagree they're appropriate. Some disagree  
5 that it's appropriate to link validity and scientifically  
6 sound to a characteristic of not preliminary or  
7 inconclusive. Others are concerned that reference to  
8 deliberative review and not preliminary forces into play the  
9 standard of significant scientific agreement.

10 FDAMA makes reference to SSA or significant  
11 scientific agreement but not in the context of authoritative  
12 statements. FDAMA brings in SSA further along in the  
13 process and for the first notification, the issues we dealt  
14 with never got to the SSA point and the standard of SSA was  
15 not used.

16 Nonetheless, SSA is a very controversial issue.  
17 But if you'll bear with me, we'll leave significant  
18 scientific agreement or SSA just for the moment and return  
19 to the question of the characteristics of authoritative  
20 statements.

21 Having general characteristics of authoritative  
22 statements generally fleshed out, generally agreed upon, FDA  
23 considered whether there was utility and whether it was  
24 appropriate for FDA to conduct a kind of screen or sorting  
25 procedure relative to authoritative statements.

1           Certainly the clear and desirable goal is to have  
2 the scientific bodies consider the statement, but question  
3 we had was was it possible for FDA to play some role and  
4 should we play some role?

5           It's difficult to understand exactly what this  
6 type of screening might be without some examples, and so I  
7 have pulled from the first notification four examples.

8           Submitted in the first notification was the  
9 statement identified as an authoritative statement for a  
10 health claim about chromium. "Scientists must often draw  
11 inferences about relationships between dietary factors and  
12 disease from animal studies or human metabolic studies and  
13 population studies that approach issues indirectly." This  
14 was from the Surgeon General's Report.

15           In looking at the statement, we could find no  
16 substance mentioned and no disease mentioned, so under the  
17 statute, the statement couldn't be considered an  
18 authoritative statement from our perspective.

19           Our question is perhaps such a statement could be  
20 screened by FDA and there would not be a need to consult  
21 with a scientific body, but that's a question and it's a  
22 question at one end of the continuum.

23           Another example from the first notification  
24 probably raises the question of preliminary or inconclusive.  
25 The statement, identified as an authoritative statement,

1 began with the phrase, "If the findings hold up in further  
2 research, eating more," and then goes on to discuss beta  
3 carotene from fruits and vegetables and cancer. Our  
4 question is could this be clearly in the domain of  
5 preliminary or inconclusive? Could it be screened?

6           It gets somewhat more complicated with our third  
7 example from the first notification. A rather definitive  
8 sentence about anti-oxidants and cancer, here bolded in  
9 white and submitted as the authoritative statement is  
10 followed immediately in the text, the publication, by a  
11 second sentence that says, "Nevertheless, many important  
12 questions need to be answered before either micronutrient  
13 supplements or food fortification can be recommended as a  
14 cancer prevention strategy. The second sentence was not  
15 included in the submission.

16           Our question is is this something that can be  
17 screened or does it need to go immediately to the scientific  
18 body which authored the statement?

19           And then finally, at the far end of our continuum,  
20 is our fourth example. This is probably not a good  
21 possibility for a screen. It reads, "High dietary carotene  
22 and possibly vitamins C and E and folate are associated with  
23 reduced risk of cervical cancer." It's about a diet-disease  
24 relationship, it doesn't appear to be qualified and we're  
25 not sure that FDA could easily screen such a statement.

1           Because it's acknowledged that the determination  
2 of whether a statement is authoritative rests with the  
3 scientific body, our question then is: Is a preliminary  
4 screen appropriate? It is useful? Is it possible? If so,  
5 could guidelines be developed for FDA? Could they address  
6 issues such as context? What is the situation? Those are  
7 our questions.

8           As I've mentioned, the scientific bodies later  
9 today will highlight how they see moving through these steps  
10 and how they see the approach to interacting within the  
11 Liaison Group. But perhaps at this point we need to  
12 emphasize that one of the most important questions we're  
13 raising today is how should or how can FDA best establish  
14 the working relationship with the scientific bodies, given  
15 that the regulatory responsibility is FDA's and the  
16 determination of whether the statement is authoritative  
17 rests with the scientific bodies?

18           What are the options? Tentatively we have  
19 followed the route of direct communication. We're asking  
20 questions about the possibility of a screen.

21           At the other end of the options continuum, there's  
22 a question of what if a scientific body is not interested or  
23 does not prefer to review each and every statement? What if  
24 they provide guidelines or general policy statements and  
25 it's the expectation that FDA will conduct the review? What

1 should we do? How should we handle this? Is it  
2 appropriate?

3 I want to move to the next phase of questions and  
4 please don't let this slide overwhelm you. It's only  
5 attempting to show that once we leave the box of determining  
6 authoritativeness, if that's a word we can use, other  
7 factors come into play. Once the decision is out of the box  
8 of the scientific body, the process returns to FDA and we  
9 have a number of questions all along the way.

10 Obviously if the statement isn't authoritative,  
11 it's intended that FDA would prohibit the use of the claim,  
12 and the process ends. And, for the most part, that's what  
13 happened with the first notification. The process ended  
14 there.

15 But if the statement is authoritative, the process  
16 continues down along the right and along the bottom of the  
17 continuum and it's possible that the issue of significant  
18 scientific agreement or SSA could arise.

19 The FDAMA legislation provides that FDA may  
20 prohibit a claim if SSA is lacking. We note that it doesn't  
21 require that FDA determine SSA, only that it may prohibit on  
22 the grounds of lack of SSA. So at some time after a  
23 statement is determined authoritative, SSA could become an  
24 issue.

25 We haven't had the opportunity to face this yet,

1 so we have a lot of questions. What is the practical  
2 application of this provision? What is FDA to do? Is it  
3 desirable to request input from the scientific bodies on  
4 significant scientific agreement? I hope it's very clear  
5 that we're very interested in input on the procedures  
6 relative to this aspect of the provisions.

7 At this point, though, we're finally entering the  
8 home stretch and it's this home stretch I'd like you to  
9 consider now, down along the bottom of the schematic. These  
10 bring up procedural issues and they bring up comparisons to  
11 existing NLEA provisions for health claims and nutrient  
12 content claims. Most of these questions, these issues, go  
13 to the heart of what is needed for a notification, what  
14 should be included in a notification.

15 As already provided for by FDAMA, the notification  
16 must identify the authoritative statement, it must provide  
17 the wording of the claim, and it must offer a balanced  
18 presentation of the scientific literature. One quick  
19 question we have is what is a balanced presentation? How  
20 should FDA use it? How should it be evaluated?

21 But then moving along into existing provisions,  
22 how do we or should we incorporate existing provisions?  
23 Section 101.13 lays out principles for nutrient content  
24 claims. It talks about things such as claim location on the  
25 label and referral statements. How do these apply to FDAMA

1 provisions?

2           Section 101.14 for health claims gives certain  
3 definitions, plus it invokes disqualifying levels for the  
4 claim and the so-called jelly bean rule. What's to happen  
5 with these provisions?

6           Secondly, what is the best approach if the  
7 authoritative statement does not provide information on an  
8 effective level? What do we do in the absence of an  
9 effective level for the notified claim? Are such claims  
10 misleading to consumers if an effective level is not  
11 established?

12           Third, what about the analytical method for  
13 compliance purposes? Certainly this is an important part of  
14 the regulatory framework. Is it likely that an  
15 authoritative statement would contain discussions of  
16 analytical procedures? What are we to do without this  
17 information? Who's responsible for it?

18           And finally, last but certainly not least is the  
19 issue of the wording of the claim. The notifier is required  
20 to submit the wording of the claim, but what about the  
21 provisions of 101.14? Clearly under 101.14 claim wording is  
22 an important concern. There's a desire not to mislead the  
23 consumer. Claims need to accurately reflect the science and  
24 allow consumers to understand the claim within the context  
25 of the total daily diet. How should this be done? How

1 should the decisions be made? And how should the evaluation  
2 be carried out?

3 In short, for this home stretch along the bottom,  
4 what are the approaches to be used? What about existing  
5 provisions? What's to be in a notification? In short,  
6 what's needed and who does it?

7 My last set of questions for setting the framework  
8 are important questions with very broad impact. The first  
9 is, as I'm sure many of you know, FDAMA provides, in the  
10 case of health claims, only for conventional foods. FDAMA  
11 does not extend health claims for authoritative statements  
12 to dietary supplements.

13 FDA has proposed to extend the idea of a level  
14 playing field and has proposed to expand the FDAMA  
15 provisions to dietary supplements. The comment period for  
16 this proposal closed April 6 but still today these issues  
17 are ones that we're putting on the table for discussion.

18 Second, given the statutory language and some  
19 legislative history, FDA has taken the tentative approach  
20 that the FDAMA notification process cannot be used to modify  
21 existing claims. We'd like your input on this issue.

22 And then thirdly, the legislation is silent on  
23 whether the notification should be made public when received  
24 or whether it should be considered confidential. FDA has  
25 not made a decision on this but clearly we will have to

1 soon, and again we encourage your input.

2           If I could have the lights up, that, more or less,  
3 bring to close this framework. We are certainly interested  
4 in hearing today's discussion. Admittedly, we've put out a  
5 large set of complicated questions, but we think these are  
6 very important questions, so we look forward to today's  
7 input. And thank you.

8           [Applause.]

9           MR. LAKE: Thank you, Chris. I think that does a  
10 nice job of laying out the issues or the framework for the  
11 further discussion.

12           Let me remind you that we have had available when  
13 you came in cards on which you can ask questions. We've  
14 come to a point where you have the opportunity to ask  
15 questions you may have at this time. I guess we have people  
16 who collect the cards. Yes, here they are.

17           As they are doing that, I failed to mention at the  
18 beginning that FDA is making a transcript of the entire  
19 meeting. Also one of you has asked to videotape the meeting  
20 and so we have someone doing that, as well. The transcript  
21 is ours. I'm not sure who owns the videotape but one of you  
22 out there does.

23                           **QUESTIONS FROM THE AUDIENCE**

24           MR. LAKE: We actually did bring our lawyer and I  
25 think this first question may be for him or some

1 combination. She wants to be sure, I think, that I don't  
2 refer all the questions to she and David, so I will move  
3 over to the other microphone as they consult on the answer  
4 to the first question.

5 Do we have other questions that people want to  
6 bring forward at this time? Well, we'll respond to this one  
7 and then take others as they come.

8 DR. LEWIS: The question is we're not quite sure  
9 but about the federal agencies not represented on the  
10 initial list of Liaison Group, such as NASA, the Veterans  
11 Administration and the Department of Agriculture.

12 I guess just to clarify, we've certainly included  
13 in the four federal agencies tentatively the U.S. Department  
14 of Agriculture. The statute provides for federal scientific  
15 bodies that have responsibility for human nutrition or human  
16 nutrition policies, I believe. In fact, we can read it.

17 "Scientific body of the U.S. government with  
18 official responsibility for public health protection or  
19 research directly relating to human nutrition, such as NIH  
20 or CDC."

21 The question here is why--I think the question is  
22 why have we not included NASA, the National Aeronautics and  
23 Space Administration, or the Veterans Administration.

24 Again as we've mentioned, all of this is open for  
25 comment, but our initial read was that these agencies likely

1 were not ones directly responsible for human nutrition  
2 research or nutrition policy. But again we're open for  
3 comment.

4 MR. LAKE: We do have another question.

5 DR. LEWIS: The question we have here is how is  
6 "employee" defined? Is an expert who's been hired to  
7 conduct scientific research an employee?

8 I think this is an interesting question but it's  
9 also a question that is largely in the domain of the  
10 scientific bodies and I would probably defer that to them.

11 I think the statute is indicating within the  
12 context of the statute that there's a great deal of interest  
13 in it being from the scientific body and not therefore some  
14 employee of the body speaking. Whether this is someone  
15 hired by the agency I think is also open for further  
16 discussion.

17 I don't think I see or we see FDA making this  
18 call. This would be something that the scientific body  
19 would have to indicate. It's difficult for us to tell, for  
20 instance, when something published under someone's name is,  
21 in fact, representing some policy decisions by the agency or  
22 whether it's the individual's own statement.

23 This, by the way, is David Dorsey from our Office  
24 of Chief Counsel. And, of course, interpreting the statute  
25 always requires at least one lawyer, and he's been very

1 active in this process.

2 MR. DORSEY: This poses three questions. The  
3 first is were the meetings of the Liaison Group FACA  
4 meetings or meetings subject to the Federal Advisory  
5 Committee Act and were they open to the public?

6 The answer to that was we would say no. The only  
7 attendees at that meeting were representatives of federal  
8 agencies and therefore they wouldn't have been subject to  
9 FACA, I believe. We didn't make transcripts, so those can't  
10 be made available. There was no person there transcribing  
11 them.

12 And will such meetings be subject to FACA in the  
13 future? Again I think the answer is no, they wouldn't be  
14 subject to FACA. Whether they would be open is certainly, I  
15 guess, a question and we'd like to hear input about that  
16 from people.

17 DR. LEWIS: One of the questions I have is could  
18 you comment on the kinds of publications that could carry  
19 authoritative statements?

20 It's one of the reasons we have the panel, the  
21 scientific body panel with us today, is that we feel that  
22 it's the individual agency's decision both as to what  
23 they've done in the past that could be authoritative  
24 statements and how they wish to handle the future of  
25 authoritative statements. So I would defer this question to

1 them later on.

2           And likely another question that says shouldn't  
3 the scientific body set aside a specific publication that  
4 could be used as the basis for claims? I think this is an  
5 interesting question. It's really a two-pronged issue in  
6 that how scientific bodies might deal with authoritative  
7 statements in the future is one set of questions, but how we  
8 deal with existing publications now--that is, statements  
9 made in the past--is another.

10           Again I would take this question, shouldn't the  
11 bodies set aside publications for authoritative statements,  
12 and defer that for their discussion later on.

13           MR. DORSEY: This question says, "Ms. Lewis stated  
14 that the legislation does not require FDA to determine SSA  
15 affirmatively but does provide that FDA may prohibit a claim  
16 if there is not SSA. Where does the legislation provide  
17 that?"

18           Okay, this has specifically just to do with health  
19 claims and Section 303 of FDAMA included--added two  
20 provisions to Section 403(r)(3). Those were provisions (C)  
21 and (D). And (r)(3)(D) states the following--well, (C) was  
22 the provision that provided for the notification process  
23 based on authoritative statements from scientific bodies.

24           And Section 403(r)(3)(D) or 21 U.S.C. 343(r)(3)(D)  
25 states, "A claim submitted under the requirements of clause

1 (C) may be made until such time as the Secretary issues a  
2 regulation under the standard in clause (B) (i)."

3           And clause (B) (i) reads as follows: "The  
4 Secretary shall promulgate regulations authorizing claims of  
5 the types described in subparagraph (1) (B)"--those are  
6 health claims--"only if the Secretary determines, based on  
7 the totality of publicly available scientific evidence,  
8 including evidence from well designed studies conducted in a  
9 manner which is consistent with generally recognized  
10 scientific procedures and principles, that there is  
11 significant scientific agreement among experts qualified by  
12 scientific training and experience to evaluate such claims,  
13 that the claim is supported by such evidence."

14           So the FDAMA provision itself referenced the  
15 significant scientific agreement standard articulated in  
16 403(r) (3) (B) (i) and stated that the Secretary or FDA may  
17 issue a regulation prohibiting or modifying a claim based on  
18 using that standard.

19           DR. LEWIS: I didn't say all of that but, in fact,  
20 that's the derivative of how we're able to say that  
21 significant scientific agreement is an issue in FDAMA.

22           I have a question about how have the four federal  
23 agencies reacted to the idea of being asked the direct  
24 questions. I'm assuming that's the question that they also  
25 would want to answer, but I would just indicate that vis-a-

1 vis the Secretary's letter to the agencies, we received very  
2 prompt input from the four federal agencies and were  
3 immediately given the contact person to form the Liaison  
4 Group.

5 They all attended the meetings and when they could  
6 not personally attend, did send substitutes and took active  
7 part in the discussions.

8 So I guess if I were to characterize the reaction  
9 to this, I would say they were cooperative and interested.  
10 For further individual comments I would suggest again we  
11 hold this to this afternoon when the scientific bodies are  
12 present.

13 MR. DORSEY: This is a question that reads, "Can  
14 qualified"--underlined--"health claims be made that  
15 accurately reflect an authoritative statement which  
16 describes a relationship that is not conclusive?"

17 Of course, as Dr. Lewis described, FDA's tentative  
18 approach was that a statement that describes the scientific  
19 evidence about a relationship as preliminary or inconclusive  
20 wouldn't be an authoritative one. But assuming that's not  
21 the case, which I suppose is the premise of the question,  
22 it's really asking, I think, a question about Pearson,  
23 Pearson versus Shalala, a case that many of you I'm sure are  
24 aware of. And that certainly wasn't our initial approach  
25 and we're interested in hearing people's reactions to this

1 further.

2 I guess all I can say for now is that the agency  
3 is discussing how to react to Pearson with the Department of  
4 Justice, and those discussions are on-going. And currently,  
5 at least, Pearson didn't apply to conventional foods and  
6 authoritative statements or health claims based on  
7 authoritative statements are currently authorized--I'm  
8 sorry--health claim based on authoritative statements are  
9 currently authorized only for conventional foods.  
10 Therefore, we don't believe the Pearson decision applies in  
11 that context directly. But I'm sure we'll hear more comment  
12 about it later as the day proceeds.

13 DR. LEWIS: I have two questions that while they  
14 aren't exactly related, I think I can more or less answer at  
15 the same time.

16 "Could you please describe who or what people and  
17 offices within CFSAN review the notification, conduct the  
18 check-in and make the final decision after consulting with  
19 the liaison groups? And does FDA possess adequate resources  
20 to implement FDAMA with respect to existing claims"

21 In the case of the offices involved within CFSAN,  
22 it's, of course, the Office of Special Nutritionals in  
23 conjunction with the Office of Food Labeling that conducts  
24 the review and a check-in. The staff will vary depending on  
25 the nature of the issue and staff resources.

1 I suppose does FDA possess adequate resources to  
2 implement FDAMA is one of those questions I think we get 40  
3 times a day, 100 times a year, and the answer is always the  
4 same. We are doing the best that we can.

5 Certainly there is a statutory hammer on this and  
6 when that happens, we work very hard to complete this  
7 process in a timely manner.

8 I also have a question that says, "Dr. Lewis said  
9 that the determination of what is authoritative rests with  
10 the scientific body. For the sake of consistent policy and  
11 since FDA has been authorized to administer FDAMA, shouldn't  
12 FDA be the ultimate arbiter?"

13 These discussions are interesting, specifically I  
14 think when the scientific bodies begin to talk about this  
15 process. I think the clear intent of FDAMA was to provide  
16 an alternative approach for the scientific review component  
17 of health claims and, to a certain extent, nutrient content  
18 claims that was conducted by FDA.

19 The statute indicates that the scientific basis  
20 could be established by others, specifically relevant  
21 federal agencies and the National Academy of Sciences, and  
22 that this scientific basis should be the basis for a claim  
23 if appropriate. That's not to say FDA doesn't have  
24 responsibilities around this in a regulatory mode, but it is  
25 evident that FDAMA intended that scientific review could be

1 conducted elsewhere.

2 So the issues for us today are not what FDA should  
3 do relative to the scientific basis but how FDA should  
4 interact so that the outcome, an appropriate claim, is  
5 conducted in a way that's consistent with the statute.

6 MR. DORSEY: This question reads, "What language  
7 in Section 403(r)(3)(C) does FDA rely upon to support the  
8 agency's assertion that an authoritative statement must  
9 contain a balanced presentation of scientific literature?"

10 Let me just clarify. I don't believe FDA's ever  
11 asserted that the authoritative statement must contain a  
12 balanced presentation of scientific literature. Rather,  
13 what we believe is that the statute requires that the  
14 notification of a claim based on the authoritative statement  
15 must include such balanced presentation of scientific  
16 literature.

17 And that can be found in 403(r)(C)(ii)(III), where  
18 it says, reading it slightly--I'll try to pull it out--a  
19 person has to submit to the Secretary at least 120 days  
20 before the first introduction in interstate commerce of the  
21 food with the label containing the claim a notice, a copy of  
22 the statement referred to in subclause I, a copy of the  
23 authoritative statement and 3, a balanced  
24 representation--it's not presentation but representation--of  
25 the scientific literature relating to the relationship

1 between a nutrient and a disease or health-related condition  
2 to which the claim refers.

3 And there's a parallel provision in 403(r)(2)(G)  
4 with respect to nutrient content claims based on  
5 authoritative statements.

6 MR. LAKE: I'm going to give Chris and David a  
7 break because I actually got one question that I think I can  
8 answer, so you can be looking at the others.

9 This is an interesting question, actually. I will  
10 read it. "Has a user fee arrangement been considered  
11 whereby applicants would pay a fee for the notification  
12 review process?" And, of course, the statute certainly does  
13 not provide for anything like that at the present time.

14 If you have been following, though, budget  
15 discussions and what-not, you know that the administration  
16 is pursuing user fees in areas where user fees have not been  
17 pursued before, particularly with regard to things where the  
18 industry actually can get some benefit; i.e., you're asking  
19 the agency to do something, are willing to pay for the  
20 resources to have that consideration.

21 The idea of user fee in FDAMA actually came up in  
22 two places. One, the Prescription Drug User Fee Act was  
23 reapproved. That's the major user fee provision relating to  
24 drugs. Also there was consideration of user fee in the  
25 context of a premarket notification system for food

1 packaging materials. That was agreed to by the Senate. It  
2 was not agreed to by the House, so it did not become a part  
3 of FDAMA, but there is an on-going reconsideration for  
4 whether that should be included in the future.

5 Also there have been broader considerations of  
6 perhaps premarket approval for food additives.

7 I have not heretofore heard the issue of user fees  
8 raised in the context of health claims, but if there is any  
9 interest in exploring that, I think we would be open to that  
10 discussion.

11 DR. LEWIS: I have a question that I really like.  
12 I think it goes to the heart of the kinds of mechanistic  
13 issues we've been wrestling with. I think there are, in the  
14 last year on this FDAMA notification process, there have  
15 been very deep philosophical discussions and very  
16 mechanistic discussions, all of which have very broad  
17 ramifications.

18 This question is, "Does FDA intend to notify the  
19 submitter if it does not intend to modify or prohibit the  
20 submitted claim?"

21 I can't tell you the hours of discussion we've had  
22 trying to decide procedurally what to do. Certainly I  
23 mentioned earlier the idea of are in-coming notifications  
24 confidential? Should they be put in a public docket? If  
25 they're in a public docket, 120 days ticks by and the

1 question is at the end of 120 days if there's no action,  
2 what does this mean?

3           So I think this question, "Does FDA intend to  
4 notify the submitter if it does not intend to modify or  
5 prohibit the submitted claim?" is the tip of the iceberg of  
6 a lot of questions about how we deal with this.

7           If a claim is authorized by statute in the sense  
8 that we do nothing, both how does the notifier know that 120  
9 days has passed and nothing terrible is happening? On the  
10 other hand, how does the world at large know?

11           We haven't resolved these questions. We haven't  
12 gotten to that process and it's certainly something we need  
13 to know for implementing regulations. So we're interested  
14 in these discussions today.

15           MR. DORSEY: This poses three questions. "Does  
16 FDAMA apply to medical foods? If not, why not? And if not,  
17 do you see that changing any time in the near future?"

18           I guess I can answer the first two questions as a  
19 lawyer. The third one is in some sense more question for  
20 policy people or maybe even Congress.

21           But "Does FDAMA apply to medical foods?" I think  
22 the answer is no and the reason would be that FDAMA--both  
23 Sections 303 and 304 of FDAMA amended 403(r), added  
24 provisions to paragraph 403(r) of the Act and 403(r)(5)(A)  
25 states that this paragraph does not apply to infant formulas

1 subject to Section 412(h) and to medical foods, as defined  
2 in Section 5(b) of the Orphaned Drug Act.

3 So the statute, by its terms, doesn't make the  
4 health claim provisions apply to medical foods, and so the  
5 FDAMA amendments themselves wouldn't, either.

6 And then as to whether that could change, I think  
7 because it's in the statute, it appears that it would be up  
8 to Congress to make that change.

9 DR. LEWIS: I have a question that reads, "Given  
10 the dynamic realities of the information age for both the  
11 government and the public-private sector, i.e., the Internet  
12 and e-commerce, how do you see the process of cybersourced  
13 statements based upon either early published studies, peer-  
14 reviewed, or federal agency authoritative source statements  
15 based upon SSA?"

16 I'm not quite sure I understand the question but  
17 perhaps it's going to a couple of points. One is I think  
18 could an authoritative statement be published in the sense  
19 of being on the Internet? What does to be published mean?  
20 And certainly in our first attempts to consider implementing  
21 regulations, the question of what is published came up.

22 Pulling something from the Internet, does that  
23 fall into the category of published? There are a number of  
24 groups, I think, that are taking a look at what the Internet  
25 means and how this might impact on us is something that

1 we've not yet resolved.

2 The second part of the question--

3 MR. LAKE: Chris, could I maybe just make a  
4 comment there, too? I think there's also an issue about to  
5 what extent it is possible to construe certain information  
6 that manufacturers might put up, say on a web page, might be  
7 considered as labeling, as opposed to advertising.

8 That is an issue that the agency is considering  
9 very broadly in the context of all FDA-regulated products  
10 and are also discussing with the Federal Trade Commission  
11 and it would be my expectation that some policy will be  
12 proposed on that in the not too distant future. It is a  
13 very interesting question, however.

14 Go ahead, Chris.

15 DR. LEWIS: The second part of the question  
16 concerning early published studies, as opposed to statements  
17 based on SSA, I think for us, the issue is has a federal  
18 scientific body or the Academy issued an authoritative  
19 statement. Whether the statement is based on significant  
20 scientific agreement or early or published studies goes to  
21 the heart of what is an authoritative statement, and those  
22 are the questions we're asking today.

23 So I think the latter half of this question is  
24 certainly one that we're not equipped to answer yet.

25 A question that I have here is, "Will there be or

1 does a mechanism exist whereby data may be submitted to a  
2 scientific body in order to generate a claim that is  
3 submission of a study or studies conducted in Europe or  
4 elsewhere?"

5           Again you're in a domain that we're out of. How a  
6 federal scientific body or the Academy would want to go  
7 about its scientific reviews, how it would want to issue  
8 statements is something we can't address and one of the  
9 reasons we have the scientific body panel this afternoon.

10           I would also indicate that the purpose, I suppose,  
11 for submitting data to this group would not be to generate a  
12 claim but to generate an authoritative statement that then  
13 could be put in a notification for a claim.

14           One question is, "Has there been any thought or  
15 concern on how the use of health claims would be regulated  
16 by the FDA? The concern relates to the vast amount of  
17 claims that are being made by companies for their products  
18 that are clearly making drug claims" and something--the  
19 comment goes on.

20           MR. DORSEY: "The concern relates to the vast  
21 amount of claims that are being made by companies for their  
22 product that are clearly drug claims and little to nothing  
23 is being done at this point to stop these claims from being  
24 made."

25           DR. LEWIS: I think we need to be careful that we

1 don't mix authorized health claims with structure-function  
2 claims, and I'm not suggesting that this person was doing  
3 this. Claims on food labels that are health claims are  
4 authorized by the agency and they are only specific claims.  
5 They're preauthorized by the agency.

6 So how the use of health claims could be regulated  
7 by FDA, that's how we regulate them. They are authorized.

8 To the extent that we're able to locate and  
9 identify unauthorized claims, we do take action. Admittedly  
10 our resources aren't as cushy as we'd like them to be and  
11 I'm sure some things fall through the cracks, but we do have  
12 authorized claims and we do recognize that there are  
13 unauthorized claims and we do try to take actions against  
14 them.

15 MR. DORSEY: This question says, "How does FDA  
16 plan to deal with changing authoritative statements, given  
17 that the direct link to scientific bodies but also the  
18 likelihood that scientific thinking on a particular matter  
19 will evolve?"

20 I think it may be that one reason Congress added  
21 403(r)(3)(D) and 403(r)(2)(H), which allows the Secretary or  
22 FDA to issue a regulation prohibiting use of a claim, is if  
23 the scientific evidence has changed to such a degree that it  
24 warrants prohibiting the claim, then the agency would be  
25 authorized to do so.

1           So that may be at least a partial response to that  
2 question.

3           DR. LEWIS: I have a question that reads, "Does  
4 the all-or-nothing status of the significant scientific  
5 agreement criterion serve the public well? It fails to  
6 communicate the uncertainties that always exist and makes it  
7 difficult for the government to change its mind in light of  
8 evolving science. Would a numerical rating system serve us  
9 all better?"

10           I think in order to answer this question I have to  
11 go back to the original provisions for health claims. And  
12 FDAMA, if you'll recall, does not really, in effect, change  
13 the end point of a health claim--a health claim is a health  
14 claim is a health claim--but instead changes the process by  
15 which a health claim is authorized.

16           The question that it fails to communicate the  
17 uncertainties that always exist and makes it difficult for  
18 the government to change its mind--during the original  
19 discussions on health claims, there was a great deal of  
20 interest in making sure that these claims were stable over  
21 time. In fact, the purpose of the significant scientific  
22 agreement standard is to ensure that these claims would  
23 remain stable over time because there was a great deal of  
24 concern that changing claims on labels only undermines the  
25 consumer's belief that certain things could be done for

1 their health and also belief in the credibility of the  
2 label.

3 I think that's why significant scientific  
4 agreement is a fairly difficult, albeit not impossible, end  
5 point to reach, that the purpose is that the government  
6 would not have to change its mind periodically, that it  
7 should not reflect evolving science but should, in effect,  
8 reflect solid science.

9 Now the question also goes to the heart of well,  
10 nothing is ever known for sure, and that's why the wording  
11 is "may reduce the risk." There was clear effort to make  
12 sure that the public did not believe this was a magic  
13 bullet. That's why the claim needs to be set in the context  
14 of the total daily diet and qualified in any way that's  
15 appropriate, so the consumer understands that they're  
16 reducing their risk but not an absolute.

17 I'm not sure that's exactly the answer to the  
18 question that the questioner was looking for but the purpose  
19 of health claims was ultimately certainly not that they  
20 would change and have to be responsive to emerging science.  
21 They aren't intended to reflect emerging science under the  
22 current provisions.

23 Is this my question? I guess it is. "Will FDA  
24 accept authoritative statements published prior to the  
25 effective date of FDAMA?"

1           Absolutely. There's nothing in the provisions  
2 that talks about dates of this, other than currently in  
3 effect. And again the issue is those four points for  
4 authoritative statements: currently in effect, published  
5 about a disease relationship and not an individual.

6           We have had discussions in the Liaison Group and  
7 you'll be able to talk with them later this afternoon about  
8 what "currently in effect" means and we did feel, through  
9 those discussions, that that's something that's up to the  
10 individual agency. FDA probably cannot determine when  
11 something is currently in effect.

12           FDAMA doesn't grandfather anything forward or  
13 backward. It simply makes the provision "currently in  
14 effect." So if it was issued 10 years ago and the agency  
15 still considered it--the scientific body still considers it  
16 currently in effect, then it's currently in effect.

17           MR. LAKE: Is that all the questions?

18           DR. LEWIS: I believe that's all we have, yes.

19           MR. LAKE: Okay. Well, let me first thank the  
20 audience for asking a number of very good questions. I  
21 assume as the program goes on some of these questions or the  
22 panelists will shed light on some of these questions and  
23 there will be a further for you, two other further  
24 opportunities, actually, to ask further questions.

25           Let me also thank my fellow panelists for doing

1 the heavy duty answering. They certainly sounded like  
2 thoughtful answers to me, so I appreciate that.

3 At this time we will take a break and we will  
4 reconvene at 10:00. Thank you.

5 [Recess.]

6 MR. LAKE: Mr. Levitt has not yet arrived, so I  
7 think what we will do is go ahead and begin with the panel  
8 and when Mr. Levitt does appear, we will bring him to the  
9 podium.

10 **COMMENTER PANEL PRESENTATION**

11 MR. LAKE: Thank you for returning promptly. We  
12 will go ahead and go with hearing from our very  
13 distinguished panel. In fact, they're so distinguished that  
14 the only way we could figure out how to appropriately order  
15 them is to simply do it by alphabetical order, so we are  
16 doing that.

17 We are asking each of the panelists to talk for 10  
18 minutes. I will send a signal at about eight minutes, if I  
19 may, to let you know that your time is nearing the end. And  
20 at the end of that we will have a further opportunity for  
21 one, a panel discussion and also for questions from the  
22 audience.

23 And again when Mr. Levitt arrives we will, after  
24 the completion of whoever is talking, go ahead and bring him  
25 to the podium.

1           Why don't we go ahead and begin? The first  
2 speaker is Dr. Annette Dickinson from the Council for  
3 Responsible Nutrition.

4           DR. DICKINSON: Thank you, Mr. Lake, very much.  
5 We appreciate being here.

6           The Council for Responsible Nutrition is a trade  
7 association representing the dietary supplement industry.  
8 We have about 100 member companies ranging from bulk  
9 ingredient suppliers to finished product manufacturers and  
10 ranging from manufacturers of national brand products to  
11 manufacturers of those hundreds of different brands of store  
12 brands of products that you see in your supermarkets, drug  
13 stores and health food stores.

14           Our member companies distribute their products  
15 through the mass market, health food stores, direct sales  
16 and mail order.

17           We are committed to working cooperatively with FDA  
18 to resolve regulatory issues and we are pleased to have been  
19 invited to participate in this public meeting to discuss  
20 FDAMA health claims.

21           CRN submitted extensive comments to FDA generally  
22 supporting the FDA's denial of the nine health claims  
23 submitted by petition in 1998 while, at the same time,  
24 expressing strong concerns about some of FDA's approaches to  
25 evaluating those claims.

1 FDAMA authorizes health claims, as we know, based  
2 on authoritative statements of scientific bodies. In its  
3 1998 guidance document and also in the decision on denying  
4 health claim petitions, FDA appears to be unduly limiting  
5 its definition of scientific bodies and appears to greatly  
6 expand the congressional requirements for authoritative  
7 statements.

8 FDA indicates that NIH and CDC would qualify as  
9 scientific bodies, as specified by FDAMA, but implies that  
10 the individual institutes at NIH may not. If I  
11 misunderstand this provision, I apologize, but this is my  
12 reading of the guidance.

13 This is contrary, I believe, to the mission  
14 statements and to the expectations of the individual  
15 institutes, which are, in fact, the bodies recognized as  
16 authorities in their respective fields of research and  
17 policy at NIH.

18 Further, it is the mandate of those institutes to  
19 produce educational information for consumers and health  
20 professionals and for use in policy situations.

21 FDA should therefore recognize the individual  
22 institutes at NIH as scientific bodies for purposes of  
23 FDAMA.

24 CRN believes that an authoritative statement is  
25 one that is made publicly by a scientific body with the

1 intent that consumers and health professionals will rely on  
2 it. As emphasized by FDAMA, it is obviously not the  
3 statement of an individual, but a statement to which the  
4 scientific body has lent its authoritative support and the  
5 support of its expertise and reputation.

6           There was clearly no intent in FDAMA that anyone  
7 be allowed to put words into the mouth of a scientific body  
8 with which it might not agree or to take any statement made  
9 by that body out of context. Therefore, the statement must  
10 be one that the scientific body made intentionally for  
11 public advice and it must be considered thoroughly in  
12 context.

13           However, a scientific body, we believe, should not  
14 be invited by FDA to decide whether a statement is  
15 authoritative because under those circumstances, the body  
16 might be tempted to decide that a statement is authoritative  
17 under most circumstances and in the context of their  
18 educational information, but for one reason or another not  
19 authoritative in its opinion for purposes of FDAMA health  
20 claims.

21           We are concerned that FDA's proposal to ask  
22 scientific bodies to affirm that certain statements are  
23 authoritative invites them to do exactly that.

24           In its guidance document and in its response to  
25 the 1998 petitions, FDA adds three new requirements, as Dr.

1 Lewis mentioned, to those of FDAMA in determining which  
2 statements are authoritative. FDA say the statements must  
3 have undergone deliberative review, must reflect the  
4 official policy of the body and must not relate to  
5 preliminary or inconclusive evidence.

6 CRN believes these requirements all go too far.  
7 Instead, it should be sufficient that the scientific body  
8 has relied upon its own internal processes to arrive at an  
9 authoritative statement consistent with the manner in which  
10 it normally produces information intended for education and  
11 the guidance of consumers, health professionals and policy-  
12 makers.

13 It is inappropriate for FDA to establish any  
14 separate requirement regarding the manner in which each  
15 scientific body reaches its own conclusions.

16 If a scientific body views the evidence on a diet-  
17 disease relationship to be persuasive, even though  
18 inconclusive, then FDA should accept the possibility that an  
19 authoritative statement could be made about that fact. In  
20 such a case, the petitioner who wishes to use the claim  
21 should, of course, include the full statement, complete with  
22 qualifiers.

23 The recent Pearson versus Shalala decision by the  
24 Court of Appeals requires FDA to give consideration to  
25 qualified health claims for dietary supplements under NLEA

1 and it should also apply to consideration of FDAMA claims,  
2 we believe

3           This would not, of course, allow a statement to be  
4 taken out of context or used without the appropriate  
5 qualifying language expressed in the original statement.  
6 For example, it is conceivable that an appropriate  
7 scientific body might conclude in the near future that  
8 although more research is needed, there is sufficient  
9 evidence to justify a recommendation that consumers use  
10 supplements and fortified foods containing RDI amounts of  
11 folic acid and vitamin B-12 to lower homocysteine levels and  
12 potentially, potentially underlined, reduce the risk of  
13 heart disease.

14           If this statement were published as a conclusion  
15 or recommendation by a scientific body, then it should be  
16 eligible as the basis for a FDAMA health claim, with the  
17 qualifications included.

18           In making its final determinations on NLEA health  
19 claims for dietary supplements in 1994, FDA made the  
20 decision that there should be a level playing field for  
21 dietary supplements and for conventional foods and that the  
22 same rules and procedures should apply to both.

23           The Commission on Dietary Supplement Labels agreed  
24 with that determination and CRN fully supports it.

25           Therefore, it is appropriate, as FDA has already

1 proposed in proposed regulations, that the same procedures  
2 for FDAMA health claims should apply to dietary supplements,  
3 as well as to conventional foods.

4 I'd like to address one more issue just briefly  
5 and that is the issue of a dietary supplement advisory  
6 committee in the priority-setting meetings last summer. CRN  
7 has testified there and in other locations about the  
8 importance of a dietary supplement advisory committee that  
9 FDA could use in making decisions about health claims or any  
10 other issue relating to dietary supplements, and I'd like to  
11 reiterate the importance that we put on the existence of a  
12 dietary supplement advisory committee with appropriate  
13 expertise to help FDA deal with these issues.

14 Thank you very much.

15 MR. LAKE: Thank you, Annette, both for the  
16 content and the fact that you actually saved Joe a little  
17 bit of time here.

18 Let me next introduce the director of the Center  
19 for Food Safety and Applied Nutrition. He has long  
20 experience with FDA, beginning in the General Counsel's  
21 Office, working later in the Commissioner's Office, came to  
22 CFSAN from the Center for Medical Devices. He's getting  
23 close to a year and a half now at CFSAN.

24 He is very engaged, a quick study. He's become  
25 very interested in the whole area of health claims and

1 gotten obviously involved in authoritative statements.

2 So without taking any further time of his, let me  
3 introduce Joseph Levitt.

4 **OPENING REMARKS**

5 MR. LEVITT: Thank you very much. I apologize for  
6 the tardiness of my arrival and I thank you for going on  
7 with the program and fitting me in.

8 However, I would like to just take a step back and  
9 just anticipate, as if I were the first speaker and somehow  
10 had the physical capability to get downtown at a decent  
11 hour, and just try to generally set the stage for this  
12 meeting--why we're having it, what we're hoping to get out  
13 of it, what we encourage all the speakers to be doing today.

14 Number one, I think it's important just to note  
15 that I was not personally involved in any of the FDAMA  
16 negotiations, the discussions on the Hill with respect to  
17 the food provisions. I was actually quite involved with the  
18 medical device provisions but they're really largely  
19 separate and divorced from this.

20 But I think as we approach any law, implementation  
21 of any law, we really have to start with what does the law  
22 say on its face and what additional guidance does Congress  
23 give us in the legislative history?

24 There is always a temptation for those who were  
25 involved to say, "I was there and I know what this really

1 meant. And we were all there--I wasn't personally but many  
2 of us were there and many of us were there and we all know  
3 what it really meant." But the way the system really works  
4 is Congress tells us what they really meant and they guide  
5 us in the legislative history for what else they really  
6 meant, and a lot of the other stuff around that is really  
7 kind of distant. We need to kind of exert, I think, some  
8 discipline and tie ourselves to what does the law say, what  
9 does the legislative history say, and how do we go from  
10 there? I think that's point number one.

11 Point number two is that the Center has tried to  
12 implement this provision of the law. We came out within the  
13 first spring, as everybody knows, with a guidance document  
14 on this particular provision. We also came out with--I  
15 don't know if we called it actually an interim rule, an  
16 interim final rule on the first set of notifications.

17 Frankly, our preference would have been to have  
18 had more time back then for stakeholder input, but the  
19 timing and everything was such that we just didn't have it,  
20 so we did the best thinking that we could on our own.

21 We've gotten a lot of comments on both the  
22 guidance and the first set of Federal Register notices. And  
23 I guess I would call the reaction kind of quite mixed.  
24 There are some groups that strongly favor the approach we  
25 took. There's also a considerable number of people and

1 comments that think we have pointed too far in one  
2 particular direction.

3           And when we saw that, I said we did the best we  
4 could without public input; let's pause and let's open up  
5 the process. I'm very much in favor of what I think of as  
6 participatory policy development. I think the developing  
7 regulatory policy that really works includes a meaningful  
8 involvement from stakeholders, and that's why we're having  
9 this today.

10           So the first thing I would ask today, as I'm sure  
11 people will, is to really come in with your best ideas and  
12 views of how we ought to be implementing that provision.  
13 And I have every confidence that everybody will do that.

14           The second one is a little harder. The second  
15 request I have is not just to focus on your own comments but  
16 listen to those that differ from yours. You'll actually  
17 find yourself feeling a little more like we feel because you  
18 will hear comments from this side and comments from that  
19 side and it will not be so easy to say, "All right, we had  
20 this meeting; now it's clear."

21           What we want is for today's comments to really  
22 help inform us on the best way to go forward. We don't have  
23 to come out with consensus. That's not by any means a  
24 needed objective. If it happens, that's great, but  
25 sometimes by getting everybody together and listening to

1 each other we can see a little more of how these differing  
2 points of view maybe can mesh in some ways. And I think we  
3 should be looking for those opportunities but recognize that  
4 we're going to have to think for those opportunities because  
5 coming in and looking at the comments, I can't say it's  
6 entirely obvious, to me, anyway.

7           So I think we have to all come with an open mind.  
8 I can assure you that FDA will come with an open mind and  
9 will hope very much that this day provides us with a  
10 foundation with which we can move forward and have, as Dr.  
11 Henney's top priority for the agency has said over and over,  
12 full implementation of FDAMA both to the letter of the law  
13 and to the spirit of the law.

14           I think the last thing I would ask, and it's kind  
15 of hard in a big, public room like this--you know, we're up  
16 and everybody's got microphones and there's a video camera  
17 out there and somebody's transcribing the meeting. It feels  
18 very formal. And that's okay; it is a formal setting in a  
19 way that it helps define the rules of engagement, just in  
20 terms of how we proceed.

21           But I really would urge people to be open, even  
22 within this setting, to be open, to be candid. It's okay  
23 for this to be a working session and for us to move the  
24 agenda forward to the extent that we can in this kind of  
25 session.

1           But overall, I think that we can only benefit by  
2 all coming together and hearing the different points of  
3 view, coming back to what the statute says, what the  
4 legislative history says, what fundamentally is in the best  
5 interest of American consumers.

6           I think that we all recognize that the  
7 authoritative statement provision of FDAMA is one piece of a  
8 broader framework of how we're going to get good health  
9 information to consumers. We want it to be reliable. We  
10 want it to be information that consumers can reasonably act  
11 on. And there's a long history of trying to provide this,  
12 starting with NLEA, and FDAMA is very much, I think, a  
13 progression along that direction.

14           So I think final thing is in addition to what the  
15 statute says, what the legislative history says, what the  
16 different points of view say, is how we're going to take  
17 this and really make into what is in the best interest, what  
18 is going to provide the most benefit to the American  
19 consumers.

20           With that, I thank you very much and I will gladly  
21 turn the program back to Mr. Lake. I will be able to stay  
22 for much of the remainder of the morning but will need to  
23 sneak out at some point for the rest of the other activities  
24 that I need to be involved in today.

25           Thank you very much for coming. I think this is

1 an excellent turn-out and I'm pleased to see the panelists  
2 we have.

3 [Applause.]

4 MR. LAKE: Thank you, Joe.

5 **COMMENTER PANEL PRESENTATIONS - CONTINUED**

6 MR. LAKE: Now we will pick up with our panelists  
7 and the next speaker is Mr. Michael Ford from the National  
8 Nutritional Foods Association.

9 MR. FORD: Thank you. The National Nutritional  
10 Foods Association, NNFA, wishes to thank you for inviting me  
11 here to speak this morning as a member of this panel. As  
12 the token male on the panel I especially appreciate it. I'm  
13 used to that sort of thing.

14 NNFA represents close to 3,000 health food stores  
15 and about 1,000 suppliers and distributors of natural  
16 products, including health foods and dietary supplements and  
17 natural ingredient cosmetics and, as such, our members have  
18 a vital interest in communicating scientifically established  
19 relationships between their products and health-related  
20 conditions.

21 I want to focus on five issues this morning in my  
22 comments. Basically, to tell you what I'm going to tell  
23 you, we support the idea of the FDA clarifying just exactly  
24 what these authoritative statements are meant to be.

25 Secondly, we urge you to look at the plain language of the

1 Act as your best guide. Third, we'd like you to consider a  
2 little broader definition perhaps of allowable sources. We  
3 want you to be innovative in looking at this.

4 Fourthly, as has been stated, there's an  
5 inexorable link to the issue of significant scientific  
6 agreement that obviously you've addressed this morning and  
7 I'm sure you will continue to address. And finally, in  
8 league with my colleague Dr. Dickinson, we also believe that  
9 FDA should be the ultimate arbiter in the issue of what is  
10 an allowable statement and perhaps you need to establish a  
11 dietary supplement advisory committee to help you in that  
12 regard.

13 Let me go into a little depth on my five points.  
14 We support your proposal to clarify by rulemaking that  
15 dietary supplements, as well as conventional foods, are  
16 covered by the authoritative statement provisions of FDAMA.  
17 Dietary supplements, as you know, are also foods and FDA has  
18 applied the health claim standards of NLEA to dietary  
19 supplements and conventional foods on an equal basis. So it  
20 follows that Section 303 of FDAMA, which amends those health  
21 claim standards, should extend to supplements.

22 Secondly, Congress has explicitly defined an  
23 authoritative statement that can be used to support a health  
24 claim. An authoritative statement has four elements that  
25 you've mentioned. It must be issued as an authoritative

1 statement by a scientific body, which has been well defined  
2 as a government research agency. It must be published. It  
3 must be currently in effect and it must be a statement about  
4 the relationship the nutrient and a disease or health-  
5 related condition to which the claim refers.

6           These criteria could not be any clearer. Congress  
7 has drafted a precise definition which requires no  
8 augmentation or amplification by regulation, guidance or  
9 otherwise. It's very much in that respect like the Dietary  
10 Supplement Health and Education Act.

11           We believe that additional criteria, which have  
12 been mentioned, such as deliberative review by the  
13 scientific body and identification of nutrient levels are  
14 already covered by the statutory criteria.

15           We urge you not to approach this as; What are we  
16 going to do about this runaway train? We think that the  
17 approach should be: What is the best way to get information  
18 to people, not how many filters can we put up?

19           Third, while FDAMA provides that authoritative  
20 statements be published by governmental agencies, the  
21 private nutrition-related research sector should be  
22 considered part of the authoritative statement process.  
23 Many of the clinical studies and other data cited in an  
24 authoritative statement as grounds for its conclusions will  
25 likely have been generated by private research entities,

1 such as medical schools and teaching hospitals, clinics or  
2 medical societies, and many of these entities may have  
3 received governmental funding from the very research  
4 agencies identified by you and by the Act.

5 We encourage the government scientific bodies who  
6 issue authoritative statements, we encourage them to foster  
7 nutrition-related research by resource-intensive private  
8 research institutions. This is bound to further the  
9 interest of the public health and give you a little more  
10 novel approach to seeking out sources.

11 Fourth, as I said NNFA maintains the significant  
12 scientific agreement standard for health claims is  
13 absolutely linked to FDAMA's authoritative statement  
14 standard. This is so because by FDAMA's very terms, an  
15 authoritative statement can serve as a substitute for a  
16 determination that there is significant scientific agreement  
17 supporting a health claim.

18 Secondly, in the alternative, FDA can prohibit or  
19 modify a health claim based on an authoritative statement  
20 if, notwithstanding the conclusion of the statement, the  
21 agency decides by regulation that significant scientific  
22 agreement for the claim is lacking.

23 The interplay between the significant scientific  
24 agreement and authoritative statement standards will require  
25 FDA to take the recent Pearson court decision into account

1 in implementing FDAMA's authoritative statement provisions.  
2 Pearson directs FDA to promulgate a concrete definition of  
3 the term significant scientific agreement for evaluating the  
4 validity of health claims. If FDA were to consider  
5 prohibiting or modifying a health claim based on the  
6 authoritative statement because the agency believes the  
7 claim is not based on significant scientific agreement, it  
8 cannot do so until it defines the term itself.

9 Finally, we urge you not to give away the  
10 authority to make your decisions on what qualifies as a  
11 claim based on an authoritative statement. Where health  
12 claims for dietary supplements are involved, we look to the  
13 FDA to really make those regulatory decisions. It is a  
14 regulatory decision, not so much a scientific decision, as  
15 to what is going to be used.

16 If you need assistance in determining some  
17 problems that may come up--it's certainly conceivable--if  
18 there are problems that need to be fleshed out, we urge you  
19 to create a dietary supplement advisory committee to help  
20 you with that. I think that that group would be much better  
21 positioned to help you on this and many other scientific  
22 issues that come before you.

23 And we would like some consistency in the policy  
24 that you develop on these statements and I think in order to  
25 do that, it really needs to come from your agency, not from

1 research institutions. Thank you.

2 MR. LAKE: Thank you.

3 Next we have Tracy Fox from the American Dietetic  
4 Association. Tracy?

5 MS. FOX: Thank you and good morning.

6 My name is Tracy Fox and I'm the senior federal  
7 regulatory manager with the Government Affairs Office of the  
8 American Dietetic Association. My written comments also  
9 express the views of the American Heart Association and the  
10 American Cancer Society.

11 With over 70,000 members, ADA's mission is to  
12 serve the public through the promotion of optimal nutrition,  
13 health and well-being. We believe that health and nutrient  
14 content claims authorized for foods and dietary supplements  
15 should be based on the totality of the publicly available  
16 scientific evidence, including results from well designed  
17 studies conducted in a manner that is consistent with  
18 generally recognized scientific procedures and principles.

19 The Food and Drug Administration Modernization Act  
20 did not change this overarching public health need.

21 We are deeply committed to assuring that  
22 information communicated to consumers on food and dietary  
23 supplement labels is truthful and not misleading. ADA's  
24 been active in labeling issues for many years, both on its  
25 own and in coalitions comprised of numerous organizations.

1 We took an active role during the debates surrounding  
2 passage of FDAMA and worked closely with members of Congress  
3 and their staffs to strike a healthy balance between  
4 expediting the claim authorization process and ensuring that  
5 claims were scientifically sound.

6 We congratulate FDA for holding this open meeting  
7 and soliciting input from various organizations on the  
8 complex issues surrounding health and nutrient content  
9 claims and thank FDA for inviting ADA to participate in this  
10 panel.

11 Since it would be impossible to address the many  
12 questions that have arisen from FDAMA, my comments are  
13 limited to those areas of particular concern to ADA,  
14 specifically the scientific underpinning of health and  
15 nutrient content claims. And, as mentioned earlier, my  
16 comments also reflect the views and concerns of the American  
17 Heart Association and American Cancer Society.

18 I'll talk first about authoritative statements.  
19 What is an authoritative statement? Is it any statement  
20 made by an appropriate scientific body about the  
21 relationship between food substance or nutrient and a  
22 disease or health-related condition? ADA believes that all  
23 statements published by scientific bodies are not  
24 necessarily authoritative. Indeed, it is scientifically  
25 naive to assume otherwise.

1 FDAMA uses the term "authoritative" and presumably  
2 the Congress intended FDA to give that term some meaning.  
3 We believe FDA would shirking its responsibilities and  
4 failing to comply with the intent of the law if it did not  
5 decide when a statement is or is not authoritative.

6 To this end, a preliminary screen is essential.  
7 We support FDA's approach of using a process that includes  
8 communication between FDA and the scientific body to  
9 determine whether or not a statement is authoritative.

10 We also agree with the concept put forth by  
11 Secretary Shalala on an authoritative statements liaison  
12 group. FDA can't determine whether a statement is  
13 authoritative in a vacuum. The scientific body to which a  
14 statement is attributed must be consulted early on regarding  
15 the authoritative nature of a statement.

16 Regarding the National Academy of Sciences, we  
17 recognize the challenges that are presented in terms of FDA  
18 utilizing NAS as a scientific body. We do recommend that  
19 FDA look to NAS as scientific advisers. Since NAS research  
20 is partially funded by government bodies, sometimes solely  
21 funded, the scientific liaisons from these bodies should  
22 serve as a primary contact with the appropriate NAS  
23 representatives serving as key scientific advisers.

24 ADA agrees with the seven characteristics of an  
25 authoritative statement that FDA has identified in the

1 framework for discussion that Dr. Lewis spoke about this  
2 morning. However, FDA should not be limited in its  
3 discussions to only those seven, just as it should not be  
4 limited in discussions with only the liaison of a particular  
5 scientific body.

6           The agency should engage in whatever deliberations  
7 and clarifications it deems necessary and consult with a  
8 variety of experts to determine whether a statement is  
9 authoritative. FDA must also remain the final arbiter for  
10 these determinations.

11           ADA firmly believes that for a statement to be  
12 valid or scientifically sound, it cannot be preliminary or  
13 speculative. Common sense should dictate this. If just any  
14 statement in a public from a scientific body is allowed to  
15 form the basis for a health claim, many misleading and  
16 potentially harmful statements would appear on food labels,  
17 resulting in millions of confused and distrustful consumers.  
18 And ultimately, this would defeat one of the primary  
19 purposes of FDAMA--to provide scientifically sound choices  
20 to consumers that may enhance their health.

21           There's another risk if FDAMA is interpreted to  
22 allow preliminary or speculative statements to form the  
23 basis for a claim. If authoritative statement is too  
24 broadly characterized or defined, this could have a very  
25 serious and chilling effect on statements by scientific

1 bodies, research in this country and the publication of new,  
2 emerging and potentially promising theories.

3           Researchers and scientific bodies they work for  
4 could be reluctant to share new ideas and outcomes for fear  
5 that they would be taken out of context or exploited  
6 commercially without an adequate scientific basis. No one  
7 benefits from this scenario--not consumers, manufacturers,  
8 researchers, not the scientific bodies issuing the  
9 statements. This again would undermine the very purpose of  
10 the law.

11           I'll talk a little bit about significant  
12 scientific agreement. ADA asks whether it's logical and  
13 efficient to apply the SSA criteria only after a statement  
14 has been found to be authoritative. We realize that FDA has  
15 determined that the application of SSA comes later in the  
16 notification review process, as described in the framework  
17 for discussion, but in practical terms, we suggest that  
18 consideration be given to incorporating the concept earlier.

19           For example, a scientific body should be allowed  
20 and indeed encouraged to assess the degree of SSA during the  
21 generation of or deliberation about an authoritative  
22 statement. It seems reasonable and more efficient that an  
23 assessment of SSA be considered as one outcome of the  
24 deliberative review, a characteristic for determining if a  
25 statement is authoritative.

1           In this light we urge FDA to consider renaming the  
2 characteristic or describing it as deliberative review and  
3 assessment of SSA.

4           For the intent of FDAMA to be realized, ADA urges  
5 FDA to expeditiously outline criteria for characteristics of  
6 SSA, just as it has done for authoritative statements. The  
7 need for these characteristics cannot be overstated. The  
8 timing of when SSA is applied, for example, whether it's in  
9 the initial review, during the assessment of whether a  
10 statement is or is not authoritative, or in the final steps  
11 toward a claim is less important than providing guidance  
12 about SSA itself.

13           Defining a set of characteristics of SSA that can  
14 be widely understood and applied will only be beneficial to  
15 the scientific bodies, the private sector, health  
16 professionals, and the public. Even if the characteristics  
17 are, by necessity, imprecise, such information, which could  
18 be refined over time, is a necessary step that would assist  
19 both the private sector and government agencies in  
20 implementing FDAMA.

21           To initiate the process and outlining the  
22 characteristics of SSA, we urge FDA to convene a  
23 multidisciplinary group representing the designated  
24 scientific bodies, as well as external experts, to examine  
25 the issue and outline characteristics, with the expectation

1 of providing guidance to industry and consumers. Areas of  
2 expertise represented should include but not be limited to  
3 nutrition epidemiology, clinical nutrition research, basic  
4 research, public health and ethics. An example of a committee  
5 structure to provide such guidance would be FDA's Food  
6 Advisory Committee.

7 I'd like to now address the issue of context. ADA  
8 sees two distinct but related context issues within FDAMA.  
9 The first context issue addresses whether or not an  
10 authoritative statement is taken out of context from the  
11 source document.

12 Let's take, for example, the following  
13 hypothetical statement from a publication from a scientific  
14 body. The statement would read: "There's a growing body of  
15 research demonstrating the relationship between increased  
16 consumption of Substance Z and decreased incidence of  
17 stubbed toes. This increased consumption of Substance Z is  
18 also associated with a high incidence of toe loss, thereby  
19 resulting in fewer stubbed toes."

20 Taken out of context, the health claim based on  
21 this statement could read, "Substance Z helps prevent  
22 stubbed toes." While we realize that no responsible  
23 manufacturer would make such a claim, FDA should not be  
24 powerless to prohibit something like this from occurring.

25 The second context issue relates to whether or not

1 a claim is stated in the context of the total diet and the  
2 claim is not misleading. In other words, using the scenario  
3 above, does the claim, Substance Z, help prevent stubbed  
4 toes, assist consumers in understanding the relative  
5 importance of Substance Z in the overall diet?

6 ADA recommends that FDA consider looking at a  
7 system established under Title III of the National Nutrition  
8 Monitoring and Related Research Act to assist in the review  
9 of potential claims which are clearly dietary guidance, to  
10 assure that they are based on valid, scientific or medical  
11 knowledge and, very importantly, that they are not  
12 misleading to consumers.

13 If health claims are to help consumers make  
14 informed choices, then consumers must be informed. In this  
15 light, ADA recommends that FDA require notification packages  
16 from manufacturers to include information on the effective  
17 level of the substance that is the subject of a claim, as  
18 well as information on levels of the substance that are  
19 potentially harmful.

20 Consumers need to know how much of a substance  
21 they need to consume for it to be effective. They also need  
22 to know how much is too much in terms of no added benefit or  
23 potential harm. It's unrealistic to assume that FDA can  
24 examine these issues and make these decisions, along the all  
25 the other FDAMA requirements, in a 120-day period. This

1 information must be provided by the manufacturer as part of  
2 the notification package.

3 Information on effective levels and potentially  
4 harmful levels must also be included either as part of a  
5 health and nutrient content claim or somehow be displayed on  
6 the label so that consumers can see and understand it. This  
7 information is also essential for nutrition professionals,  
8 such as registered dietitians, so we can educate consumers  
9 about the potential benefit of certain nutrients and  
10 substances.

11 We also recommend that the manufacturer submit a  
12 copy of the notification package or, at a minimum, the  
13 sections related specifically to the claim and the source  
14 document to the scientific body at the same time the  
15 official package is submitted to FDA. This will facilitate  
16 more timely discussions between FDA and the scientific body.

17 Until FDA determines how best to implement FDAMA,  
18 a final decision about applying FDAMA provisions to dietary  
19 supplements should be deferred. ADA agrees that the playing  
20 field for health and nutrient content claims on foods and  
21 dietary supplements should be level. However, there are far  
22 too many unanswered questions, as we have seen and heard  
23 today, and we'll hear a lot more today, I'm sure, for ADA to  
24 recommend at this time that FDAMA provisions right now apply  
25 to dietary supplements.

1           We recognize the important positive health  
2 benefits that certain nutrients and food components can have  
3 but no claims will be useful unless they are supported by  
4 sound science and information is provided to consumers in  
5 the context of an overall healthy diet in a way that they  
6 can understand and apply.

7           Again we thank you for inviting us here today and  
8 we welcome the opportunity to discuss our thoughts further.

9           MR. LAKE: Thank you for those comments.

10           Next we have Ilene Heller from the Center for  
11 Science in the Public Interest.

12           MS. HELLER: CSPI thanks FDA for the opportunity  
13 to appear on this panel. CSPI is a nonprofit consumer  
14 organization supported by more than 1 million members that  
15 has worked since 1971 to improve national health policies.

16           In enacting the Food and Drug Administration  
17 Modernization Act, Congress made a procedural change to the  
18 means by which manufacturers could legally market products  
19 containing health claims. In lieu of petitioning the FDA  
20 for a regulation to permit the use of a new health claim or  
21 nutrient content claim, manufacturers may now make such  
22 claims without going through the rulemaking process.

23           Such claims are permitted so long as the claims  
24 are based on an authoritative statement from a scientific  
25 agency of the U.S. government or the National Academy of

1 Sciences and FDA does not object.

2           Although Congress created a streamlined  
3 alternative to the rulemaking route, the Senate committee  
4 report makes it clear that this legislation "maintains the  
5 rigorous scientific standard health claims must meet under  
6 existing law."

7           The House report appears to permit the FDA to  
8 apply an even higher standard than the existing scientific  
9 agreement. The report states that the FDA must determine  
10 "whether the authoritative statement upon which the  
11 notification is based is supported by scientific consensus  
12 to the extent the Secretary considers appropriate to allow  
13 the claim."

14           Congress provided limited guidance as to what  
15 constitutes an authoritative statement. It must be a  
16 published statement by a scientific body of the U.S. with  
17 health and nutrition responsibilities or the NAS, must be  
18 currently in effect, cannot be the work of an individual in  
19 his own capacity and must concern the relationship between a  
20 nutrient and a disease or health-related condition.

21           Congress further concluded that the statement must  
22 be based on a deliberative review by the scientific body of  
23 the scientific evidence. Statements meeting these criteria  
24 are subject to a presumption of validity.

25           Congress did not, however, specify the point at

1, which a statement from a qualifying agency becomes  
2 authoritative. Nor did it specify whether the FDA or the  
3 agency responsible for the statement should determine  
4 whether the statement is authoritative. And it also did not  
5 address coordination issues that are raised when more than  
6 one agency is involved in making a determination as to the  
7 permissibility of a particular claim. In the time allotted  
8 to me I will address these issues.

9           First, when does a statement become authoritative?  
10 Because Congress did not define the point at which a  
11 statement by a qualifying scientific agency becomes  
12 authoritative, it is the role of the FDA to make this  
13 determination. As the Supreme Court has stated in the  
14 Chevron case, the power of an administrative agency to  
15 administer a congressionally created program necessarily  
16 requires the formulation of policy and the making of rules  
17 to fill any gap left, implicitly or explicitly, by Congress.

18           In determining the point at which a published  
19 statement by a qualifying federal agency constitutes an  
20 authoritative statement, the FDA must consider the  
21 definitiveness of the statement. The dictionary definition  
22 of authoritative is official, entitled to credit or  
23 acceptance, conclusive. Finality appears to be the key.

24           For example, if an agency issues a final executive  
25 regulation interpreting an ambiguous statement, courts have

1 held that this is considered to be an authoritative  
2 statement from the executive.

3           Similarly, a decision by the Supreme Court, the  
4 court of last resort, is considered authoritative because it  
5 is the final step in the appeals process. As the Supreme  
6 Court has stated, "It is this court's responsibility to say  
7 what a statute means, and once the court has spoken, it is  
8 the duty of other courts to respect that understanding of  
9 the governing rule of law." A judicial construction of a  
10 statute is an authoritative statement on the meaning of the  
11 statute.

12           In analogous regulatory proceedings, other  
13 agencies have provided concrete examples of what makes a  
14 statement authoritative. For example, in a discussion of a  
15 proposed rule governing refrigerants, the Environmental  
16 Protection Agency cited a report by the Intergovernmental  
17 Panel on Climate Change as being authoritative.

18           Quoting from the EPA, "The first IPCC report was  
19 developed by 170 scientists from 25 countries and was peer-  
20 reviewed by an additional 200 scientists. Since that time,  
21 the number of scientists developing and reviewing the report  
22 has grown. This group comprises most of the active  
23 scientists working in the field today and therefore the  
24 report is an authoritative statement of the views of the  
25 international scientific community at this time."

1           The FDA has appropriately drawn the line between  
2 authoritative and preliminary statements in its actions  
3 surrounding the rejection of nine petitions for health  
4 claims filed by Weider Nutrition International. Press  
5 releases, progress reports on specific projects and analyses  
6 conducted on behalf of a particular agency by an outside  
7 contractor did not reflect the kind of deliberative study  
8 that Congress envisioned when it adopted the authoritative  
9 statement requirement.

10           Congress intended the authoritative statement  
11 process to provide an alternative to an FDA rulemaking  
12 proceeding only if another agency with scientific expertise  
13 had thoroughly addressed the issues that would otherwise  
14 need to be raised in a petition.

15           Congress wanted FDA to be able to rely on data  
16 from other agencies that was comparable to the data the FDA  
17 would rely on in its own regulatory proceeding to justify  
18 the issuance of rules permitting health claims or nutrient  
19 content claims.

20           The fact that Congress determined that  
21 authoritative statements must be based on thorough  
22 scientific analyses is demonstrated by the fact that the  
23 statute gives the FDA final approval authority over health  
24 claims based on the findings in another agency's  
25 authoritative statement. In modifying or prohibiting a

1 health claim based on authoritative statements, the FDA is  
2 required to evaluate the claim to determine whether there is  
3 significant scientific agreement among experts qualified by  
4 scientific training and experience to evaluate such claims  
5 and that the claim is supported by such evidence.

6           Second question is who should determine whether a  
7 statement is authoritative? The FDA has established  
8 liaisons with the various scientific agencies with authority  
9 over health and nutrition. We believe that these designees  
10 should be responsible for determining whether a statement is  
11 authoritative.

12           To facilitate the determination of whether a  
13 statement is authoritative, we would recommend as follows.  
14 Manufacturers who wish to make a claim based upon an  
15 authoritative statement should submit a notification letter  
16 to the FDA. FDA, after verifying that the notification is  
17 complete, should submit it to the agency whose authoritative  
18 statement is the basis for the claim.

19           The notification should be promptly placed on the  
20 public docket and indicate the date of referral to the  
21 relevant government agency.

22           To facilitate review by the public, notification  
23 should be placed in a single public docket entitled health  
24 and nutrient claims based upon authoritative statements.

25           The agency to whom the notification is sent should

1 determine whether it can certify that A, the statement is  
2 the result of a thorough and extensive investigation by the  
3 agency of the scientific issues at issue and represents the  
4 authoritative opinion of the agency; B, that if a report was  
5 conducted by an outside contractor, the agency has adopted  
6 the contractor's findings as its own; C, the manufacturer's  
7 claim can reasonably be based on the authoritative statement  
8 of the agency; and D, with respect to health claims, the  
9 statement represents significant scientific agreement.

10           Following the receipt of a written notification  
11 from the agency that reviewed the authoritative statement,  
12 FDA will determine one, whether it agrees with the  
13 determination of the other agency and two, whether the label  
14 claim needs to be modified to comply with the terms of  
15 Sections 101.13 or 14 of the FDA's regulations.

16           In conclusion, there's no doubt that Congress  
17 intended to provide an alternative procedural route for  
18 manufacturers to obtain approval to make legitimate health  
19 and nutrient content claims. But providing an alternative  
20 route is not synonymous with providing a less stringent  
21 standard for claims.

22           If another agency has thoroughly addressed an  
23 issue, manufacturers should be permitted to rely on another  
24 agency's findings, but if another agency has not thoroughly  
25 addressed an issue, the FDA cannot view its statements as

1 authoritative. To do so would make a mockery of a statute  
2 that's designed to protect the consumers from false and  
3 misleading statements.

4 MR. LAKE: Thank you. Next we will hear from  
5 Regina Hildwine of the National Food Processors Association.

6 MS. HILDWINE: Thank you very much. I'm grateful  
7 very much for the opportunity to present NFPA's views on the  
8 claims provisions of the FDA Modernization Act of 1997.

9 The National Food Processors Association is the  
10 principal scientific trade association that represents the  
11 \$430 billion food processing industry. This morning I'm  
12 going to discuss authoritative statements and make some  
13 remarks on significant scientific agreement. Of necessity,  
14 my points are top line. NFPA addressed these topics and  
15 other topics in greater depth in written comments we filed  
16 in October of '98, as well as those we are filing in  
17 association with this meeting.

18 Before I discuss our main points, NFPA believes  
19 that it is important to begin with some remarks both  
20 retrospective and prospective.

21 NFPA has been thinking about FDAMA-type health  
22 claims for five years. The germ of the FDAMA claims  
23 provisions emerged from a petition which NFPA filed with FDA  
24 on October 25, 1994. In that petition, NFPA requested  
25 several actions which would increase flexibility for making

1 nutrient content claims and health claims.

2 One key NFPA request was that FDA should permit  
3 truthful, non-misleading health claims based on the findings  
4 of a governmental body responsible for public health  
5 protection or research directly relating to human nutrition.

6 On First Amendment grounds, NFPA had argued that  
7 this action would relax what we viewed as overly restrictive  
8 criteria for making health claims only through FDA prior  
9 authorization. NFPA also wanted to ensure that there would  
10 never be another folic acid health claim disaster in which  
11 FDA had rejected a health claim on folic acid and neural  
12 tube defects despite a clear CDC recommendation about this  
13 diet-disease relationship.

14 In May 1995, NFPA received an extensive  
15 preliminary response from FDA and in this letter FDA  
16 indicated it would propose rules on most of the actions that  
17 we had requested. FDA proposed those rules in December of  
18 '95 and the final rules are currently pending.

19 From FDA's letter and the December 1995 preamble,  
20 it is well known that FDA denied NFPA's request to establish  
21 an alternate framework for health claims. FDA stated that  
22 by law, it could not authorize health claims without FDA  
23 prior approval. This, of course, was the signal to pursue  
24 the remedy through legislation.

25 NFPA drafted legislation to establish an

1 alternative to FDA prior approval of health claims and this  
2 formed the model of the FDA Modernization Act provisions on  
3 health and nutrient content claims. The final statutory  
4 language now bears a striking resemblance to the language in  
5 the NFPA petition, sort of like the way a child resembles  
6 its parent.

7           That's the backward look. For the forward view,  
8 NFPA believes that FDAMA claims implementation will be  
9 influenced by other factors. First there's FDA's 1998  
10 proposed rules governing structure-function claims for  
11 dietary supplements in which FDA proposed to revise the  
12 definition of disease for the health claims general  
13 principles. Amending the definition of disease clearly  
14 would impact all types of health claims, both those  
15 established through petition and those established under  
16 FDAMA.

17           Also prospective is what I like to call the  
18 Pearson effect--the impact of the court's decision in  
19 Pearson, et al v. Shalala on FDAMA health claims. The  
20 government says Pearson's about dietary supplements but it  
21 is also about health claims, and the rules and policy  
22 governing health claims are identical for foods and dietary  
23 supplements.

24           Under Pearson, FDA apparently would have to permit  
25 qualified health claims which were stated in a non-

1 misleading way, that accurately reflect preliminary or  
2 possibly emerging science. This is only one aspect of the  
3 Pearson effect, which undoubtedly will have profound impact  
4 on health claims policy.

5           Questions for today. What is an authoritative  
6 statement and who can make it? FDAMA authorizes two  
7 essential groups; that is, the scientific bodies of the  
8 United States government with official responsibility. I  
9 won't read exactly from the statute. You have plenty of  
10 written material on that. Or the National Academy of  
11 Sciences or any of its subdivisions.

12           We believe that every institute of NIH is a  
13 scientific body of the United States government that meets  
14 the FDAMA criteria, but under FDA's interpretation,  
15 subdivisions of federal agencies apparently could not issue  
16 authoritative statements. We believe this is misguided.  
17 The word "subdivisions" in FDAMA applies only to the  
18 National Academy of Sciences for the simple fact that the  
19 NAS is not a government body and the scope of its authority  
20 must be specified.

21           NFPA believes that the appropriate scientific  
22 bodies of the U.S. government should include the following,  
23 and this is not an exhaustive list from HHS, USDA and other  
24 federal departments, and I'm just going to flip through  
25 these rapidly. They're articulated in copies of my slides

1 and presentations that are out on the desk.

2           In our view, other bodies, such as the National  
3 Science Foundation and the Life Sciences Research Office,  
4 could also qualify when carrying out federal  
5 responsibilities under contract to a federal scientific body  
6 that's charged with public health responsibility. We  
7 believe it would be the burden of the claim notifier to  
8 determine that the U.S. government scientific body has the  
9 level of responsibility that FDAMA directs.

10           What kinds of statements are authoritative  
11 statements? Authoritative statements do not mean ex  
12 cathedra. It doesn't mean that you need a big, giant neon  
13 arrow saying this is authoritative.

14           NFPA believes, first of all, an authoritative  
15 statement should be consistent with the agency mission and  
16 the program responsibility of that agency or its  
17 subdivision. An authoritative statement should include any  
18 published statement of a federal scientific body concerning  
19 a diet-disease relationship that is prepared within the  
20 scope of the body's delegated legal authority and consistent  
21 with the scope of responsibilities of the subdivision, as  
22 reflected in the publicly available materials describing the  
23 mission and the scope.

24           For example, the National Cancer Institute would  
25 be authoritative on statements about cancer. The National

1 Heart, Lung and Blood Institute would be authoritative on  
2 cardiovascular diseases.

3 The determination of an authoritative statement  
4 should rest on the agency's or subdivision's authority to  
5 issue statements on diet-disease relationships and not on  
6 whether the specific review, in fact, constitutes a  
7 surrogate for FDA petition approval, and that would be in  
8 the judgment of FDA.

9 NFPA believes it should be the burden of the  
10 notifier or the user of the claim to determine that the  
11 statement is authoritative or within the mission and scope  
12 of the agency or subdivision.

13 It would be arbitrary to decide whether a  
14 statement is authoritative through informal consultation  
15 between FDA and the scientific body. Determination of an  
16 authoritative statement should not be open to interpretation  
17 of either FDA or the scientific body.

18 NFPA believes that an authoritative statement does  
19 not need to be official policy of the scientific body as a  
20 whole; nor does it need to reflect only diet-disease  
21 relationships that are firmly established. We believe that  
22 authoritative statements only need to be within the scope of  
23 delegated responsibility of the scientific body.

24 There should be no obstacles erected for FDAMA  
25 health claims that would make it appear that FDA is creating

1 an architecture of premarket approval to overlay premarket  
2 notification. FDAMA health claims are, in fact, a different  
3 type of health claim than the type established under NLEA,  
4 just the way that GRAS is a different type of status of a  
5 substance compared to food additives.

6 In closing, I want to say a few words about  
7 significant scientific agreement and how it should apply to  
8 FDAMA health claims.

9 First of all, FDA, we believe, has misinterpreted  
10 significant scientific agreement in the years since NLEA and  
11 now would be a good opportunity to reexamine it, especially  
12 since the Pearson decision directs FDA to do just that.

13 The NLEA amendments place the term in this  
14 context, that there is significant scientific agreement  
15 among experts qualified by scientific training and expertise  
16 to evaluate such claims, that the claim is supported by such  
17 evidence.

18 NFPA believes this standard means that scientists  
19 in this area generally would agree that the health claims  
20 statement, as expressed, with any qualifying information, is  
21 supported by the currently available published scientific  
22 evidence. The necessary degree of agreement would be less  
23 than unanimity, even less than consensus. It simply means  
24 general agreement.

25 But more importantly, agreement about what? The

1 law makes it clear that it is the claim about the diet-  
2 disease relationship that must be supported by the evidence  
3 and not the relationship between the dietary component and  
4 the disease which must be fully established.

5 Under the NLEA, significant scientific agreement  
6 should be determined by posing a simple question. If the  
7 scientists in an area reviewed the science on this issue,  
8 would they generally agree that the specific health claim  
9 made, considering the exact words used, is supported by the  
10 body of this evidence? This standard does not require that  
11 scientists would draft the health claim by using precisely  
12 the same language but only that they would concede, from the  
13 standpoint of a reasonable consumer, that the claim fairly  
14 represents the body of scientific evidence and is not  
15 misleading.

16 There are many more ideas along these lines and  
17 must be explored and really this is just a beginning. NFPA  
18 is grateful for the opportunity to share these views. Thank  
19 you very much.

20 MR. LAKE: Thank you. Our final panelist is Dr.  
21 Bernadette Marriott from the Northern Arizona University and  
22 you're going to do this from the floor, I gather.

23 DR. MARRIOTT: We're having technical  
24 difficulties.

25 [Pause.]

1 MR. LAKE: Okay, that is going to take a minute,  
2 so maybe we can ask a question or two of the other  
3 panelists.

4 Maybe now's an opportunity to give a minute or two  
5 to the panelists to comment on anything they've heard from  
6 the other panelists. So we'll be thinking about that as  
7 we're waiting for this technical difficulty to get resolved.

8 The other thing is that those of you in the  
9 audience, again if you have cards, you can begin to write  
10 your questions. We'll be getting to those in a little bit,  
11 as well.

12 **COMMENTER PANEL DISCUSSION**

13 MR. LAKE: Annette, why don't we start with you?  
14 You were the first speaker. If you have any comment that  
15 you wish to make relative to any of the other panelists, you  
16 might want to do that now. Or I guess the other alternative  
17 is if you have a question of the other panelists, now would  
18 be a time for that, as well.

19 DR. DICKINSON: I guess I can start by saying that  
20 I certainly sympathize with the point that Mr. Levitt made  
21 earlier, which is that discussing all of these issues is  
22 going to be ultimately useful but it may not immediately  
23 result in any clear consensus among the people who are  
24 commenting on it, as we have seen in our first panel here.

25 I think, though, there's one thing that we would

1 all agree on, which is that the purpose of FDAMA is to allow  
2 us to make more use, more use for consumers in labeling, to  
3 make use of labeling as a way of getting information to  
4 consumers about what scientific bodies think is important  
5 for them to know.

6 I think if we focus on that as the underlying  
7 driving factor here, it can help maybe cut through some of  
8 the apparent disagreement that we have on definitions of  
9 other terms that might come into play as we make that  
10 decision.

11 I think that all of us would like to see FDA  
12 implement this in a way that, in fact, facilitates the  
13 spread of the information that is agreed upon by scientific  
14 bodies to consumers, using labeling as the mechanism for  
15 that distribution. And however much we may disagree on  
16 defining authoritative or defining other terms that may come  
17 into play here, I think if we focus on that as the driving  
18 factor, that maybe it helps to resolve some of those  
19 disagreements.

20 MR. LAKE: Thank you for those additional  
21 comments.

22 Michael, do you have something?

23 MR. FORD: Well, I think there was agreement among  
24 us that we really want FDA to take the ball and run with it  
25 here. I think there's agreement among us that the language

1 of FDAMA is pretty straightforward and does not require  
2 voluminous regulation to be published. My organization  
3 would say the same thing about the Dietary Supplement Health  
4 and Education Act.

5           And I didn't mean to make anyone wince when I  
6 mentioned the runaway train in connection with looking at  
7 this provision as a runaway train. When there is a runaway  
8 train, there's the brakeman and the engineer and the  
9 brakeman has one simple task--make the doggone thing stop.  
10 But engineer has to look at innovative approaches to make  
11 sure that nobody gets hurt. Maybe he'll decrease the steam  
12 pressure. Maybe he'll even consider putting the wheels in  
13 reverse. And we hope that you'll take the engineer's  
14 course, not the brakeman's course.

15           MR. LAKE: Thank you for that.

16           Tracy, do you have some comment?

17           MS. FOX: I think I'd just like to reiterate what  
18 Dr. Dickinson said about looking at the consumer and what  
19 does the consumer need. That's something ADA thinks a lot  
20 about in terms of what information is useful to consumers  
21 that they can apply in the context of a diet.

22           And I think that's an important key that  
23 regardless of how we define authoritative statement, when  
24 and if significant scientific agreement comes into play, the  
25 ultimate goal is to basically inform consumers with sound

1 science. And I think that's a goal that hopefully we can  
2 reach at some point, but that should be the goal of FDAMA  
3 and hopefully one of the outcomes of our discussions today.

4 MR. LAKE: Thank you. Ilene?

5 MS. HELLER: I agree with what Joe Levitt said  
6 earlier, that we have to do what's fundamentally best for  
7 the consumer. And I think for authoritative statements to  
8 be meaningful, they really have to be authoritative. It's  
9 like the Surgeon General's statement on cigarettes:  
10 cigarettes are hazardous to your health. That's the kind of  
11 meaning that we have to have behind these statements.

12 The public has to know that when the government  
13 speaks out on a statement, the government is in agreement  
14 among the different agencies. Otherwise it becomes  
15 meaningless.

16 MR. LAKE: Thank you. Regina?

17 MS. HILDWINE: I think that we really need to  
18 focus on the whole general concept of scientific  
19 substantiation and what FDAMA means particularly in the  
20 light of NLEA health claims.

21 In NLEA health claims, it's the petitioner that  
22 has to prove something. With FDAMA-type health claims, it's  
23 the government that concludes something and states  
24 something. And because the government states it, then it  
25 becomes something that you could translate into labeling.

1 I've always liked to use the example of the  
2 Dietary Guidelines for Americans in which the government  
3 makes recommendations to consumers on what they should eat,  
4 on how they should eat and talks about reduced risk of  
5 certain diseases. And in the Dietary Guidelines for  
6 Americans bulletin there often are tentative or preliminary  
7 statements made. Nevertheless, the government feels  
8 comfortable enough to recommend these actions to consumers.

9 And we've always made the point that if it's okay  
10 for the government to say in a publication, then it should  
11 be okay to take those very words and put them on a label.

12 MR. LAKE: Thank you.

13 It looks like we have our technical difficulty  
14 resolved, so we will hear from our final panelist. In the  
15 meantime we're accumulating some questions, as well, but why  
16 don't you go ahead and proceed?

17 DR. MARRIOTT: I'm sorry for the delay. It  
18 appears that there was a power surge or failure or something  
19 like that.

20 My name is Bernadette Marriott. I'm a vice  
21 provost and dean of graduate studies at Northern Arizona  
22 University. As such, here I am representing myself as an  
23 individual scientist. Unlike the other panelists, I am not  
24 representing a specific organization, so my comments today  
25 do not represent Northern Arizona University or the Arizona

1 Board of Regents, which is the governing body that regulates  
2 the Arizona State Universities.

3 I'm very grateful to the FDA for inviting me here  
4 today and I'll take Mr. Levitt's comments to heart because  
5 as an individual, I will be using a few lighter remarks  
6 today.

7 FDAMA raised many issues that deal with how  
8 science progresses and how policy is made. These issues are  
9 not only pertinent to food and dietary supplement health  
10 claims but also have far-ranging ramifications in terms of  
11 the rapidity with which science progresses and how it is  
12 transmitted to the public and also interpreted for the  
13 public and the consumer.

14 My purpose here today is to address several  
15 selected issues that are raised by FDAMA and presented as  
16 questions in today's framework for discussion. I'm going to  
17 comment on the existing situation in science, with several  
18 suggestions for ways the FDA and the designated scientific  
19 bodies could help.

20 I'd like to remind the audience that while all of  
21 us in this room may read the Federal Register on a regular  
22 basis, the people out in the hinterland, whom I represent,  
23 don't necessarily read it on a regular basis.

24 Today I'm going to address several different  
25 issues: definitions of authoritative statements,

1 significant scientific agreement, and also the FDA process,  
2 specifically the time frame, the steps that they've proposed  
3 and who is involved and how.

4           We read the Federal Register. However, most of  
5 the public and consumers see information about what's going  
6 on here today from a slightly different perspective.

7           Here we have a recent cartoon from Arlo and Janis  
8 where Arlo, the scientist with the white rat, goes home to  
9 talk to Janis. "Studies show how moderate activity is as  
10 good for you as strenuous activity but they don't recommend  
11 that people stop going to the gym. Studies show high fiber  
12 food doesn't reduce colon cancer but they don't recommend we  
13 cut back on eating it. Red wine can be good for you, but  
14 they won't say we should drink it. Something's fishy."

15           I think as we move forward we need to make sure  
16 that nothing is fishy about how we interpret authoritative  
17 statement and how the FDA moves forward with its process in  
18 a very direct and singular fashion.

19           So the current situation is that the public and  
20 consumers are very confused about the mixed messages  
21 regarding health claims. The confusion stems from multiple  
22 messages from multiple sources. Confusion also stems from  
23 what we are grappling with here today--no clear source and  
24 definition of an authoritative statement.

25           The public, the consumer, assumes that any

1 information that originates with a federal scientific body  
2 is authoritative. Now we know, as statements are put  
3 together from various scientific bodies, that they have  
4 different levels of presentation, different levels of  
5 authority behind them. But when this is presented outside  
6 of the government framework, all of these statements are  
7 regarded by the consumer as authoritative.

8           So FDAMA and authoritative statements have led us  
9 to weigh several different arguments. The Congress, in  
10 proposing FDAMA, said that the current process is cumbersome  
11 and may result in critical health benefit time loss, such as  
12 what was exemplified by the folic acid issue. And therefore  
13 health claims can cite authoritative statements--and we've  
14 talked many times today about how this was originally  
15 defined by FDAMA--of key federal scientific bodies, and  
16 these were named and several were given as examples.

17           The FDA has taken what was presented in the law  
18 and further characterized authoritative statements by adding  
19 three additional points. I beg to point out that these  
20 could be the beginning of a more definitive conclusion about  
21 what an authoritative statement is.

22           Now here we're all talking about health claims and  
23 health claim issues, but if you step back, we're also  
24 talking about authoritative statements in general, as was  
25 exemplified by one of the other panelists.

1           The FDA also further elaborated on key federal  
2 scientific bodies and, as several of the panelists have  
3 indicated here today, this can also bear additional  
4 discussion.

5           In terms of the scientific bodies and how they're  
6 weighing these issues, public education information is not  
7 authoritative. That's one of the statements that has come  
8 out of some of the scientific bodies. Others disagree.  
9 There needs to be internal consensus within each scientific  
10 body as to how they're going to present the information that  
11 is based on science.

12           Again we come back to the public, consumer and  
13 industry. When is a statement authoritative? We need some  
14 help. Scientists, as well, need help because they are  
15 tasked with interpreting their data for the public.

16           We need to keep in mind, in terms of scientific  
17 statements, that one person's deliberative review can be  
18 very biased, depending upon the materials chosen to review.  
19 Therefore, an authoritative statement must include some type  
20 of group review or consensus or multiple reviews to really  
21 become authoritative.

22           Science has been progressing very, very rapidly  
23 and will continue to progress. With this, there are  
24 evolving roles for scientists and for federal scientific  
25 bodies. Scientists are researchers. They're authors.

1 They're now tasked at most universities and research  
2 institutions as being scientists/entrepreneurs.

3           So with raising money for one's own research and  
4 supporting one's own research, can we bring forward issues  
5 of conflict of interest and intellectual property, which I  
6 also want to raise in relation to authoritative statement.

7           Scientists are also politicians and in some  
8 instances expected to be public relations specialists.

9           Federal scientific bodies--they conduct research,  
10 they support research, and they do this very well. They do  
11 it carefully and with separation of the groups that do both  
12 of these possibly conflicting types of activities.

13           They interpret research results, they educate the  
14 public and they also have to present a public image. These  
15 different roles for federal scientific bodies can also often  
16 cause internal conflict as they are weighed with the success  
17 of the organization.

18           Authoritative statements. We've heard a number of  
19 different characteristics. Some of them are easier to  
20 discern. Whether the relationship exists or not is fairly  
21 straightforward. Whether it has been published is fairly  
22 straightforward. Where it has been published and whether  
23 that constitutes an authoritative statement based on the  
24 source of the publication needs more discussion.

25           It's fairly straightforward, the characteristic

1 that it's not a statement of an employee, and we can fairly  
2 quickly understand whether something is couched in the  
3 language of being preliminary or inconclusive.

4           However, I feel that the more controversial issues  
5 that we need forward on as quickly as possible are what  
6 constitutes the deliberative review, whether official policy  
7 should be a part of this, and the term that people seem to  
8 be skirting around the edges of a little bit is whether an  
9 authoritative statement is currently in effect. In other  
10 words, what is the acceptable time line? Is something from  
11 1989 acceptable as currently in effect? And whether or not  
12 it can contain qualifiers. I tend to support the comments  
13 of several people on the panel that it can contain  
14 qualifiers.

15           I'm going to go out on a limb a little bit here.  
16 Authoritative statements have raised the issue of how  
17 agencies provide educational material, whether they're  
18 written by public relations-trained individuals based on  
19 their reading or consulting with scientists, and whether or  
20 not the review of these materials that are put forward as  
21 educational and therefore very carefully worded yet simply  
22 worded have a review level that is such that they can be  
23 authoritative statements.

24           We need recommendations, summary or review pieces  
25 that are scientifically peer-reviewed within the scientific

1 bodies. Congress states that these are routinely compiled.  
2 That is true; they are routinely compiled. These need to  
3 see the light of day and they need to be presented for what  
4 they are, which is authoritative statements.

5 Agencies need to step forward. Educational  
6 materials, if not reviewed, need to be reined in because the  
7 public, the consumer views these as authoritative  
8 statements. The agencies need to decide whether they are or  
9 they aren't. Agencies also need to respect the scientific  
10 expertise of one another.

11 Some suggestions regarding authoritative  
12 statements. FDA and the named federal scientific bodies  
13 need to speak as one voice. I suggest that they identify a  
14 list of no less than five model authoritative statements  
15 examples and they publish a white paper that includes these  
16 models and explains the approach, essentially, a set of  
17 standards about the relationship or nutrient level, where  
18 these authoritative statements can be published, acceptable  
19 locations on an agency by agency basis that are defined.

20 Defining "currently in effect," what is the  
21 acceptable time frame? How far back in scientific history,  
22 with the dynamism of science, can we go and still have an  
23 authoritative statement? They need to explain the type of  
24 deliberative review among recognized scientific experts in  
25 the field and explain the criteria that are necessary to

1 have an authoritative statement.

2 Is a consensus statement that is prepared by non-  
3 experts in the field, whether they are experts in other  
4 fields, considered an authoritative statement when we're  
5 talking about a diet and health issue?

6 We need guidance on whether or not they may  
7 contain qualifiers but are not preliminary. In other words,  
8 the scope needs to be carefully examined. What literature  
9 is needed for a claim?

10 Authoritative statements and scientific bodies.  
11 Federal bodies must in general take the lead based on their  
12 mission and define the issues jointly, recognize the  
13 authority of subunits to make authoritative statements  
14 representing their scientific expertise. NCI, NHLBI, et  
15 cetera represent the expertise, as has been said on this  
16 panel, with their respective disciplines.

17 Each federal body needs to determine who  
18 represents that body, designate a process for what  
19 represents authoritative statements and again designate  
20 publications that will contain these statements from their  
21 agencies or subunits.

22 As NIH is an example, each institute has its own  
23 public information office or an office that manages review  
24 of information for accuracy and currency. There's also an  
25 organization called the Nutrition Coordinating Committee.

1 They have a subcommittee that reviews nutrition education  
2 materials across NIH. Does the NCC-reviewed material  
3 represent an authoritative statement of NIH on nutrition?

4 This needs to be addressed.

5 Each scientific body or subunit needs to designate  
6 again who and the process for which it will be represented  
7 in terms of authoritative statements.

8 The FDA process should proceed as it has been  
9 outlined by Chris in her initial discussion piece. However,  
10 I think initially, within the scientific bodies, they need  
11 to designate one scientific liaison per body, and this would  
12 mean for the subunits, as well, if so designated by the  
13 overarching agencies.

14 The bodies need to decide on an internal process  
15 for their own review and the bodies need to establish  
16 guidelines. The FDA then can use their 120-day notification  
17 process. They can check that the pieces are in place, using  
18 the issued guidelines. The FDA can distribute the claims to  
19 the federal bodies with the confidence that these bodies  
20 have an established review process in place and are not  
21 retesting their statements time and time again.

22 Then the authoritative statements that come back  
23 to the FDA can go to the Liaison Group for reviews for SSA.  
24 This is a secondary process. And it appears that this  
25 Liaison Group may be a good group to look at the SSA overall

1 for these claims.

2 The FDA process must include context review  
3 initially. The notification needs to include balanced  
4 presentation and literature review, but the FDA and the  
5 liaison panel need to give some guidance on this.

6 The bottom line is that the bodies cannot disallow  
7 all statements. This is a great concern, that the  
8 statements that the public and the consumer is turning to  
9 from these agencies and believing in cannot suddenly be  
10 disallowed as they're put under the light of authoritative  
11 statement. The liaison panel needs to have clear membership  
12 with a rotation policy and the ability to determine SSA by a  
13 designated process.

14 Just quickly, the other questions that were asked  
15 for this meeting: Should expansion of federal bodies be as  
16 listed in the guidance for industry? Yes, plus the DOD and  
17 the VA and their subunits when they focus on these issues.  
18 Both of these organizations do set nutrition policy for  
19 special populations and for special environments.

20 Should health claims based on authoritative  
21 statements be used for supplements? Yes. Should the  
22 notifications be put in a public docket? Yes, but again in  
23 concurrence with other members on the panel, one docket, not  
24 by company.

25 I'd like to remind you that the food supply and

1 related issues are becoming more complex daily. On our  
2 horizon, not too far off, we may see color-coded  
3 vegetables--asparagus purple, which contains high potency  
4 zinc and is labeled as such; green asparagus with regular  
5 potency but well characterized; yellow asparagus, high  
6 potency vitamin E; orange asparagus, high potency beta  
7 carotene. We will be able, within the next 10 years, to  
8 choose diet based on genetic risk factors and individual  
9 preferences.

10 The FDA and the scientific bodies need to act now  
11 to be prepared to handle these issues, as well as  
12 authoritative statements.

13 Again the public and the consumer is reading much  
14 more of this type of information than they are the Federal  
15 Register. Here we see a cartoon by Cathy. We see a Power  
16 Bar in the middle with all of the different nutrients  
17 carefully labeled. We see a man over on the right. He's  
18 called a power smoothie. He's sensitive. He has wit and  
19 charm.

20 He asks Cathy, "Would you like to go out  
21 sometime?" She says, "What bonus nutrient do you provide?"  
22 "Excuse me?" he says.

23 "This is the age of nutritional enhancement. What  
24 do you offer?" "What?" he says.

25 "Calcium, soy protein, vitamin C, vitamin E, folic