

1 acid, bran, zinc, ginkgo biloba, echinacea, fiber,  
2 electrolytes. Read the labels. Everything's beefed up,  
3 boosted, fortified, enhanced, energized. Even a bowl of  
4 Fruit Loops has 11 essential vitamins and minerals. What's  
5 your added health benefit? What minimum FDA requirement do  
6 you satisfy? Why, with the universe of 6 billion single  
7 men, should I hand over three prime time hours of my life to  
8 you?"

9 He says, "I haven't run from the room screaming  
10 yet and no one else has in this room." She says, "Ah, an  
11 excellent source of stamina. How's Tuesday?"

12 Again this is where our consumers are getting  
13 their information.

14 In conclusion, scientific bodies need to act  
15 quickly to establish internal processes and designated  
16 publications. The bodies and FDA need to continue to work  
17 together and I recommend that they publish a white paper  
18 that contains models of authoritative statements and clear  
19 guidelines and definitions. If the FDA moves forward to  
20 designate its process quickly and that is clear and widely  
21 available to the consumer as well as to those individuals  
22 who are directly concerned, the end result will be less  
23 confusing for the public, a more direct path for industry  
24 and we will be prepared for new food questions and new foods  
25 that are just down the pike. Thank you.

1 [Applause.]

2 MR. LAKE: Thank you. And as you're moving back  
3 up to rejoin the panel, I think I will turn now to Mr.  
4 Levitt to ask the first question.

5 **QUESTIONS FOR THE PANEL**

6 MR. LEVITT: Thank you. I have to begin with a  
7 confession. I'm only a moderate source of stamina myself.  
8 I'm going to have to be leaving shortly. I get to argue for  
9 our budget this afternoon and I certainly don't want to miss  
10 that opportunity, but I'm glad I got to hear all the  
11 presentations. Annette, I'm sorry I came in midway through  
12 yours but I'll be sure to go back and read it.

13 I would like to just first reflect on something I  
14 said before and ask people to think about, not to answer  
15 now. But as you go back and hear the discussion, it's okay  
16 to come back to us afterwards and say, "You know, I've  
17 rethought this and it would make sense to move a little in  
18 this direction." I don't want people to feel like--I know  
19 we all represent organizations; people have to go back and  
20 check back home with the people they represent. But it is  
21 okay to have evolving thinking if part of the public  
22 discussion helps persuade.

23 And I'll give you just two particular points to  
24 kind of start thinking on. One has to do with a lot of the  
25 discussion I heard this morning on just what is an

1 authoritative statement. I think it was Michael Ford that  
2 said the statute is pretty clear on its face, and Regina  
3 expanded on that by saying it's pretty clear it's any  
4 published statement.

5           And I guess the honest question I have is I have a  
6 feeling if Congress meant that authoritative statement meant  
7 any published statement, they probably could have figured  
8 out how to write any published statement, that that's more  
9 of a common word. But authoritative, it seems to me, must  
10 mean something more than any published statement.

11           And while I know you've come in with a position  
12 that represents your organization and you probably need to  
13 stick to that now, I guess I'd ask people or others to  
14 think, is there something that people can offer more than  
15 any published statement that seems to reflect authoritative?

16           MS. HILDWINE: If I could just respond to that?

17           MR. LEVITT: Please.

18           MS. HILDWINE: I believe what I said was that any  
19 published statement that was in the scope and responsibility  
20 of the authority of the government agency, and I think  
21 that's very important because there are very few government  
22 agencies that have authority for every segment of public  
23 health protection or research directly related to human  
24 nutrition. And as a consequence, there are going to be some  
25 areas that are the appropriate turf for one agency or

1 another.

2           The examples that I gave were that the National  
3 Cancer Institute would be authoritative on statements about  
4 cancer, but the National Heart, Lung and Blood Institute  
5 would be authoritative on statements related to  
6 cardiovascular disease.

7           If you reverse those areas, you can envision a  
8 situation in which the National Cancer Institute might make  
9 statements related to cardiovascular disease but it raises  
10 some questions as to whether or not that's in the scope of  
11 their authority and their responsibility.

12           So I think the agency that makes the statement has  
13 to match well with the statement that's being made.

14           MR. LEVITT: That's a fair comment. I would still  
15 ask you to go back and think. I think still any published  
16 statement within the scope of authority still strikes me as  
17 a good bit away from authoritative.

18           MS. HILDWINE: I will certainly think about it but  
19 this, of course, raises other questions. You know, what's  
20 the government putting out these days? And should consumers  
21 view them as authoritative recommendations in any sense?

22           This is a really important thing for us to  
23 explore, but this is a situation where the first statement  
24 is being made by the government and I think that we need to  
25 look at what's behind that environment.

1 MR. LEVITT: Thank you. My second question comes  
2 from the other direction a little bit. A number of  
3 commenters today have said that FDA was too limited in the  
4 either number or designation of scientific bodies that have  
5 been officially designated by us or identified by us is  
6 maybe a better phrase, as recognized scientific bodies here.

7 I don't know if any of the other panel  
8 members--Tracy or Ilene or any of the others would also  
9 encourage, as some of the other speakers have, that we  
10 expand that list and in what way?

11 MS. FOX: I think in looking at the law, clearly  
12 there are examples that are given and I also recall from the  
13 debates with the staff of members of Congress during the  
14 FDAMA debates that it was always my understanding and I also  
15 thought the staff's understanding that the entities that  
16 were identified, certainly the ones that were provided as an  
17 example and I think also others that were envisioned, would  
18 be entities responsible for conducting research that would  
19 apply generally to the public, not to small subsets of  
20 populations, not to pockets of the population for which we  
21 could then identify an authoritative statement to apply  
22 broadly.

23 And I think that's the concern that the entity  
24 should be one that really does publish for the most part or  
25 at least conduct research for the most part that can be

1 applied fairly broadly to the population because that's who  
2 is reading health claims, not particular entities of an  
3 organization.

4 MR. LAKE: All right. Now we will proceed with  
5 some other questions.

6 DR. LEWIS: We have two and then I think both  
7 David Dorsey and I have some questions, as well, but to try  
8 to be responsive to the audience, the first question I have  
9 from the audience says, "Did I understand correctly that CRN  
10 and others believe that FDA should be the final decision-  
11 maker on whether statements are authoritative and NFPA  
12 disagrees? That is, the scientific body to which the  
13 statement is attributed should decide?" That's the  
14 question.

15 So did they understand correctly that CRN and  
16 others believe FDA should be the final decision-maker on  
17 whether the statement is authoritative but NFPA believes the  
18 scientific body should decide when it has an authoritative  
19 statement?

20 DR. DICKINSON: They are correct at least in the  
21 first part of that, that CRN believes FDA needs to make the  
22 final decision about whether a statement is authoritative  
23 and should not basically buck that decision to the  
24 scientific body.

25 MS. HILDWINE: But they're not correct in what

1 NFPA stated and I hope that I was able to communicate this  
2 clearly.

3           We believe that a lot of the authoritative  
4 statement issue is going to be on the face of it, that first  
5 of all, it's the burden on the claim notifier to assure that  
6 the statement is authoritative and secondly, that the  
7 authoritative statement, while you don't have to ask the  
8 scientific body if it's authoritative, that it comes out of  
9 the context that that is where the scientific body has its  
10 authority.

11           But in fact, we see that the final judgment is  
12 FDA's but that the burden of demonstrating it to FDA belongs  
13 to the claim notifier. It gets a little complicated but I  
14 think that's exactly how I would characterize it.

15           MR. LAKE: Thank you both.

16           DR. LEWIS: I have a second card from the audience  
17 and it's directed to Dr. Dickinson and Miss Heller. It's a  
18 fairly long question. I'll go ahead and read it all the way  
19 through and then we can go through it again if clarification  
20 is needed.

21           Again to Annette Dickinson and Ilene Heller,  
22 "FDAMA provides responsibilities to FDA on appropriateness  
23 for health claims or nutrient content claims based on  
24 authoritative statements of scientific bodies.

25           "One, if NIH or CDC or the National Academy says

1 the statement is authoritative, FDA can accept this  
2 determination or can reject it with explanation. Two, if  
3 NIH or CDC or the Academy says the statement is not  
4 authoritative, FDA can say it is authoritative.

5 "Three, if NIH does issue an authoritative  
6 statement and CDC does likewise but the conclusions or  
7 recommendations on the same scientific data differ, A, what  
8 should FDA do? B, regardless of what FDA does, what  
9 recourse do the two conflicting agencies have? And C, who  
10 is responsible for informing the public of the basis for the  
11 disagreement?"

12 I think it's an interesting question. It's a long  
13 one. Again it's directed to Dr. Dickinson and Miss Heller  
14 but I don't see any reason why others can't comment on this,  
15 as well.

16 MR. FORD: I'm certainly willing to defer to Dr.  
17 Dickinson.

18 DR. DICKINSON: You're so kind.

19 I certainly take the point that even if a  
20 scientific body makes its own determination of whether  
21 something is authoritative, that doesn't necessarily mean  
22 that FDA has to accept that determination. They could agree  
23 or they could disagree. I think that was the only point  
24 being made in the first part of that question.

25 The second part of it, what if two agencies differ

1 and come to different conclusions? I think that's a  
2 situation where frankly from my point of view as to what I  
3 see as reasonable and what I think CRN sees as reasonable,  
4 it is very significant information for consumers that that  
5 has occurred. It may not be the basis for a FDAMA health  
6 claim, but it certainly should be the basis for information  
7 that those agencies and possibly FDA in some fashion would  
8 want to convey to consumers as to why they arrived at  
9 different conclusions based on the same scientific evidence.

10 I'm sure that if this were to occur, and it  
11 probably has occurred--I know it has occurred on some  
12 instances--I'm sure that the respective agencies would be  
13 publishing statements regarding their conclusions,  
14 publishing papers which would then get in the media. The  
15 media would be discussing how come it is that CDC thinks  
16 this way and FDA thinks that way? And it would actually, in  
17 the long run, I think, contribute to a very useful  
18 discussion that would help resolve that issue.

19 I think that if you have that kind of issue, it  
20 clearly is not yet ripe for a FDAMA health claim, that you  
21 should not have a FDAMA health claim in two different  
22 directions on the same subject from two different agencies.

23 So I think that in that case, FDA's logical  
24 decision would be that there is not agreement, significant  
25 scientific agreement or any other term that they might

1 ultimately choose to define that. There is not agreement  
2 among the authoritative bodies on this issue.

3 I don't think that necessarily means that on every  
4 case they have to poll the scientific bodies to determine  
5 the level of agreement, but I think that in those cases that  
6 may come up where there is, for one reason or another,  
7 dramatic disagreement, that certainly would not lead to a  
8 FDAMA health claim, at least in my view.

9 MS. HELLER: I would echo Annette's statements on  
10 this. I think FDA has to be the final arbiter on decisions  
11 by other agencies because if FDA finds that there's other  
12 information by other agencies, particularly within the  
13 government, that's contradictory, it is just going to  
14 confuse consumers. FDA has to make the ultimate decision as  
15 to whether there's significant scientific agreement.

16 And I think Annette had a really good point about  
17 the situation where if two agencies disagree with each  
18 other, there shouldn't be a health claim on that but there  
19 should be some airing of this to the public. Let the public  
20 know that two agencies are conflicting about this and get  
21 some more input on it.

22 MS. FOX: There's just one point I want to make in  
23 terms of ADA also supports FDA being the final arbiter once  
24 there's been a vetting and a good open discussion with the  
25 scientific body. And I think it's important because

1 scientific bodies for the most part, up to this point,  
2 haven't been in the business of regulating health claims on  
3 foods, and FDA has for many, many years.

4 I think that's an important point, that regardless  
5 of--I don't want to say regardless of what the science says  
6 but there might be a number of other factors that have to be  
7 considered because we're talking about health claims on food  
8 labels, not just straight science at this point.

9 MR. FORD: I would agree with that, as well. We  
10 look to the research agencies to do the research and the  
11 regulatory agencies to regulate and that is your charge, to  
12 regulate under this provision of FDAMA. And it's up to the  
13 company to do its best to convince you that it has used an  
14 appropriate source and the way they've perhaps qualified it  
15 makes it a reasonable claim, but it's up to you to make that  
16 final decision.

17 And I want to put another plug in here for the  
18 idea of perhaps getting assistance from a discrete dietary  
19 supplement advisory committee in these areas.

20 DR. LEWIS: Does anyone else on the panel wish to  
21 make a comment on that before we move to another question?

22 MS. HILDWINE: I did want to sort of throw another  
23 perspective into the mix. What happens in the valid  
24 situation in which the science is absolutely equivocal; that  
25 is, it's right down the middle. This has happened. Your

1 conclusion depends on how you view this and all of the  
2 factors that you bring into your interpretation of the  
3 science.

4 One government scientific body interprets the  
5 science tending toward a particular way; another equally  
6 qualified authoritative government scientific body  
7 interprets the same science tending the opposite direction.

8 Is it appropriate to make such a statement as the  
9 basis for a FDAMA health claim? Possibly, and for this we  
10 have to look, I think, to the Pearson decision. The Pearson  
11 decision says that if language--essentially it says if  
12 language is appropriately qualified and you give consumers  
13 more information rather than less, how can they be misled?  
14 If a health claim were to state on a label "While all  
15 government agencies do not agree on this perspective, this  
16 government agency has said that this particular thing" and  
17 perhaps expand upon that.

18 So, in fact, in this situation, and it's a fairly  
19 common situation, where the science is very much equivocal,  
20 even though it is well developed and robust and has been  
21 studied for many years, it may be possible to make well  
22 qualified health claim statements that give consumers more  
23 information rather than less information and therefore do  
24 not mislead.

25 MR. FORD: You may wish to consider perhaps a

1 standardized or standard disclaimer-type language to  
2 accompany perhaps a qualified claim. That might be an  
3 approach. I think the disclaimer has worked well with  
4 DSHEA. It might work well in this instance.

5 DR. LEWIS: Bernadette, did you have anything you  
6 wanted to add?

7 DR. MARRIOTT: I'll say that the discussion  
8 between or among scientific bodies, which clearly gives  
9 their rationale for their approach or their conclusions, can  
10 do nothing but help the public and the consumer, providing  
11 them with more information on which to make their decisions.

12 DR. LEWIS: I believe FDA in the voice of David  
13 Dorsey has a question and so we'll turn to him now.

14 MR. DORSEY: My question is directed at least  
15 initially to Annette Dickinson and CRN's proposal. I guess  
16 I want to try to characterize what your proposal is and I  
17 hope you'll correct me if it's a mischaracterization, and  
18 then I'll ask you to flesh out some details more. There's  
19 one particular issue that I'd like you and others to  
20 address.

21 It seems to me that you're basically saying or CRN  
22 is basically saying that an authoritative statement is a  
23 recommendation to consumers to consume a certain nutrient  
24 because of its relationship with a disease. And it's only  
25 when it's a recommendation to consumers that it should be

1 considered authoritative.

2 In the particular example you gave, and I'm  
3 wondering, is that an accurate characterization of your  
4 approach? And also if you could fill in some of the details  
5 about how we would identify, how FDA, for example, or anyone  
6 would identify when a statement is, in fact, a  
7 recommendation.

8 One example you gave was the example you gave with  
9 folic acid and homocysteine included the level of folic acid  
10 required, and certainly the authoritative statement, the  
11 folic acid neural tube defect statement from CDC, also  
12 identified the level.

13 Is that something that you think any authoritative  
14 statement must include, a level? And if not, why not? If  
15 it doesn't, who has to provide it? Is it something FDA is  
16 required to come up with? Should the notifier give it to  
17 us? And I'd like others to respond, as well, if possible.

18 DR. DICKINSON: First of all, I would be a little  
19 bit broader than using just the term recommendations. I did  
20 say that in our view, an authoritative statement is a  
21 statement that an agency means to be acted on by consumers  
22 and by others. In other words, it's not just a statement  
23 they make in passing in kind of thinking about the state of  
24 the evidence. It's a conscious statement that they make  
25 intending that consumers, health professionals and others

1 will pick it up and do something with it.

2           So whether that necessarily characterizes it as a  
3 recommendation or whether they might call it something else,  
4 but basically it's that. It's an intentional statement.  
5 It's something that they mean to be acted on.

6           I do think that the level that is recommended is  
7 an important feature, as is required among the general  
8 requirements for health claims. I think that if the  
9 authoritative statement itself does not embody that  
10 information, then certainly it is an appropriate piece of  
11 information for FDA to add to it as part of a definition of  
12 what kinds of products are eligible for that FDAMA health  
13 claim. Presumably there will be a statement of eligibility  
14 that goes along with that claim and it would not simply be  
15 allowed for anything that has either a trace or a huge  
16 amount of something in it.

17           MR. DORSEY: So if I may follow up, you're saying  
18 you think FDA should identify the level but the notifier  
19 would not be responsible to identify the level?

20           DR. DICKINSON: Ideally, the notifier would  
21 incorporate that as part of their petition to you. But if  
22 they do not, I think that ultimately somebody has to make a  
23 decision on what the threshold level is for a product to  
24 bear that claim.

25           MR. LAKE: Do others wish to comment on that

1 question or answer?

2 DR. LEWIS: I have more or less a related  
3 question. Maybe we could incorporate that into the  
4 comments. It's both a question I had and one that has come  
5 from the audience.

6 The question from the audience is how can all of  
7 the factors that need to be looked at adequately by FDA in  
8 terms of making decisions, whether they're decisions on  
9 effective levels or methods of compliance, how can that all  
10 be accomplished in 120 days?

11 As I was listening, I also had the same set of  
12 questions in my mind. I know what we've gone through in the  
13 first experience of 120 days and it seems like a short  
14 amount of time to accomplish all of the tasks.

15 I do know from reading the statute and I'm sure  
16 David would agree that FDA can still act after 120 days, but  
17 at that point the claim is already on the market and that  
18 seems to be a somewhat disingenuous approach to regulating  
19 these.

20 So I think the notion of timing on all of this,  
21 especially given what is being suggested as being on FDA's  
22 plate, is one I'd like to hear a few comments on.

23 MS. HELLER: I think you've just made the argument  
24 for public notice as soon as a notification is filed with  
25 the FDA, so this way you can get the input on the levels

1 from people who would know about this from various agencies,  
2 various groups that have an interest in these products, and  
3 that will provide you with the information.

4 MS. FOX: I think also in terms of the  
5 notification package, I think that does need to be about as  
6 complete as possible in terms of identifying effective  
7 levels of nutrients or substances. I think a lot of the  
8 homework has got to be done before it hits the FDA door  
9 because if it's not, then there's going to be more need for  
10 FDA to send out for more information, which does stop the  
11 clock and restarts the 120-day period.

12 So I think it's to the benefit certainly of FDA,  
13 to the manufacturer, to consumers who can get the  
14 information sooner for that package to be about as complete  
15 as possible.

16 MR. DORSEY: If I can ask a follow-up, there's  
17 language in the legislative history that says a problem with  
18 the petition process was the burden it caused on  
19 manufacturers. It takes a lot of money and a lot of time to  
20 assemble a typical health claim notification.

21 And part, it seems, of the notification process  
22 was to relieve the burden, especially for smaller  
23 manufacturers, I think as identified in the legislative  
24 history.

25 And one thing we've been discussing at FDA and

1 we'd like to hear your thoughts about it is it's a nice idea  
2 to front-load as much of the stuff into the notification,  
3 but that ups the burden on the notifier and it doesn't seem  
4 that that's something we should do, given the intent to  
5 minimize the burden on notifiers. And yet we have to  
6 balance these two concerns.

7           Anyone have suggestions?

8           MS. HELLER: I think the balance is struck by the  
9 fact that when someone files a petition for a claim, they  
10 have to provide all the information. In the case of a  
11 notification, they're relying on a government agency that  
12 has already done the work, and they may have to attach a  
13 bibliography of other relevant studies, but it's still  
14 nowhere near the amount of data that needs to go into a  
15 petition. So I think the burden is still much less for an  
16 authoritative statement than it would be for a petition.

17           MS. HILDWINE: I would agree with that. The  
18 burden is less but the burden is still squarely on the  
19 notifier.

20           To develop a health claim petition, the petitioner  
21 not only puts together a literature review of the science  
22 but often sponsors the scientific research themselves. We  
23 are usually talking several millions of dollars. This  
24 precedent has been established in the case of health claim  
25 petitions that have come in to FDA already.

1 For a FDAMA health claim, the process of drawing  
2 the conclusion about the diet-disease relationship and  
3 making a statement about the diet-disease relationship is  
4 with the government scientific body or the parts of the  
5 National Academy of Sciences. The notifier then has to do  
6 the homework. They have to identify the statement. They  
7 have to make sure that the science to support the statement,  
8 at least in terms of outlining the published science that's  
9 well documented.

10 Somewhere throughout that science to support the  
11 government statement, there's going to be information about  
12 the levels, the effective levels of the substance that's in  
13 the claim.

14 The burden is squarely on the notifier. I think  
15 it has always been envisioned as that process. But it is a  
16 different type of burden than the burden of scientific proof  
17 that you have to assemble and in some cases sponsor  
18 research, submit that to FDA and essentially prove your case  
19 with that particular burden. It's different.

20 DR. DICKINSON: I think in addition to that, in  
21 the case of the small manufacturer, they will have  
22 associates that they can cooperate with in terms of  
23 gathering that information--either their trade associations  
24 or other groups, ad hoc groups that they may put together of  
25 interested manufacturers.

1 I think that the benefit of having a claim like  
2 that approved or being able to use a claim like that under  
3 FDAMA is sufficient to justify that investment.

4 MR. FORD: I think that you'd find there's some  
5 precedent under the Dietary Supplement Act with structure-  
6 function statements. While companies need only notify the  
7 FDA, they must have the substantiation to support the  
8 statement on the label. I know when the FDA gets around to  
9 rigorous enforcement of that particular section of DSHEA,  
10 you'll find that the substantiation is out there, in varying  
11 degrees certainly, but it's out there. The companies have  
12 to accept that burden within the guidelines that you create  
13 for specifically what must be submitted.

14 DR. LEWIS: We've got three more questions from  
15 the audience, one for Dr. Marriott, one for Regina Hildwine  
16 and then a general one concerning NIH consensus conferences.

17 For Bernadette, could you elaborate more on why  
18 FDA and the scientific bodies need to define an  
19 acceptable--they've used the term time frame but I think  
20 they're referring to currently in effect? Do you need a  
21 guideline or a rule? Should one be developed in which a  
22 decision becomes antiquated; for example, all decisions made  
23 prior to 1989. Could you elaborate on that?

24 DR. MARRIOTT: I was asking for either the liaison  
25 panel working in conjunction with the FDA to put some

1 guidelines around the time frame. I picked 1989 only  
2 because that was when the last RDAs were delivered and also  
3 when the Diet and Health Report was published, two pivotal  
4 publications. Parts from the Diet and Health Report may be  
5 currently viable, but other parts clearly are not.

6 So does that constitute an authoritative  
7 statement? What parts of that do? That's something that  
8 the National Academy of Sciences will have to address in  
9 their talk this afternoon. However, I'm just requesting  
10 that there be some guidance in terms of time frame in  
11 general and then some specific suggestions related to some  
12 pivotal documents.

13 DR. LEWIS: And then we have a question for Regina  
14 Hildwine. You say that even if two government scientific  
15 bodies disagree on interpretation of data, the health claim  
16 can still be used, as long as there is a qualifier  
17 statement. Doesn't this directly contradict the intent of  
18 significant scientific agreement?

19 The idea of SSA means that scientific bodies agree  
20 on data, not disagree. Is it possible for three out of four  
21 bodies to agree and consider this SSA? To have it split  
22 down the middle, this is not significant scientific  
23 agreement. It isn't consensus or general agreement.

24 MS. HILDWINE: I did raise the question of whether  
25 it would be appropriate for a FDAMA health claim but I

1 maintain that communicating more information to a consumer  
2 relative to these findings certainly would ensure that the  
3 claim is not misleading. And I think that's where we are  
4 really going, that significant scientific agreement frankly  
5 is a guard, a guarantee to ensure that the claim is not  
6 misleading.

7           Now perhaps a 50/50 split--okay, that's going to  
8 be a real conundrum. I think everybody's going to have a  
9 real probably with 50/50. A 75/25 split is significant  
10 scientific agreement. Two out of three is significant  
11 scientific agreement. Significant scientific agreement does  
12 not have to be unanimity, does not have to be consensus, has  
13 to be general agreement.

14           I think we need to keep in mind that scientific  
15 bodies may not always be basing their recommendations  
16 entirely on science, that, in fact, there can be some basis  
17 of history and tradition as to why they might base certain  
18 recommendations.

19           Well, I'm frankly looking forward to the continued  
20 debate on just what is significant scientific agreement but  
21 from our point of view, it does not mean consensus and it  
22 does not mean unanimity.

23           DR. LEWIS: We also have a general question, so  
24 I'll throw it out for any interested panel member. It  
25 reads, "Often NIH holds a consensus conference with a report

1 derived from a group of scientists not expert in the field  
2 being evaluated. Their findings may be in opposition to  
3 other NIH subunits or office statements. Should such  
4 consensus statements be given the same weight as to  
5 deliberative review from NIH as a whole?"

6 MS. FOX: Sounds like a question for NIH.

7 DR. LEWIS: We can hold it for the scientific  
8 panel discussion and we are having quite a few--

9 DR. DICKINSON: It's also part of the problem with  
10 defining NIH as a whole as the only part of NIH that can  
11 take a position. I think it would be relevant information  
12 that a consensus conference concluded A and that some  
13 subdivision of NIH, some center or institute at NIH has a  
14 different conclusion and again to air the reasons why those  
15 two different conclusions occurred, not necessarily as part  
16 of a FDAMA health claim if there's not enough agreement for  
17 that, but certainly as information that consumers should be  
18 aware of.

19 And while I'm talking, I'd like to also just  
20 enthusiastically endorse what Bernadette suggested in terms  
21 of a white paper that would actually give us a few examples  
22 of statements that we would all agree hopefully are  
23 authoritative statements of scientific bodies, with  
24 appropriate designation of levels of intake and all of that  
25 kind of thing, because I think part of what makes it

1 difficult to discuss this now is that the only comprehensive  
2 document anybody has put in front of us to look at is the  
3 petition that FDA received last year, which has some  
4 problems in terms of being the sole driving force of the  
5 discussion.

6 I think it would be enormously helpful if FDA or  
7 anyone else in the audience were to prepare a white paper  
8 putting forth some examples, some good, solid examples of  
9 claims that actually should be made or if someone submitted  
10 a new petition to FDA on that, I think it would help clarify  
11 a lot of these questions, because I think right now people  
12 are fearing things that probably are not very likely to  
13 happen, and if we had some positive examples in front of us,  
14 I think we could see that more clearly.

15 DR. MARRIOTT: Thank you, Annette.

16 I think that the scientific bodies that have been  
17 designated by legislation and those indicated also by FDA  
18 can identify what they consider authoritative statements  
19 from within their own bodies, and that would be a start  
20 because otherwise, I feel we will continue the discussion  
21 somewhat in circles and with fear on all sides as to what  
22 might be misconstrued in one area or another.

23 MR. LAKE: I think we have one final question from  
24 the audience.

25 DR. LEWIS: We do have one final question and it

1 indicates that it has to do with the analytical methods. It  
2 says, "Is it appropriate to request analytical methods vis-  
3 a-vis the notifier? How do you handle the wide variety of  
4 variability among ingredients and the lack of batch to batch  
5 consistency of the ingredients? The quality of these  
6 ingredients vary greatly."

7 The question is analytical methods for compliance  
8 purposes.

9 DR. DICKINSON: I think it is reasonable to expect  
10 the notifier to submit an analytical method for something if  
11 they're proposing a claim for which there is not currently  
12 an accepted analytical method for the ingredient.

13 MS. HILDWINE: We would agree with that. The  
14 issue relative to variability of ingredients, in part, goes  
15 to the good manufacturing practices of the manufacturer, but  
16 there's also going to be an issue relative to the  
17 reliability of the method.

18 If there is no established official method for a  
19 particular substance, then, in fact, the notifier should  
20 provide that information, complete information on the  
21 analytical method, including limits of detection and any  
22 analytical variability.

23 MR. LAKE: Thank you.

24 Before we adjourn for lunch I have a couple of  
25 announcements, but before I get to those, let me thank each

1 and every member of the panel this morning. I think your  
2 opening comments were very useful and I think the continuing  
3 discussion has also been very helpful to us and I think to  
4 the audience. So I think we should give them a round of  
5 applause.

6 [Applause.]

7 MR. LAKE: A couple of announcements. One, let me  
8 announce that the Food and Drug Administration will be  
9 holding a public meeting on the overall strategy for  
10 regulating dietary supplements under the Dietary Supplement  
11 Health and Education Act. The meeting will be held on June  
12 8 of 1999 in the auditorium of the Cohen Building at 330  
13 Independence Avenue, Washington, D.C.

14 Now we had some Federal Register announcements of  
15 this in the back. I am told that we have run out of those,  
16 but let me give you a couple of alternative ways of getting  
17 the information.

18 One, the information is on the Internet at  
19 [www.cfsan.fda.gov](http://www.cfsan.fda.gov). Or if you want to leave your name and  
20 fax number at the sign-up desk in the back, we can provide  
21 you with that additional information.

22 Also, I've had inquiries about how to get the  
23 transcript. We are hopeful that it will be available in  
24 about 15 days and it will be available from our Dockets  
25 Management Branch. The charge will be about 10 cents per

1 page.

2           The other inquiry I had was relative to the  
3 videotaping that is going on. Again the thing that FDA is  
4 doing is having the meeting transcribed. The videotaping is  
5 being done by a private party. If you have questions about  
6 how you might obtain that or whether it will be made  
7 available in some fashion to others of you, I will refer you  
8 to the gentleman who's doing the taping. I hope that's not  
9 too much of a burden on him, but if you have questions, you  
10 should address those to him.

11           With that, let me remind you that we want to start  
12 promptly at 1:00. We will have the scientific panelists at  
13 that time and their schedule is very tight, so we want to  
14 begin promptly at 1.

15           I thank you for being very attentive this morning  
16 and look forward to seeing you again at 1:00.

17           Lunch again, if you go down to the right to  
18 corridor 3, you can go downstairs and get something there or  
19 you can go elsewhere. Thank you.

20           [Whereupon, at 12:07 p.m., the meeting recessed  
21 for lunch.]

A F T E R N O O N   S E S S I O N

[1:04 p.m.]

MR. LAKE: Good afternoon, ladies and gentlemen. Thank you for returning promptly. We're going to go ahead and begin this afternoon's session because some of our panelists are going to have to leave.

We do have one substitution. Dr. Phillip Schwab is here for Dr. Eileen Kennedy and he is going to have to make his presentation and run, so we're going to give him the floor first.

**SCIENTIFIC BODY PANEL PRESENTATION**

DR. SCHWAB: Thank you very much. Thank you for the opportunity to address this public meeting on behalf of USDA. I'd like to apologize for Dr. Kennedy, the Deputy Undersecretary for Research, Education and Economics. She's actually out of the country this week and was unable to give the comments today.

But USDA is pleased to participate in this process and we're also very happy to supply the facility for this meeting.

The agency definitely has an open mind on this issue and certainly appreciates the valuable comments and the input that we're hearing from the public today. Clearly this is a complex issue which has emerged from a complex piece of legislation and will require a great deal of

1 consultation and careful thinking to work through.

2 My comments this afternoon will be brief and  
3 generally reflect the current state of thought about this  
4 issue at USDA as we are currently developing more thoughts  
5 on this process, in consultation with the Liaison Group.

6 The issue of defining what is or is not an  
7 authoritative statement is particularly difficult for  
8 science-generating agencies like USDA and I'm sure for my  
9 colleagues here on the panel, as well.

10 What would constitute an authoritative statement  
11 from USDA? Who should decide if the statement is  
12 authoritative? Who should decide when a statement is no  
13 longer current? These are all critical questions which must  
14 be answered to properly administer this provision of the FDA  
15 Modernization Act.

16 USDA has heard and does appreciate the various  
17 perspectives on this issue that have been expressed here  
18 today.

19 Now I'd like to provide just a little bit of  
20 perspective on how USDA views this issue. USDA directly  
21 employs thousands of scientists through the Agricultural  
22 Research Service, Economics Research Service and other  
23 agencies. USDA also indirectly supports thousands more  
24 through competitive grants and our land grant partners.  
25 These scientists are constantly generating new information,

1 developing new technology and publishing their research  
2 results. This includes science and technology directly and  
3 indirectly related to diet, health and nutrition.

4           Communicating with our customers about research  
5 results is a vital and integral part of our research mission  
6 and we use a variety of media to do that. The sheer volume  
7 of scientific information generated by USDA scientists and  
8 disseminated by our extension partners has the potential to  
9 lead to a great deal of confusion over what constitutes an  
10 authoritative statement from USDA.

11           Two examples which may help define the question we  
12 are examining today. First, USDA, after a great deal of  
13 deliberation and consensus-seeking, issues broad dietary  
14 guidelines. These guidelines are general in nature but  
15 result from years of nutrition and health research and can  
16 be applied generally across the population. They are  
17 updated when the need arises or science changes, again  
18 through a deliberative process. This is one example of  
19 something that could be interpreted as an authoritative  
20 statement from USDA.

21           On the other hand, USDA scientists make thousands  
22 of recommendations every day for thousands of applications,  
23 based on the best science available at the time. Fertilizer  
24 recommendations, animal nutrition and health, water quality  
25 protection are just some of the examples of areas where our

1 science and extension partners give advice and transfer  
2 scientific results from the laboratory to the field.

3           Likewise, our extension home economist partners  
4 and expanded food and nutrition education program case  
5 workers are just two examples of how USDA-affiliated groups  
6 sometimes give advice to people on proper nutrition and  
7 diet.

8           These recommendations that cover a broad range of  
9 issues are not, from USDA's perspective, what we would  
10 consider to be authoritative statements based on consensus  
11 or broad deliberation.

12           From the discussion this morning and from  
13 legislative intent, it seems clear that individual  
14 investigator publications or employee statements do not  
15 constitute authoritative statements. We learned time and  
16 time again that preliminary research results are constantly  
17 revised and refined with the discovery of new information.

18           From the perspective of USDA, an authoritative  
19 statement is the product of deliberation and broad consensus  
20 which forms long-term and replicated scientific conclusions.  
21 But there is a huge continuum. There's the dietary  
22 guidelines that are the result of broad consensus-seeking  
23 and those every-day recommendations that an extension agent  
24 or home economist gives on diet and nutrition. And where  
25 should the line be drawn between a recommendation and an

1 authoritative statement?

2           And I appreciate the good input that all of you  
3 are providing to that question today and we'll continue to  
4 work on implementing those recommendations.

5           USDA is clearly going to continue to work with FDA  
6 when claims are submitted on the basis of USDA statements.  
7 USDA has been and will continue to be an active partner in  
8 the Liaison Group process. The agency has every incentive  
9 to carefully consider and review whether a particular claim  
10 represents an authoritative statement on behalf of the  
11 agency. And we welcome further discussion on this complex  
12 issue as we work to continue to define our policy and our  
13 relationship with FDA.

14           I apologize for having to run out. I'm due at  
15 another speaking commitment in about 15 minutes. So thank  
16 you very much for this opportunity and I look forward to  
17 seeing the comments from the process.

18           MR. LAKE: Thank you.

19           The remaining panelists will be introduced  
20 according to alphabetical order. The next speaker will be  
21 Dr. William Harlan from NIH.

22           DR. HARLAN: Good afternoon. It's a pleasure to  
23 join you. I'm the associate director for disease prevention  
24 of the National Institutes of Health, within the Office of  
25 the Director.

1           What I'd like to present today is the way in which  
2 we've approached the issue of what is an authoritative  
3 statement and then the process for determining whether it's  
4 an authoritative statement in response to the FDA queries.

5           You saw this morning these blocks where the Food  
6 and Drug Administration supplies to an agency a statement  
7 and asks whether it's an authoritative statement. The  
8 agency then makes a determination and responds back to the  
9 FDA.

10           I'm going to open this middle box, at least as far  
11 as the NIH is concerned. Let me point out first that the  
12 National Institutes of Health actually is 25 institutes and  
13 centers and, in addition, the Office of the Director. And  
14 from the very first authorization of NIH it was to conduct  
15 health research, but another important part of that was to  
16 interpret and report the findings to the public, to health  
17 providers and to researchers of that research.

18           So it's in the authorization of NIH and has been  
19 there from the beginning, for now over 50 years.

20           The product of the research that's supported are a  
21 very large number of reports, and I've tried to break them  
22 down here so that we could talk about them in an informed  
23 way.

24           First of all, we support research throughout the  
25 entire country and throughout the world through grants and

1 contracts. These scientists who are supported may report  
2 their results without our review. And, as a matter of fact,  
3 we don't try to abridge their First Amendment rights by even  
4 attempting to review what they say.

5 So they may say, as a result of the research that  
6 they have conducted, a number of different things for which  
7 we have no review and no responsibility with respect to how  
8 they've interpreted the science.

9 We also have about 15 percent of our budget is  
10 engaged in intermural research and these researchers also  
11 may report their results. Their research is reviewed  
12 generally before it's sent out but more from the perspective  
13 of the quality and the validity of the research, rather than  
14 the interpretation of the research.

15 Those are, however, reports by individual  
16 scientists and often contain very speculative comments,  
17 speculation on the future direction of research, on the  
18 mechanisms that might be included.

19 Periodically the reviews are initiated by an IC,  
20 an institute or center, or the Office of the Director and  
21 are reviewed by the sponsoring institute and center before  
22 release, and the membership on many of these is usually  
23 nonfederal or federal, usually both, and the review is  
24 designed to assess all the available information, the so-  
25 called totality of evidence, and arrive at statements that

1 represent a consensus or identify controversies that need  
2 further exploration.

3           Let me give you an example of how one might move  
4 from the second of these to the third of these. Very  
5 frequently we conduct large clinical trials. The results of  
6 those large clinical trials are put forward in a public  
7 announcement of the result of the trial and yet that's not  
8 considered a statement that has reviewed all the evidence.

9           Following the release of a large clinical trial,  
10 we quite frequently impanel a group of individuals to look  
11 at the results of that study, that trial, in association  
12 with all of the foregoing research and come to a conclusion  
13 about the interpretation and the utilization of the  
14 information that's being provided.

15           Now there are also reviews that are initiated by  
16 an institute or center and by the Office of the Director  
17 that are not reviewed and approved by NIH and the question  
18 came up this morning about consensus conferences.

19           Just a quick reminder. The consensus development  
20 conferences, the membership is all nonfederal. There is no  
21 review of the statement made by the consensus panel and, as  
22 a matter of fact, the institutes and centers may disagree  
23 with the statement made by the consensus panel.

24           Those of you who are familiar with the consensus  
25 conference on mammography for women under 50 years of age

1 two years ago will recognize that the consensus panel came  
2 to one conclusion and following that, the National Cancer  
3 Institute impaneled a group of federal and nonfederal  
4 individuals to look at the information and came up with a  
5 different conclusion. So consensus conferences are not, in  
6 our view, authoritative statements.

7 We also develop a lot of public education  
8 materials and they're developed by individual institutes and  
9 centers, often in collaboration across the institutes and  
10 centers. They may be designed by individuals. They're  
11 reviewed by staff. And where they have to do with  
12 nutrition, they're reviewed by the Division of Nutrition  
13 Research Coordination, Education Subcommittee or by their ad  
14 hoc groups.

15 Most of these contain statements that are based on  
16 recommendations that have come from prior institute and  
17 center assessments. That is, they seldom are groups  
18 impaneled to come up with an authoritative recommendation at  
19 that moment, looking at all of the science. Rather, they  
20 are to interpret and to carry forward the recommendations  
21 that may have been made by an earlier panel, this one down  
22 at the bottom, and put it into an educational framework.

23 Incidentally, not all of those educational  
24 programs are currently reviewed necessarily by a panel of  
25 federal employees or by a group within NIH. So, in fact,

1 some of them would not have had that agency review that  
2 would form the general agreement or consensus.

3 The definition of authoritative statement that  
4 we've used is included here. None of this is terribly new  
5 to you except I would emphasize a couple of things.

6 As we looked to some of the earlier statements, it  
7 was apparent that it should be a statement that's in  
8 context, and some of the statements had been taken out of  
9 context so that it gave one set of meanings when, in fact,  
10 another was intended, even by the author. And some of the  
11 context that's removed contains this kind of speculative  
12 statement or discussion of possible further studies that  
13 might be done or further actions that might be taken by the  
14 public.

15 Current statement I think is a bit difficult  
16 because, in fact, we've never sat down and tried to  
17 determine when a statement was no longer current, except for  
18 consensus statements, which are reviewed periodically, now  
19 about every two or three years, to be sure that they are  
20 current. But we've not done that and clearly it's done at  
21 the time that one is asked what is an authoritative  
22 statement.

23 We have used the view that this is a consensus  
24 from the NIH perspective, that is, as a single agency,  
25 keeping in mind that with 25 institutes and centers, with a

1 good deal of joint funding, a good deal of joint interest,  
2 that no one institute owns the nutritional area or, in fact,  
3 many different areas, with respect to any particular  
4 disease. In fact, the trend is very strongly for the  
5 institutes to fund jointly projects that are involved with  
6 modalities such as diet and exercise that cut across many  
7 different disease entities.

8           Moreover, many of the institutes have cross-  
9 interests. The National Institute on Aging, for example,  
10 obviously has common interests with the Cancer Institute,  
11 with the Heart, Lung and Blood Institute. The National  
12 Center for Complementary and Alternative Medicine obviously  
13 has an interest that cuts across almost all of the other  
14 programmatic institutes.

15           So we've taken the position that we do need to  
16 have an understanding within the total agency about any  
17 particular statement.

18           Now these things that they are not, I think we've  
19 discussed already.

20           Let me say something about the process that's  
21 used. What we have done is to identify representatives from  
22 the institutes and centers that have expertise in nutrition  
23 and nutritionals, and I have coordinated the reviews with  
24 the input from those individuals and we have simply taken  
25 the statement that was presented to us, followed up on the

1 information, made an interpretation of that and supplied  
2 that interpretation back to the FDA. We've not been  
3 involved in looking at whether the claim is a legitimate  
4 claim with respect to the statement, only whether the  
5 statement is, in fact, an authoritative statement that  
6 represents the view of the agency.

7 We would intend to continue to do this with  
8 coordination across the institutes and centers and provide a  
9 single view that represented the view of the entire agency.  
10 And secondly, we hope, as we move along through this, that  
11 we'll begin to have some meetings that will allow us to come  
12 to a better common understanding, I think, of what would  
13 constitute an authoritative statement. We've been operating  
14 very much on an ad hoc basis thus far.

15 I'll stop at that point. I think I've answered  
16 some of the questions that arose this morning but I'm sure  
17 there will be others. Thank you.

18 MR. LAKE: Thank you very much. That was very  
19 informative.

20 Next we're going to hear from Dr. Linda Meyers,  
21 DHHS.

22 DR. MEYERS: Thank you. I'm pleased to be here  
23 today as the acting director of the Office of Disease  
24 Prevention and Health Promotion in the Office of Public  
25 Health and Science in the Office of the Secretary in the

1 Department of Health and Human Services.

2           The Office of Public Health and Science is headed  
3 by Assistant Secretary for Health and Surgeon General David  
4 Satcher.

5           Given our smaller role and portfolio in relation  
6 to my colleagues from NIH, CDC and USDA, I'm going to keep  
7 my remarks very brief.

8           Surgeon General Satcher spends much of his time  
9 talking with and especially listening to the American  
10 people, including around priorities that encompass achieving  
11 healthy lifestyles through community and individual  
12 interventions. So I'm sure he would want me to thank FDA  
13 for convening this meeting and you all for participating in  
14 this opportunity to talk and to listen.

15           The timing of this meeting is particularly useful  
16 to us because we are still working on operationalizing our  
17 role related to authoritative statements.

18           I have appreciated the opportunity to hear the  
19 perspectives this morning and I look forward to further  
20 discussion this afternoon.

21           I wanted to mention three assumptions that  
22 underlie my comments. One, that it is important to educate  
23 consumers about healthful food choices; two, the use of  
24 authoritative statements, if used appropriately, can  
25 facilitate this; and three, we in public health have an

1 obligation to work to achieve the expeditious translation of  
2 sound scientific evidence to consumers in ways that they can  
3 apply to improving their health.

4 A number of questions are on the table for  
5 discussion today. I'm going to comment on only several of  
6 them, recognizing that these are "draft thoughts," if you  
7 will, and not "authoritative statements."

8 Before I do that, let me explain what falls in our  
9 portfolio. When I began, I mentioned that the Surgeon  
10 General was also the Assistant Secretary for Health. This  
11 dual role is rather unique and encompasses responsibilities  
12 as the senior adviser for public health and science to the  
13 Secretary, thereby providing senior professional leadership  
14 on population-based public health and clinical preventive  
15 services, directing program offices housing a variety of  
16 essential public health activities, providing senior  
17 professional leadership across HHS on White House and  
18 secretarial initiatives involving public health and science,  
19 guiding and providing technical assistance to 10 regional  
20 health administrators, and directing the Public Health  
21 Service Commission Corps.

22 The Surgeon General is generally viewed as the  
23 nation's doctor and is charged also with enhancing the  
24 public's understanding of public health issues and focussing  
25 attention on critical health issues.

1           You are familiar with Surgeon General's Reports.  
2 The Surgeon General also issues proceedings of workshops and  
3 has issued letters. Of the 30 or so Surgeon General's  
4 Reports, many on tobacco, there has been one on nutrition in  
5 1988 and one on physical activity in 1996. These are listed  
6 on the Surgeon General's website if you're  
7 interested--surgeongeneral.gov, which, by the way, is being  
8 updated and enhanced for release later this month.

9           Reports on oral health, mental health and dietary  
10 fats and health are expected at different points within the  
11 next year.

12           These reports are characterized by review and  
13 discussion of key and often contentious scientific issues of  
14 public health importance and by specific recommendations.  
15 They are also characterized by a deliberative review  
16 process.

17           The overall recommendations are generally regarded  
18 to be as firm as the collective scientific wisdom of the  
19 Public Health Service and the broader scientific community  
20 allows. They are not the work of an individual employee and  
21 they go through a formal clearance process within HHS, so  
22 one might characterize the recommendations as official  
23 positions.

24           Thus, a Surgeon General's Report is an  
25 authoritative document and one would think its

1 recommendations are authoritative statements. However, it  
2 is difficult for me to argue that each sentence in the  
3 document should carry the same weight as a recommendation  
4 because many are providing background or commenting on  
5 differing perspectives.

6 The same might be said for the Dietary Guidelines  
7 for Americans, which is also coordinated for HHS by the  
8 Office of Public Health and Science.

9 To the extent that a recommendation is cited as an  
10 authoritative statement, that would seem clear-cut and  
11 require little additional consideration by a scientific  
12 body. We have not seen that, however. What we have seen is  
13 individual sentences used that are just background or that  
14 are taken out of context, and I think that has made our task  
15 more challenging.

16 Dr. Satcher often quotes John Gardner's statement  
17 to the effect that life is full of golden opportunities  
18 masquerading as irresolvable problems. I am hopeful that  
19 today's discussion will move us in the opportunities  
20 direction. And as we move in that direction, I think we  
21 need to make sure that our actions derive from and are  
22 driven by a science base, address important public health  
23 priorities, and resonate and are useful to the American  
24 people in their health decisions.

25 MR. LAKE: Thank you for those comments.

1           Before going to our two final panelists, let me  
2 remind you that at the end of the presentations by the  
3 panelists, there will be further opportunity for questions  
4 and again we will use the same procedure we used this  
5 morning of you filling out cards and our people bringing the  
6 up to us.

7           The next speaker is Dr. Dixie Snider from the CDC.

8           DR. SNIDER: Thank you very much. I, too,  
9 appreciate the opportunity to be here and engaged in this  
10 dialogue about authoritative statements.

11           I'm the associate director for science at the  
12 Centers for Disease Control and Prevention. And in order to  
13 help you understand CDC's role in assisting FDA in  
14 implementing FDAMA, I wanted to provide you with some  
15 explanation of the role of CDC in the public health  
16 community and say a few words about how we develop and  
17 disseminate health messages.

18           Of course, CDC is a part of the Department of  
19 Health and Human Services and our mission is to promote  
20 health and quality of life by preventing and controlling  
21 disease, injury and disability. And we would consider  
22 appropriate health claims as being a part of that mission.

23           As part of our mission, we work very closely with  
24 other agencies within the Public Health Service, in  
25 particular FDA and NIH. We routinely share new findings and

1 pertinent information and even do joint investigations and  
2 research projects with them. We're all working toward the  
3 common goal of improving the nation's health.

4 We also work with the department and all the  
5 recommendations regarding human nutrition are reviewed by an  
6 interagency Nutrition Policy Board prior to release.

7 CDC began in 1946 as a malaria control program and  
8 many people consider us still an infectious disease agency,  
9 but we're really much more than that now. We work closely  
10 with state health departments, with local health departments  
11 and many other partners throughout the nation to accomplish  
12 our mission and we monitor health, detect and investigate  
13 disease outbreaks, perhaps one of the things we're most  
14 noted for, conduct research, develop and advocate sound  
15 health policies, implement prevention strategies, promote  
16 healthy behaviors, again usually with partners in the  
17 community, such as health departments and other community-  
18 based organizations.

19 We're not a regulatory agency but rather, we're  
20 focussed on carrying out all these activities. And since  
21 our inception, we've played an essential part in the  
22 prevention and control of a number of diseases, such as  
23 smallpox, polio, Legionnaires disease, AIDS, hanta virus,  
24 eboli and, more recently, hendra virus and influenza H9 and  
25 whatever comes along.

1           The scope of our activities has broadened and  
2 while we still maintain our historic commitment to the  
3 prevention and control of infectious diseases, today we  
4 address virtually all of the major health threats, from  
5 environmental hazards such as lead poisoning to chronic  
6 diseases, such as heart disease and cancer, to occupational  
7 illnesses, injuries. And one of the characteristics is that  
8 our research programs tend to be closely linked to  
9 operational control and intervention programs.

10           As you may be aware, CDC has become very active in  
11 recent years in providing leadership in promoting healthy  
12 eating patterns and we're committed to improving the overall  
13 nutrition of the public. And many of our centers,  
14 institutes and offices are engaged in activities to further  
15 this goal, very similar to what Bill described.

16           Most activities in the area of human nutrition,  
17 however, do involve in some way the Division of Nutrition  
18 and Physical Activity in our National Center for Chronic  
19 Disease Prevention and Health Promotion. This is where many  
20 of the reports and guidelines related to nutrition and  
21 physical activity, including Surgeon General's Reports that  
22 have been mentioned, were born.

23           We disseminate information regarding nutrition and  
24 other health-related conditions in a variety of ways. My  
25 role as associate director for science is to promote and

1 support an environment of scientific excellence and  
2 integrity, as well as the rapid dissemination of scientific  
3 information.

4           And to achieve these goals, my staff and I are  
5 responsible for resolving controversial scientific issues,  
6 for developing sound scientific policies and procedures for  
7 the agency, for promoting the highest standards and criteria  
8 for scientific reports, for assuring the protection of human  
9 subjects and for facilitating the timely transfer of  
10 knowledge and information that improve public health. So  
11 that means my office gets involved with a lot of these  
12 documents we're talking about today.

13           Health information from CDC is relayed in a  
14 variety of ways--through scientific reports, articles,  
15 perhaps most notably in the Morbidity and Mortality Weekly  
16 Reports. The primary audience for most of the publications  
17 is the scientific community, although other groups may be  
18 targeted, as well.

19           And scientific reports and articles that are  
20 authored by individual employees or groups of employees in a  
21 specific center, institute or office of CDC are peer-  
22 reviewed but they do reflect, and this is again very similar  
23 to NIH, they reflect the findings, the individual opinions  
24 of the scientists within the centers, and not those of CDC.

25           On the other hand, there are other publications,

1 such as the MMWR Recommendations and Reports series, which  
2 contain in-depth articles that relay policy statements for  
3 prevention and treatment of many areas in CDC's scope of  
4 responsibilities. And it's these kinds of statements in the  
5 MMWR Recommendations and Reports series which have undergone  
6 clearance by the Office of the Director, by my office.  
7 They've been reviewed usually extensively by the other  
8 Public Health Service agencies so that we not only have  
9 consensus within our own agency but hopefully a consensus  
10 within the Public Health Service about what's being  
11 published.

12           An example of that would be the publications of  
13 the committee that I'm the executive secretary for, the  
14 Advisory Committee on Immunization Practices, where we have  
15 an FDA representative, an NIH representative participating  
16 in the deliberations of representatives from many  
17 professional societies, as well as individual external  
18 members. They come up with recommendations for the CDC  
19 director and then the director decides whether or not he  
20 accepts those recommendations and, if so, they're published  
21 in the Morbidity and Mortality Weekly Report and I would  
22 regard most of those as authoritative statements, although  
23 even then I think there would have to be some caveats  
24 because you may remember the hanta virus outbreak, I think  
25 we issued an MMWR about how to keep rats out of your home,

1 which basically represented the opinions of several experts  
2 and not too much science behind them.

3           So I think making some blanket statement about the  
4 MMWR Recommendations and Reports series would be  
5 inappropriate. However, you would commonly find  
6 authoritative statements from CDC in that particular  
7 location.

8           We do have guidelines that are on the Internet.  
9 There's a CDC Prevention Guidelines Database, which is a  
10 repository of 400 CDC guidelines for the prevention and  
11 control of public health threats. They were originally  
12 published in the MMWR's monographs or perhaps they were  
13 published as chapters in books or articles in peer-reviewed  
14 journals. And we have a steering committee which includes  
15 representatives from various components of CDC that selects  
16 entries for this database through the recommendations of the  
17 various associate directors for science and other  
18 individuals in CDC management.

19           These guidelines have undergone review and  
20 approval by my office and would be considered official CDC  
21 policy.

22           So I think we have a lot of commonalities with  
23 NIH, but a few specific examples of where authoritative  
24 statements from CDC are likely to be found. I hope this  
25 gives you a little bit of understanding of how we're

1 thinking about this.

2           And I don't have to repeat what Bill has already  
3 shown you because we operate very much the same way in terms  
4 of the process, with me serving as the central liaison, then  
5 using our various centers and institute divisions and  
6 offices, as appropriate, to look at those documents and then  
7 provide the information back to FDA. Thanks.

8           MR. LAKE: Thank you.

9           Our final speaker for this panel will be Dr.  
10 Allison Yates from the National Academy of Sciences.

11           DR. YATES: Thank you very much. I'm Allison  
12 Yates, as I was introduced. I'm the director of the Food  
13 and Nutrition Board. You've heard many times but I guess I  
14 have to spend a little bit of time reinforcing what is the  
15 National Academy of Sciences and how it does its work, to  
16 try to differentiate how the approach to authoritative  
17 statements is being interpreted within the Academy.

18           The first overhead is essentially a description of  
19 the National Academy of Sciences. It is not part of the  
20 government. It's a private corporation that was established  
21 by federal charter when Lincoln was president to essentially  
22 address issues of scientific interest that are of national  
23 interest, in response to requests from various federal  
24 agencies, from Congress at times, and then from the private  
25 sector on occasion.

1           The one basic component is all of the studies that  
2 we do, at least half of the funds that come forth to support  
3 the study are from nonprofit federal or private foundations  
4 that are not going to directly have any benefit perhaps to  
5 the outcome of the study.

6           I think it's important to talk about how the  
7 Academy operates because when you get into the language that  
8 was put into the FDAMA legislation, it makes it a little  
9 problematic for us to function as some of the other  
10 scientific bodies that were identified do.

11           The next slide just gives you an idea, when we  
12 talk about the National Academy of Sciences and its  
13 subdivisions, that there are essentially three honorific  
14 membership organizations: the Academy of Sciences, which,  
15 as I said, started in 1863, but also the Academy of  
16 Engineering and the Institute of Medicine, which all have  
17 members involved.

18           Well, there were so many questions that were  
19 coming to the Academy before World War I that the National  
20 Research Council was set up as an administrative arm. So  
21 many times you see reports of the National Research Council,  
22 which are actually reports of the National Academy of  
23 Sciences.

24           The next overhead provides a little bit of  
25 description of the Academy and what it does a little

1 differently than some other units. One is, as I said, it  
2 responds to requests from the government and the private  
3 sector, but it can make some of its own determinations.

4           Is it an appropriate request? Just because it's  
5 written into legislation that we will look at something or  
6 the Academy is to conduct a study, it doesn't mean that we  
7 have to accept that charge, and at times we don't.

8           It's allowed to specify the approach and the scope  
9 for the study. There is a contract but it's usually fairly  
10 brief for the type of work that's outlined. The Academy  
11 determines who's going to be on committees that look at  
12 these issues, what experts are going to be pulled together,  
13 and usually there's a definition of the type of expertise  
14 that will be required.

15           It has an internally built-in peer-review process  
16 for all the reports that would, in essence, be consensus  
17 reports, and as such, is a little different than other  
18 groups that may be contracted with to provide scientific  
19 assessments.

20           And typically it can also identify topics that the  
21 staff or members of the Academies or the organizations think  
22 are important and then seeking funding and, if necessary,  
23 fund from internal endowment funds, so that not all the  
24 reports from the Academy have federal sponsorship.

25           So it's somewhat independent and I imagine that

1 was the rationale for why it was included as one of the  
2 scientific bodies in the actual language of the legislation.

3           The next overhead has a few points about the Food  
4 and Nutrition Board. Here, as you see, what we're dealing  
5 with in looking at diet and health promotion, one of the  
6 major focus areas of the Food and Nutrition Board has, over  
7 time, been evaluating nutrient requirements and  
8 relationships between diet and reduction of risk of chronic  
9 disease.

10           Now, this happens to be an old slide of mine, so I  
11 didn't do it just for this meeting, but you can tell why  
12 perhaps this language went in.

13           But I want to point out that there are a number of  
14 groups within the Academy that do studies that relate to  
15 diet and health relationships. If it deals with pesticides  
16 or potential carcinogens, it may come out of another board  
17 on environmental studies and toxicology. There's a board on  
18 agriculture and natural resources. So not all the reports  
19 that might be actually under FDAMA are actually under the  
20 group that I'm involved with. So that means that we have to  
21 have more of an Academy-wide approach to how do we deal with  
22 authoritative statements.

23           The next overhead has actually the three  
24 components that we've already talked about from the FDAMA  
25 legislation, talking about, and I guess this is more from my

1 perspective, the three issues that, as one of the scientific  
2 bodies, we have to deal with would be: Is it an accurate  
3 reflection of what appears in a report? Has the group  
4 determined that it's authoritative in some sense? And then  
5 is it current?

6 Well, I brought along some of the reports actually  
7 that Dr. Marriott mentioned. This is the Diet and Health  
8 Report from 1989. It obviously has a number of statements  
9 in here relating diet and health to disease. And then  
10 there's the '89 RDA, Recommended Dietary Allowances book,  
11 which goes over the specific nutrients and their involvement  
12 in various types of diseases.

13 The real concern, though obviously, is how do you  
14 look at this and really say well, which of the statements  
15 included in here would we recognize as authoritative? And  
16 because also it's important to realize that a fair amount of  
17 what--in fact, almost all that the Food and Nutrition Board  
18 certainly does comes from specific funded projects that the  
19 project funding for diet and health went out certainly in  
20 the 1980s and we no longer funded to review these issues.  
21 We have to have a project in process where there's a current  
22 review in order to really answer a question in terms of  
23 currency. Is this still current? Well, some of the topics  
24 in here may be and others may not be.

25 Many of you know we're currently going through an

1 expanded format for developing RDAs. It's called dietary  
2 reference intakes. Well, part of this process is to look at  
3 not just things that have been previously determined  
4 nutrients but other things that are found in foods that may  
5 play a role in health. So, in a way, many of the components  
6 that are in the Diet and Health Report are being reviewed in  
7 the new process for dietary reference intakes.

8           So the real question of what's current can be  
9 problematic. And just as someone else earlier said, we  
10 don't normally say, "Aha, we declare this book null and  
11 void; it's no longer current." We typically don't reprint  
12 it and then the print runs out and so it's no longer  
13 available. If it's in a series, then we have a new edition,  
14 and that would be more obvious.

15           The next overhead goes over, though, what the  
16 Academy's response has been to providing some guidance about  
17 what would be an authoritative statement from the Academy.  
18 In fact, almost a year ago the governing board of the  
19 Academy, based on discussion of what are authoritative  
20 statements for the purpose of FDAMA, developed a policy  
21 statement which I'm going to read to you, but the major  
22 points are outlined in the overhead. And it's only two  
23 paragraphs.

24           "In the conduct of studies with regard to  
25 relationships between diet and health and in the course of

1 review of research relating to questions under study, it is  
2 possible that reports of the NRC or IOM"--Institute of  
3 Medicine--"may describe associations between foods,  
4 nutrients or food components and aspects of health. These  
5 statements would not necessarily represent authoritative  
6 statements of the NRC or IOM because they might not  
7 summarize the totality of the evidence that would be  
8 required by the Academy when formulating an authoritative  
9 statement.

10 "For example, a report may contain descriptions of  
11 the work of others or, on occasion, minority reports  
12 expressing the views of individuals. Descriptive materials  
13 and minority reports, as examples, are not considered  
14 authoritative statements of the National Academy of Sciences  
15 or any of its subdivisions.

16 "For the purposes of FDAMA, authoritative  
17 statements of the National Academy of Sciences or any of its  
18 subdivisions, including the NRC and the IOM, are limited to  
19 those that represent the consensus of a duly appointed  
20 committee or views of a duly appointed principal  
21 investigator so that they appear explicitly as findings,  
22 conclusions or recommendations in a report that has  
23 completed the institutional report review process."

24 So we are delimiting what might be considered an  
25 authoritative statement, and I think you can see that those

1 are the major points.

2 Let's go to the next overhead, which in essence is  
3 some guidance that we've provided to date.

4 As I said, we don't have a continued stream of  
5 funding to deal with authoritative statements. Actually we  
6 have no funding to deal with authoritative statements. And  
7 in truth, if one really wanted to determine if a statement  
8 that appeared in one of our books or reports was  
9 authoritative and accurate, we might have to bring the whole  
10 committee back together again and have them look and say  
11 well, is this what you meant?

12 And we did discuss that, but it was determined  
13 that really that is meeting a regulatory need, as opposed to  
14 the scientific need. If someone doesn't understand what's  
15 written in here, then we should redo the report.

16 So the determination has really been that the  
17 executive summary, by and large, and most of our reports  
18 have executive summaries, is the place that one is going to  
19 find the integration of all of the material that the  
20 committee looked at and the major findings related to some  
21 aspect of diet and health.

22 And in the case of this book, it's roughly about  
23 16 pages, so it's not a huge component but it does contain  
24 the major findings.

25 And, as an example, there may be a chapter on

1 cardiovascular disease, talking about a particular food  
2 component and it may be positive, where in another chapter  
3 dealing with cancer, it may have a negative effect, so one  
4 has to review all of that in the totality of the whole  
5 report.

6 I think that's the last overhead, I hope.

7 So I think the important thing to note is that we  
8 have chosen, because we are not part of the government, to  
9 not necessarily, in fact, to not respond to individual  
10 requests about is this authoritative or not, to provide this  
11 guidance to the regulatory bodies that are charged with  
12 enforcing the regulations and the legislation that's been  
13 passed and, as best we can, provide guidance in a more  
14 general way because within our processes, in order to make a  
15 decision--is this authoritative or not?--we would have to  
16 convene a whole committee and that's not possible within the  
17 time frame of FDAMA, within four months, or within the cost  
18 constraints of our operation. Thank you.

19 MR. LAKE: Thank you.

20 We have a few questions left over from this  
21 morning that actually relate more to this panel that we'll  
22 come to in a moment. Again we have people who will be  
23 taking any cards with questions from people in the audience.

24 But before we get to that, let me just give the  
25 panel members themselves, if you have any comments that you

1 wish to make that were triggered by comments by other  
2 members of the panel or if you have any questions of each  
3 other, now would be an opportunity to do that. I'll give  
4 you that opportunity first.

5 [No response.]

6 MR. LAKE: All right, none of those.

7 Chris, we have some questions from this morning  
8 and maybe you could start with some of those.

9 **DISCUSSION/QUESTIONS FROM AUDIENCE**

10 DR. LEWIS: One of the questions that did come up  
11 this morning that we've reserved slightly, at least, for  
12 this panel is the question: Will there be or does a  
13 mechanism exist whereby data may be submitted to a  
14 scientific body in order to generate a claim? So there's  
15 some interest in how the world at large can interact with  
16 scientific bodies relative to authoritative statements.  
17 Perhaps each of you could comment on that.

18 DR. HARLAN: I'll give it a try, if I understand  
19 the question. The question would be would someone come  
20 forward with a body of data and then ask the federal agency  
21 to evaluate that and make an authoritative statement based  
22 on that?

23 DR. LEWIS: I'm assuming that's the question, yes.

24 DR. HARLAN: I guess the only mechanism that  
25 quickly comes to mind is for someone to go to a part of NIH

1 and suggest that they have a review meeting to look, let's  
2 say, at the differences that have now arisen in opinion  
3 regarding the amount of fat in the diet or the type of fat  
4 in the diet. Then the agency would have to, I think,  
5 convene a review group to address that.

6 But I don't know that there's any kind of  
7 petitioning mechanism that I know of to do what I think the  
8 question implies.

9 DR. LEWIS: Thank you.

10 DR. YATES: Maybe I could comment. Of course as  
11 part of our DRI process, we are looking at many nutrients  
12 and food components and their role in health. So in that  
13 process, we are essentially, I think, providing at least the  
14 scientific review. But then, as I said, it's really up to,  
15 at least from our perspective, the FDA to determine is this  
16 new information authoritative. From our perspective, if  
17 it's in the summary and so on, it probably would be, based  
18 on our policy. And then determine if it's significant  
19 scientifically.

20 DR. SNIDER: From CDC's perspective, it would be  
21 very similar to the NIH response in that except for  
22 established external advisory committees where a proposal  
23 could be put forward on issues, I would anticipate, first of  
24 all, that most of our scientists who are working in a  
25 particular area under their charge are pretty well aware of

1 the scientific data, but we're certainly open to having  
2 additional data and suggestions presented to our programs.

3           Then I think what process we might choose to try  
4 to ascertain whether the strength of the evidence and how  
5 much consensus there is around the interpretation of the  
6 evidence and so forth might vary, depending upon the  
7 particular type of issue that's being addressed.

8           We have formal advisory committees around certain  
9 issues that inform certain parts of CDC. These are  
10 chartered under the Federal Advisory Committee Act. Then at  
11 other times we get ad hoc groups together or may call public  
12 meetings like this to try to ascertain the level of  
13 consensus.

14           But I guess the bottom line would be that we're  
15 always open to talking to people about the data and what  
16 that might mean in terms of how consumption of any  
17 particular food item or supplement might improve people's  
18 health and work with them to determine what the policy  
19 implications of the data might be.

20           DR. MEYERS: I think Dixie actually reflected the  
21 interest that I would have in his last few statements when  
22 he talked about the public health implications.

23           I think the broader question is is this really a  
24 relationship that is of public health significance that we  
25 in the Surgeon General's Office or in the federal government

1 should be paying more attention to and informing the  
2 consumers about, not necessarily limited to a health claim,  
3 but is it a broader issue that we need to be doing something  
4 about?

5 DR. LEWIS: And then one other question left from  
6 this morning is the question: Shouldn't the scientific  
7 bodies set aside a specific publication that could be used  
8 as the basis for claims? I'll let anyone who'd like to  
9 answer that do so.

10 DR. HARLAN: Would you repeat the question?

11 DR. LEWIS: I know it's difficult to hear up here.  
12 I'm sure for the audience it's hard to know why we keep  
13 frowning at each other but there's an incredible echo.

14 Shouldn't the scientific bodies set aside a  
15 specific publication that could be used as the basis for  
16 claims?

17 DR. HARLAN: Oh, you mean should there be a  
18 separate and identifiable publication in which all claims  
19 were to be published, and that would be the standard for--

20 DR. LEWIS: Presumably all authoritative  
21 statements, yes.

22 DR. HARLAN: Where all authoritative statements  
23 should be published. I guess none of us has really thought  
24 about doing that. At NIH, as you probably know, our  
25 inclination now is to try to put as much up in public as

1 possible by using electronic means, rather than print means.

2 So dedicating a journal or a particular site for  
3 this goes in the opposite direction from what we're trying  
4 to do now, which is to provide as much information as widely  
5 available as possible.

6 DR. SNIDER: I guess my response would be that at  
7 least retrospectively, that would seem to me to potentially  
8 work against the interests of the public health, as well as  
9 the interests of industry and others. I mean if there is a  
10 bona fide authoritative statement out there that we all  
11 could support and it doesn't happen to be in this particular  
12 designated journal or whatever we want to call it, then we  
13 should use it anyway.

14 I think in thinking prospectively about how to  
15 disseminate information and what we're disseminating, it's a  
16 useful comment or question in that not that we necessarily  
17 want to put documents that contain authoritative statements  
18 all in one place, because there are different audiences and  
19 different ways to reach those audiences. But we also might  
20 think of them as whether they are authoritative statements  
21 or not and use electronic technology that Bill was just  
22 talking about to create some file that might be considered a  
23 file in which there are authoritative statements.

24 But I think if we were to pursue that, it would  
25 require a lot more discussion and thought than we've been

1 able to give it here.

2 DR. LEWIS: We actually have now a series of  
3 questions all directed to NIH and one of them leads off with  
4 a question for us, which would be to give the name of the  
5 USDA representative.

6 Mr. Phillip Schwab, S-c-h-w-a-b, was substituting  
7 for Eileen Kennedy today for USDA.

8 Then in terms of a question for Dr. Harlan, when  
9 would NIH--when would he accept an NIH subunit statement as  
10 authoritative statement; that is, without a whole or entire  
11 NIH review?

12 DR. HARLAN: You'll have to repeat it. I still  
13 didn't hear it clearly.

14 DR. LEWIS: When would you accept an NIH subunit  
15 statement as an authoritative statement; that is, without an  
16 entire NIH review?

17 DR. HARLAN: Well actually, most of the statements  
18 that come through are seen clearly by the subunits as a part  
19 of this liaison activity and they simply are moved from the  
20 coordination office, mine, down to the subunits and then  
21 some discussion against those subunits that have a  
22 particular interest in it.

23 Osteoporosis, for example, is of interest to the  
24 Arthritis, Musculoskeletal and Skin Diseases, to the  
25 National Institute on Aging and to the National Institute of

1 Diabetes, Digestive and Kidney Diseases. So if something  
2 came through related to osteoporosis, we'd obviously want to  
3 have, at minimum, the view of those three groups.

4 Now if it's something related exclusively to  
5 cancer and there's no other source of information or no  
6 other interest, we probably would take that and simply ask  
7 them to review it, look at it and then pass it along.

8 I guess that answers the question.

9 DR. LEWIS: I think the interest is in the  
10 subunits versus the whole and you did answer that.

11 There's also another question for NIH that we  
12 discussed a little earlier this morning. Often NIH holds a  
13 consensus conference with a report derived from a group of  
14 scientists not expert in the field that's being evaluated.  
15 Their findings may be in opposition to other NIH subunit  
16 office statements. Should such consensus statements be  
17 given the same weight as to the deliberative review from the  
18 NIH as a whole?

19 DR. HARLAN: Actually we have a number of  
20 indications that this isn't the way that NIH works, even  
21 before the issue of authoritative statements came up. And  
22 the best example is the mammography conference. The  
23 consensus panel concluded that mammography was not in the  
24 interest of all women under age 50 and a panel was put  
25 together by the National Cancer Institute that came to a

1 different conclusion about a year or 14 months later. And  
2 that is the policy of NIH; that is, the National Cancer  
3 Institute policy.

4 DR. LEWIS: Now there is a question for CDC and  
5 the Academy. Have you provided authoritative statements to  
6 federal agencies other than FDA?

7 DR. SNIDER: Yes, I'm sure we have. I'm not sure  
8 of the purpose of the question or exactly how it fits in,  
9 but certainly in the development of many of the statements  
10 that we would view as authoritative statements, in addition  
11 to FDA, NIH or HRSA or AHCPR or USDA, many other people may  
12 be involved and often are involved in the development.

13 Also let me just comment also about CDC as it  
14 relates to the statements of our centers. I want to  
15 emphasize again that just because a division has a certain  
16 name doesn't mean that that is the only division or branch  
17 within CDC that has an interest and knowledge about a  
18 particular topic.

19 So one of the reasons, one of the rational aspects  
20 of this, having it as a CDC statement, something that's been  
21 approved by the Office of the Director, means that all of  
22 our scientists who have the knowledge and interest in a  
23 particular topic, even though they may not work in the place  
24 where the authoritative statement arose, the first draft  
25 appeared, there are other parts of our agency that need to

1 take a look at it.

2 And we would not feel a level of comfort of  
3 consensus within the agency until we had that opportunity to  
4 cross clearances, as well a look from the Office of the  
5 Director.

6 DR. YATES: What was the question?

7 DR. LEWIS: Have you ever provided authoritative  
8 statements to federal agencies other than FDA?

9 DR. YATES: I have to say that I don't know that  
10 we have "provided authoritative statements." What we have  
11 done is produce reports that are the result of consensus  
12 committees that are available to anyone, not just to FDA.  
13 And imbedded in these reports would be statements that one  
14 could really say meet at least the definition that the  
15 Academy has developed for what is an authoritative statement  
16 for the purposes of FDAMA.

17 DR. LEWIS: We now have a question for the entire  
18 panel and it's a follow-up, I believe, on the suggestion  
19 that Dr. Marriott put forth earlier this morning.

20 What is your opinion of preparing a white paper on  
21 specific examples of authoritative statements? Do you feel  
22 it's a practical starting point for the types of discussions  
23 we're having today?

24 DR. HARLAN: I'll start off, since I'm down at  
25 this end of the table. I think it's a reasonable thing to

1 do. I would keep in mind that there are lots of examples  
2 out there of what, in retrospect, would be called  
3 authoritative statements. If you look at the cholesterol  
4 education program, for example, regarding dietary intake,  
5 serum cholesterol and coronary heart disease, there are  
6 several iterations of that and if you wanted examples of  
7 that, you can both follow the process that was used in  
8 coming to those statements and also the exact statement  
9 itself.

10 I think writing a white paper that provides  
11 examples of both the process and the thinking that went into  
12 it, as well as examples of the actual statements that came  
13 out, might be helpful. I wouldn't think that it would be  
14 terribly difficult, at least for us, because I think we have  
15 a fair number of statements out there.

16 And I might say incidentally that most of these  
17 also were done collaboratively with the other agencies. We  
18 share with CDC, for example, membership on a lot of  
19 committees that they have and the committees that we have.  
20 So it doesn't reflect just our one federal agency, if you  
21 will.

22 One could do that, I think, without a great deal  
23 of difficulty. I don't know how helpful it would be but  
24 it's doable.

25 DR. LEWIS: I suspect the question was going to

1 the issue of perhaps what might be the function of the  
2 Liaison Group in the future and perhaps we could talk a  
3 little bit about how you see the activities of the Liaison  
4 Group.

5 I'm not looking at you specifically, Dr. Harlan.  
6 I'm looking at the entire panel.

7 DR. HARLAN: I'll sit in the middle of the table  
8 next time.

9 DR. LEWIS: Certainly the Liaison Group will  
10 undoubtedly continue to meet and I know they're having some  
11 internal discussions about how they'd like to proceed.

12 One of the questions that we have in front of us  
13 and I guess I could read the next question, is can any of  
14 the federal agencies represented envision FDA characterizing  
15 as authoritative or not authoritative a statement of that  
16 agency without consulting that agency?

17 DR. HARLAN: I couldn't visualize that but it's  
18 perhaps my view of the world.

19 DR. LEWIS: It's a question on the card, anyway.  
20 It's not FDA's question. It's a question on the card.

21 DR. YATES: Well, the Academy is not part of the  
22 Liaison Committee, so we're exempt from that question.

23 DR. LEWIS: No, actually the question says any of  
24 the federal agencies represented or scientific body, sorry.

25 DR. SNIDER: I don't think it would be the usual

1 practice. I guess I could envision it. If there was an FDA  
2 person who had been part of the whole process throughout,  
3 knew how it was developed and knew the whole story behind  
4 it, then they wouldn't have to consult us at all. But in  
5 most cases I would think that there would be information  
6 that FDA would want from the originating agency about what  
7 process was used because most of the statements don't  
8 describe process often in great detail. They don't  
9 necessarily describe how much data was looked at or how it  
10 was analyzed and some of these things would be important to  
11 know in the decision-making process.

12 So I think if nothing else, seeking information  
13 and possibly opinions, as well, but certainly information.

14 MR. LAKE: Let me ask the other panelists. What I  
15 think maybe is behind that question or at least one that it  
16 triggers in my mind is would it be the opinion of the  
17 agencies and the other scientific body represented here that  
18 as a matter of course, that FDA ought to be talking with  
19 them before making a determination about whether a  
20 particular statement is authoritative?

21 DR. MEYERS: I think there are some cases where  
22 they wouldn't need to. I think if the criteria are quite  
23 clear and if it's generally agreed a recommendation in a  
24 Surgeon General's Report is authoritative, then there would  
25 be no need to consult.

1           The area where I think it's going to be the  
2 fuzziest is the issue of currency and what's current.

3           DR. HARLAN: I agree with that. I think one of  
4 the problems we tend to forget is that science is a  
5 continuing and iterative process and that even now, as we  
6 think about the amount of fat in the diet and as a Surgeon  
7 General's Report is being written, new information is coming  
8 along that may change all of that.

9           So what is current today may not be current next  
10 year, and that's what concerns me.

11          DR. YATES: I think in terms of the Academy,  
12 that's probably the only question we would probably answer,  
13 is is there anything else that you have done that would  
14 indicate that this is not current?

15          So if we're in the middle, say, like we are right  
16 now of reviewing vitamin C and vitamin E, what we might have  
17 in the statement we would say well yes, that may be the most  
18 recent thing we did but what we're going to finalize by the  
19 end of the year is going to be more current than that. And  
20 then it's up to you to decide do you want to go ahead with  
21 whatever it is as an authoritative statement or not.

22          DR. LEWIS: I also have a question that I think is  
23 a direct outgrowth from some of my comments earlier this  
24 morning.

25          Do authoritative statements have to reflect

1 official policy of the scientific body?

2 DR. HARLAN: Official policy?

3 DR. LEWIS: Certainly I admit that in my opening  
4 remarks we indicated that we had included that as one of the  
5 three characteristics we've added. I think in experiencing  
6 this in the last year, the notion of official policy was one  
7 that I think as various scientific bodies talked about it,  
8 it was one that they didn't feel was well fleshed out or one  
9 that they could readily point to.

10 So there was concern perhaps about characterizing  
11 this using the exact term "official policy," but perhaps  
12 there were other concepts and other frameworks you put  
13 around authoritativeness that maybe were not exactly  
14 characterized by the words "official policy."

15 It has been invoked as a characteristic and  
16 perhaps that's something we need to discuss.

17 DR. SNIDER: I would think the term is probably  
18 too restrictive. In our case I think documents that would  
19 have printed on them recommendations--at least I can think  
20 of a number that would be what I would consider  
21 authoritative statements, I think the term "official policy"  
22 probably restricts the universe of documents that we would  
23 want to consider as authoritative statements.

24 DR. HARLAN: I think you might call it official  
25 position. At least that's the way I think of it, rather

1 than policy, not some overarching set of principles that do  
2 not change over time but rather the official position and,  
3 incidentally, current official position.

4 DR. SNIDER: Whatever we call it, it has to be  
5 generally understood or well defined.

6 DR. MEYERS: I agree. I like using the term  
7 "position." This may just be the bureaucracy, but the term  
8 "policy" tends to have a narrow use and triggers an  
9 unbelievable review process, in addition. So I think that's  
10 part of the reaction.

11 DR. LEWIS: We have a number of questions here but  
12 I think we have time for just one more before the break and  
13 I'll read this one.

14 "Since absolute statements are rare in science, is  
15 there such a thing as a qualified authoritative statement?"

16 DR. SNIDER: I'll comment on that. I think the  
17 panel this morning also grappled with that. To me, I think  
18 the answer is yes. I think that, as was pointed out, we're  
19 all trying to educate the public about what the science, to  
20 the best of our understanding, says about a particular  
21 nutrient.

22 And at times, the science base, as was pointed  
23 out, is equivocal. At times there is a lot that supports a  
24 particular conclusion but there are still some gaps. And in  
25 trying to be honest about what the data say, one has to be

1 less than definitive at times.

2 DR. HARLAN: I think we always have  
3 qualifications. We most frequently say on balance or  
4 looking at all of the evidence, this is the main force of  
5 the statement that's made, but there are situations in which  
6 it may not apply or we may see different information that  
7 will change the statement that we make. And sometimes we do  
8 qualify it by talking about special populations or something  
9 of that sort.

10 I think to qualify it by saying that there's a  
11 minority report, for example, on the same issue begins to  
12 take away from the educational aspect and the informational  
13 aspect for the public. I think we all have had the problem  
14 that when you say "on the one hand, on the other hand," you  
15 know, you always want that one-armed economist so that you  
16 don't get caught up in that. You'd like to come out with a  
17 statement that gives the preponderance of evidence and say  
18 "This is the message that you should carry home."  
19 Frequently within the document there will be qualifications,  
20 however, that there is other information or there's a group  
21 of people who do not respond in the same way.

22 DR. LEWIS: I know in reading some of the comments  
23 that were submitted relative to the interim final rule  
24 qualification was also discussed in terms of putting it in  
25 context. For instance, some of the soluble fiber claims are

1 always made within the context of it being a part of a diet  
2 low in saturated fat and cholesterol. So in that way  
3 qualification comes in.

4 I think there's another end of this, which is  
5 qualification of the strength of the science, as opposed to  
6 qualification of the context in which this is a  
7 recommendation. And perhaps that's something that needs to  
8 be tackled.

9 Is there someone else who wanted to tackle it?

10 DR. MEYERS: You said the same thing I was going  
11 to, that science qualification and the contextual, the  
12 context in which something is said are different and  
13 sometimes overlap, and I think we have to be very careful  
14 about that.

15 MR. LAKE: Let me thank each of you on the panel  
16 for coming and being with us this afternoon. I think we've  
17 all heard some things that have been at least enlightening  
18 to me and I think the audience and the rest of us, as well.  
19 So again thank you very much.

20 We will at this time take a break and if you would  
21 be back in about 15 minutes, we will have presentations from  
22 several speakers who asked to make presentations for this  
23 afternoon. Thank you.

24 [Recess.]

25 MR. LAKE: If people would come on in and get

1 settled again, we will begin the final session for the day.

2 **REGISTERED SPEAKERS**

3 MR. LAKE: We have a number of speakers who  
4 registered the make presentations this afternoon. Again, as  
5 with the panelists, we're asking that they limit themselves  
6 to 10 minutes.

7 The first speaker is sort of by special  
8 invitation. Donna Porter from the Library of Congress was  
9 asked by us to summarize the issues, so the first  
10 presentation will be from her. Then we will go to the  
11 others who have asked to speak.

12 Donna?

13 MS. PORTER: Thank you, Bob.

14 I'm Donna Porter. I'm a specialist in life  
15 sciences in the Congressional Research Service, which is  
16 part of the Library of Congress. I'd like to thank the FDA  
17 for the invitation to share my views on these issues  
18 surrounding the implementation of the authoritative  
19 statement provisions of FDAMA.

20 My statement today is based solely on my own  
21 perspective and views after 25 years of research in the area  
22 of nutrition policy in this government. My statement does  
23 not reflect the views of the Congressional Research Service,  
24 the Congress, the Institute of Medicine, the Keystone Center  
25 or any other organization that I've been affiliated with in

1 the last quarter century. It is rather a synthesis of my  
2 experiences with the issue of claims messages associated  
3 with the foods in these many venues.

4           From my perspective, this issue originates with  
5 the dietary goals for the United States that was issued as a  
6 staff report of the Senate Select Committee on Nutrition and  
7 Human Needs in 1977, just prior to that committee's demise.  
8 While the document's seven goals caused considerable  
9 controversy among the interested parties that were part of  
10 the food and nutrition establishment at that time, it also  
11 represented the first time that any entity of the federal  
12 government provided direction for the public on the  
13 relationship between diet, chronic disease and achieving  
14 better health.

15           Following its release and the subsequent  
16 congressional hearings, numerous government and health  
17 organizations began examining the scientific literature for  
18 the evidence that diet and disease were related and what  
19 dietary directives might be broadcast to the general public.

20           Most dietary guidance documents were relatively  
21 similar in the messages that they addressed in consumer  
22 brochures issued by the respective organizations both in and  
23 out of government.

24           The issuance of the 1988 Surgeon General's Report  
25 on Nutrition and Health and the 1989 NAS diet and health

1 study, both comprehensive reviews of diet and health  
2 literature at that time, propelled this government forward  
3 into comprehensive changes in food labeling and related  
4 health messages.

5           Now starting with authoritative statements, it  
6 seems to me that an authoritative statement for a claim is  
7 provided for under FDAMA is a statement of the consensus of  
8 the totality of the scientifically available literature on a  
9 diet and disease relationship. This consensus would have  
10 been reached by a scientific body or agency with expertise  
11 in nutrition research of either the federal government or  
12 the National Academy of Sciences.

13           When claims were first allowed, many health  
14 experts believed that limiting claims to those that  
15 paralleled dietary guidance statements issued by scientific  
16 entities, such as the ones that I've already mentioned, was  
17 a good way to match the dietary messages between nutrition  
18 education and labeling and prevent the type of Tower of  
19 Babel described by DHHS Secretary Louis Sullivan in 1989.

20           The FDAMA provisions seem to have returned us to  
21 the option of basing claims on dietary recommendations in  
22 the form of authoritative statements from scientific bodies.

23           If the petition process first is the notification  
24 alternative. It's the FDAMA provisions are an alternative  
25 to the time-consuming and authoritatively demanding NLEA

1 process procedures and standards for health claims, then  
2 NLEA seems to me to be the good standard and that the FDAMA  
3 provisions provide a fast track mechanism to facilitate the  
4 implementation of the NLEA processes, procedures and  
5 standards. Let me explain what I mean.

6           The existing petition process established by NLEA  
7 requires the manufacturer in the petition to provide the  
8 totality of the publicly available scientific evidence  
9 that's believed to establish the basis for the diet and  
10 health relationship. The petitioner must also provide  
11 information about the claim that will be made and its  
12 wording.

13           NLEA requires FDA to conduct a review both  
14 internally and with its other PHS agencies to determine if  
15 the science supports the existence of the relationship.  
16 Based on this review, FDA was directed to authorize a health  
17 claim based on this scientific review when it established  
18 that there was significant scientific agreement among  
19 qualified scientific experts that the claim is supported by  
20 that evidence. This review was subject to notice and  
21 comment rulemaking.

22           In short, health claim statements on labels and in  
23 labeling are to be specific affirmative statements that are  
24 accurate, based on the totality of the scientific evidence  
25 and able to convince qualified individuals that the food

1 substance, when used in a dietary context, will have the  
2 stated impact on a disease or other health-related  
3 condition. This standard has been in place since 1990.

4 FDAMA provided an alternative mechanism for the  
5 authorization of health claims in part because the  
6 interested parties recognized the time-consuming, resource-  
7 intensive nature of the NLEA- mandated process. It directed  
8 that health and nutrient content claims could be authorized  
9 under circumstances where an authoritative statement had  
10 been made by a scientific body of the federal government or  
11 NAS with expertise in the area of nutrition research.

12 The Act provided four criteria that we've heard  
13 repeatedly today and I will not repeat them. These criteria  
14 seem to assume several advantages that might be provided  
15 from the work of nutrition research and dietary guidance  
16 conducted by other health agencies and the Academy.

17 The work, if currently in effect, concerning a  
18 food substance and its relationship to a health condition  
19 and published as a position or a policy of that agency or  
20 the Academy, would undoubtedly represent the current state  
21 of the science and be based on a deliberative review of all  
22 the evidence available at the time at which the position was  
23 authored by that agency.

24 Authoritative statements would have both internal  
25 and external review by the issuing entity and, in the case

1 of information for the general public published by the  
2 federal government, be required to be reviewed by the  
3 secretaries of both Agriculture and Health and Human  
4 Services under the provisions of the Nutrition Monitoring  
5 and Related Research Act of 1990.

6           Such documents are generally quoted widely in the  
7 public health and dietary guidance literature, the media and  
8 textbooks. As such, these authoritative statements would  
9 represent the consensus of the scientific community at the  
10 time of their publication.

11           Authoritative limits. However, not all  
12 statements, including every line of every Academy report,  
13 would be authoritative. Committees, agencies, surgeon  
14 generals, consensus development conferences and advisory  
15 councils frequently address issues of diet and disease that  
16 are exciting preliminary findings from emerging science that  
17 need considerably more research work before they can become  
18 the basis for dietary guidance, substantiation for  
19 advertising messages or reach significant scientific  
20 agreement for health claims.

21           Many preliminary and inconclusive findings do not  
22 bear up under subsequent intense research scrutiny.  
23 Therefore it seems that the Academy or any of the agencies  
24 issuing a document that contains a statement that has been  
25 signaled as authoritative must be responsible at the outside

1 to comment on whether it considers that statement to, in  
2 fact, be an authoritative statement of that organization.

3           This determination could be achieved in several  
4 ways. The notifier could be required to provide as part of  
5 the justification the explicit opinion of the issuing agency  
6 that the statement is authoritative, or as the first step in  
7 FDA's process, it could contact the issuing agency for such  
8 a determination. And I would suggest that the 120-day  
9 response period by the agency not start until a written  
10 response is received from the agency or the Academy  
11 concerning the authoritative statement.

12           Beyond authoritative determination. Assuming that  
13 the issuing agency indicates the criteria for FDAMA are met  
14 by the statement, then FDA needs to determine whether the  
15 claim, as worded, is truthful and not misleading, juxtaposed  
16 to the context in which the authoritative statement is  
17 published.

18           The presumption of validity and availability of  
19 scientifically sound information to promote consumer  
20 knowledge and choice, as outlined in the House report on  
21 FDAMA, suggested that authoritative statements as the basis  
22 for claims must be grounded on some level of evidence that  
23 would assure consumers that the effect described could be  
24 reasonably expected to occur.

25           The official position of a scientific body could

1 be expected to be based on consensus of those knowledgeable  
2 about the relationship on which an official statement would  
3 be made. Consensus in this context would be a higher  
4 standard than that of significant scientific agreement, as  
5 outlined in NLEA.

6 A comprehensive review of FDA's initial experience  
7 of SSA as the standard for claim authorization, as outlined  
8 in the Keystone dialogue, indicates that surely there was  
9 not a consensus on any of the 10 relationships that Congress  
10 directed be reviewed for consideration for authorization as  
11 health claims. In fact, former FDA Commissioner David  
12 Kessler testified at a congressional hearing once that SSA  
13 was 51 percent of the scientific evidence.

14 Each body--that is, the scientific bodies--would  
15 need to have its own policy on what constitutes deliberative  
16 research. In fact, some of that probably already exists.  
17 Whether individual bodies would have a policy on the use of  
18 its official public statements as authoritative for the  
19 purposes of authorizing claims would need to be an internal  
20 determination.

21 FDA screening. If FDA wished to conduct an  
22 initial screen of submitted notification information, it  
23 could do so by determining whether all the required  
24 information was provided and met its criteria, along with  
25 the response of the issuing agency as to whether a statement

1 is authoritative. Then FDA could be prepared to contact the  
2 notifier if the scientific body responds that the statement  
3 is not authoritative or the agency determines that the  
4 notification information is incomplete.

5           Again it is my feeling the 120-day period should  
6 not commence until the FDA has the complete set of  
7 information before it needed to make a determination  
8 concerning the claim.

9           Clarification should be made available as to what  
10 is needed to be followed in a notification process and the  
11 information to be submitted. Likewise, the notifier should  
12 have every opportunity to provide that necessary information  
13 so that a favorable response on a claim can be made.

14           Claim meaning and application. From the Keystone  
15 Dialogue on Food, Nutrition and Health, it's clear that  
16 industry favored shorter messages for health claims. The  
17 subsequent FDA consumer research suggested that shorter  
18 messages were meaningful to consumers in cases where the  
19 claim was for a relationship on which the public had prior  
20 knowledge of a diet and disease relationship. This was not  
21 true for relationships on which they did not have prior  
22 knowledge, where only longer statements were meaningful for  
23 them in terms of understanding the message.

24           MR. LAKE: Donna, could you kind of wrap it up?

25           MS. PORTER: Okay. Concerning the general

1 principles for nutrient content in health claims, these  
2 should be applicable to the process in terms of  
3 notification. Only if the message-making and the  
4 information required of manufacturers and in labels is  
5 consistent will it be possible for manufacturers to have a  
6 level playing field and if it's not consistent, consumers  
7 will not understand the difference.

8           Finally, I just wanted to comment. I believe that  
9 dietary supplements should be allowed to make claims under  
10 the authoritative statements provisions. It seems to me  
11 consistent with the work of the commission, that that was  
12 what they had in mind. And I do believe that as soon as  
13 possible in the process, information should be made publicly  
14 available so that the rest of the universe can provide input  
15 into the process and understand what's coming forward from  
16 the agency. Thank you.

17           MR. LAKE: Thank you.

18           Let me just indicate that I would like other  
19 speakers to follow Donna's example of getting up to the  
20 podium over there.

21           The next speaker is Dr. Colon Broughton,  
22 transition director, Office of Natural Health Products,  
23 Health Protection Branch, Health Canada. I guess he'll give  
24 us a little bit of an international flavor to this meeting.

25           DR. BROUGHTON: Good afternoon, ladies and

1 gentlemen. I thank the U.S. Food and Drug Administration  
2 for the opportunity to be here to tell you about the  
3 Canadian way.

4 In the summer of 1977 the Canadian government  
5 dissolved Parliament. It was a Liberal government at the  
6 time. They dissolved Parliament, believing that they could  
7 get reelected, and indeed they did. However, the minister  
8 of health of the day did not get reelected.

9 And for those of you who know about the Canadian  
10 parliamentary system, which has some very fundamental  
11 differences between what you experience down here and the  
12 way you're governed down here, I was talking yesterday at a  
13 meeting and I said it used to tick Pierre Elliot Trudeau off  
14 no end, who was the Liberal leader in the 1970s through the  
15 middle of the 1980s, to get off an airplane following the  
16 president of the United States, who got a 21-gun salute and  
17 Trudeau only got 19 because our head of state is the Queen  
18 of England in Canada. She lives in another country, but  
19 that doesn't bother us because it gives live to the  
20 parliamentary system.

21 And in Canada, if you are a minister of the crown,  
22 equivalent to your secretaries, you must have been an  
23 elected person; i.e., a congressman, occasionally a senator.  
24 Senators are not elected in Canada so it's very similar to  
25 yours. They are chosen. But the MPs who come back to

1 Parliament, having knocked on the door, and that's the  
2 phrase they use, meaning that they got the most votes and  
3 therefore they are back on and they come in.

4           It gave the prime minister the opportunity then to  
5 assign a new minister of health because Mr. Dingwald, who  
6 had been our minister up until the proroguing of Parliament,  
7 lost his seat and Mr. Alan Rock, who was formerly minister  
8 of justice in the previous Parliament, became minister of  
9 national health.

10           The biggest single issue facing the members of  
11 Parliament, prospective members of Parliament as they went  
12 to the door was what are you going to do about herbs and  
13 botanicals, dietary supplements and the like? We want to  
14 have the freedom of choice in Canada so that we can manage  
15 our own self-care.

16           Mr. Rock, being the astute politician that he is,  
17 asked the questions within the department and we said,  
18 Minister, it's a minefield because we do not have the  
19 political will to make any changes. And right now,  
20 Minister, and as it happens right as we speak, if you wish  
21 to make a claim for a product that is going into the human  
22 body, except for medical devices and we won't worry about  
23 those because they tend to be not through the GI tract, but  
24 if you're going to put something into the body, into the GI  
25 tract, you only have two options and that is it's either a

1 food or it's a drug, and there is that interface that is  
2 managed.

3           If you make a health claim for a food, it  
4 immediately becomes a drug. It becomes a therapeutic  
5 product and it is subject to the same regulatory  
6 requirements as any pharmaceutical product that is going to  
7 end up as an over-the-counter drug or as a Schedule F; in  
8 other words, prescription drug in terms of our parlance in  
9 Canada.

10           Clearly a very unsatisfactory state of affairs.  
11 Colleagues and myself have dealt with this for 30 years. No  
12 political will to change it.

13           Mr. Rock placed the issue before a standing  
14 committee on Parliament and I have chosen to pass around,  
15 because I'm not really going to be speaking very much to the  
16 subject at hand except for a little bit at the end, but the  
17 government of Canada would not presume to tell the  
18 government of the United States what to do.

19           I have before you a boilerplate speech which  
20 spells out what has gone on in Canada and the penultimate  
21 slide shows the website where you can go and get  
22 information. There is a 1/888 number. Unfortunately we did  
23 not pay to make it North America-wide, so unless you're in  
24 Montreal or Toronto, it won't work.

25           So what happened? In November 1977 the Standing

1 Committee on Health, which is a standing committee of our  
2 Parliament comprising all parties in power--of course the  
3 Liberal government, which is the party in power, does have  
4 the most members on the committee. They are not so foolish  
5 as to think it's so open that you're going to have a free  
6 vote under those circumstances.

7           They began deliberations. They began meetings.  
8 They began video conferences. There was a write-in campaign  
9 for them and we also, at Health Canada, had a standing or an  
10 expert panel advising us. They kind of got took over and in  
11 May of 1998, which is exactly one year away, they tabled  
12 their report to the department. We gave it to the standing  
13 committee and said, "Here is more grist for your mill, sir."

14           And they took it and in November of that year  
15 about 170 days ago the committee came up with a report. And  
16 I thought I was going to bring a copy up to the podium with  
17 me but I didn't.

18           Annette, could you grab it? It's in the top of my  
19 bag. Just wave it around. It's the yellow-covered 100-page  
20 document. There you go. That's it.

21           It's the Standing Committee on Health's Report  
22 from Parliament. In there you will find, if you can get  
23 your hands on them--they're not available really anymore but  
24 on the website that I have given to you there, if you click  
25 on that in English, because we do work in both official

1 languages in Canada, click on the English side, go down to  
2 the bottom left and find a shady brook, which says natural  
3 health products.

4 Click on that and you'll go immediately into the  
5 minister's speech when, on May 26 of this year, he accepted  
6 on behalf of the government of Canada all 26 recommendations  
7 contained in the document, the Standing Committee on  
8 Health's Report. It's on the fifth line in that document  
9 and if you click on that you are immediately hot-linked to  
10 our parliamentary website and up comes that document that  
11 Dr. Annette just lifted up.

12 On about page 102 there are the 53  
13 recommendations. They cover some 16 areas and I will just  
14 very quickly go through them and tell you what those are.

15 Definitions. Mr. Rock said in his charge to the  
16 committee, would you please be good enough to tell me, give  
17 me a good definition of what natural health products are.  
18 For natural health products, folks, include your dietary  
19 supplements and others. We are saying, and it may be argued  
20 circular, it's a circular argument, as Peter Bartonhutt  
21 argued with me just the other day in a very friendly way; he  
22 said that well, what you're saying is kind of circular but  
23 anyway, I like it. I like circular ones. He said they mean  
24 nothing; you can get away with murder. And I said that's  
25 the idea.

1           The point being that natural health products in my  
2 parlance are products that are natural and for which health  
3 claims are made. Now that includes milk if you're talking  
4 about the calcium content in milk. It includes ginkgo  
5 biloba if you think it's going to hold up Alzheimer's. It  
6 talks to all of those things.

7           So we do not use or we have not formally embraced  
8 the subject of nutraceuticals, functional foods, medical  
9 foods, as you have here. The belief is, and I think you may  
10 have shared this in terms of being aware of where we're  
11 going, it would look as though the word nutraceuticals will  
12 become the umbrella word at some point in the future.

13           We don't have a problem with someone pulling out  
14 naturally and putting into a dosage form; therefore it  
15 becomes something different.

16           We are saying that there is a risk-benefit  
17 continuum and along that risk-benefit continuum sit all  
18 things. And if you're saying that you now only have this  
19 food-making claims, it becomes a therapeutic product, which  
20 it is. What the report says and the government has accepted  
21 as government policy as of March 26, that we're going to  
22 open this up.

23           The report does say to me, since I am the  
24 transition director and my minister told me that the prime  
25 minister told him, "Alan, we are not going to see this back

1 at the door, are we?" Excuse me. He said, "You can assure  
2 me that we will never see this back at the door" and he  
3 said, sounding like that well known British television  
4 series, "Yes, Prime Minister."

5 He said to me, "We're not going to see it at the  
6 door. You're going to do things that will not see it at the  
7 door" and I said, "Yes, Minister." Same part of the same  
8 show.

9 To give you an indication that that is the  
10 political will in Canada to do it, all 53 recommendations,  
11 never heard of in 10 years of existence of the committee.  
12 They normally say well, we'll take 10 or 15 and this one and  
13 that one.

14 Mr. Volpe, who was chair of that committee, was  
15 really very surprised I withstood with him because there had  
16 been absolute cabinet confidence in that regard. He did not  
17 until Mr. Rock spoke on the 26th at a health food store on  
18 Young Street in downtown Toronto which was just opening and  
19 he was pleased to say that the government was accepting all  
20 53.

21 Definitions. They didn't come with a definition.  
22 They put it back to myself and an expert advisory committee  
23 that's going to do this and advise my office of what  
24 expertise we need, what regulatory structure we need.

25 Mr. Rock said to me, "Colin, give me a statement

1 that the people of Canada will understand. We want it to be  
2 safe and efficacious." I said, "Make is safe, cleanly made,  
3 correctly labeled and advertised," and that covers it all  
4 and we believe it does.

5 And I know I'm running out of time and I will  
6 simply draw your attention to the fact that we are going to  
7 be studying all of these recommendations because all are  
8 going to be implemented.

9 We go on there and I understand there may be time  
10 for questions afterwards. You can see the organizational  
11 structure on the back sheet, that the Office of Natural  
12 Health Products stands with Therapeutic Products Program and  
13 Food Directorate and the penultimate one is our coordinates,  
14 where you can reach us.

15 And I have just one thing to say, that when I read  
16 your FDAMA Act and saw that indeed your Congress had seen  
17 fit to say that there are four areas in which you will be  
18 working, but yet there is some abrogation in the terms that  
19 it says in reference to 201FF, that these are exempt from  
20 putting in place, one of the things that you are exempting  
21 is harmonization with Canada and Mexico, and it is the  
22 Canadian government's position that we would like to see  
23 that revised and instead of saying "competent agencies of  
24 the government of the United States," it says "competent  
25 agencies and departments of the governments who are

1 signatories to NAFTA." Thank you.

2 MR. LAKE: Thank you.

3 Our next speaker is Jonathan W. Emord, counsel to  
4 Weider Nutrition International, Incorporated, American  
5 Prevention Medical Association, Pure Encapsulations,  
6 Incorporated and Dr. Julian Whitaker. He's with Emord &  
7 Associates, P.C.

8 MR. EMORD: Thank you for the opportunity to speak  
9 today. I appreciate it.

10 I'm an attorney who practices constitutional and  
11 administrative law before the federal courts and agencies.  
12 I'm also the attorney who successfully argued the Pearson  
13 versus Shalala case, so it's a distinct privilege for me to  
14 have an opportunity to speak in advance of any final rules  
15 on this question because I believe it touches so dearly upon  
16 our constitutional rights under the First Amendment and upon  
17 the question of ultimately who has the power to say what is  
18 and what is not permissible in the realm of health claims  
19 for dietary supplement products and for foods.

20 FDA has two legal masters. It has the statute and  
21 it has the Constitution. Today I will describe in brief the  
22 plain meaning and purpose of FDAMA Section 303, the  
23 constitutional limits on agency authority under Pearson  
24 versus Shalala and an alternative to the nine interim final  
25 rules that I think better comports with both the statute and

1 with the constitutional requirements of the First Amendment.

2 First, Pearson versus Shalala, because this  
3 decision is truly a landmark case that affects FDAMA, as  
4 well as any instance in which the Food and Drug  
5 Administration will regulate health claims for foods or  
6 dietary supplements.

7 Pearson's constitutional analysis governs every  
8 instance where FDA would presume to limit access to  
9 information of any kind pertaining to foods and dietary  
10 supplements and particularly health claims, which were an  
11 issue in Pearson.

12 In the context of claims based on authoritative  
13 statements of government health agencies, Pearson requires  
14 FDA to permit every such claim and to rely upon reasonable  
15 disclaimers to cure any potential to mislead.

16 You see, Pearson is predicated upon a long  
17 constitutional heritage, from In re RMJ in 1979 up to 44  
18 Liquor Mart, in which the Supreme Court has said  
19 consistently that if commercial information is not  
20 inherently misleading but is only potentially misleading, it  
21 is incumbent upon government to allow the information to  
22 reach consumers with disclaimers as its remedy, as opposed  
23 to outright suppression.

24 The court, in Pearson versus Shalala, utterly  
25 rejected the Food and Drug Administration's justification

1 for suppression in lieu of disclaimers and imposed upon the  
2 agency this constitutional requirement, bringing it in line  
3 with every other agency of government, both federal and  
4 state, under our Constitution.

5 Thus, Pearson remains a constitutional guidance  
6 for this agency to deal with the issues of health claims,  
7 whether they arise under FDAMA or whether they arise under  
8 FDCA Section 305(b), 304(b) or any other aspect of agency  
9 regulatory authority and discretion.

10 So the agency is beholden to the Constitution and  
11 the First Amendment and must not suppress outright claims of  
12 nutrient-disease relationships when it may use disclaimers  
13 to allow the information to reach consumers and correct the  
14 misleadingness--the court's term--in the claim.

15 Thus, the message of Pearson versus Shalala is  
16 that disclosure over suppression is a constitutional  
17 imperative that FDA may not ignore. It should be the  
18 centerpiece of discussions on these issues and it should be  
19 both a starting point and an ending point because it really  
20 does subsume in a massive way, under the Constitution,  
21 anything that the agency attempts to do with respect to  
22 claims on nutrient-disease relationships.

23 The statutory meaning. FDAMA Section 303 is,  
24 despite probably today's discussions, not a complex matter,  
25 actually. In its own terms, FDAMA Section 303 is different

1 from the FDCA Section 304(b) in that it does not, by its own  
2 terms, delegate to the agency discretion as to how to define  
3 things, such as authoritative statements, and such as the  
4 procedure to be used in implementing the Act.

5           Instead, in an extraordinary departure from prior  
6 statutory law, it defines those things in the statute  
7 itself, thereby not delegating to the agency any discretion  
8 as to what the specific definitional provisions mean but  
9 providing it instead within the context of the statute.

10           Congress, it must be remembered, reacted, as the  
11 Senate and House reports on this issue make clear, reacted  
12 adversely to FDA's refusal to authorize under, the  
13 significant scientific agreement standard, a folic acid  
14 neural tube defect claim for three and one half years and  
15 attributed to FDA's failure to approve the claim  
16 approximately 2,500 preventable neural tube defect births  
17 each such year.

18           It was that that was the impetus, as you clearly  
19 see in the Senate and House reports, for the enactment of  
20 FDAMA Section 303, the purpose of which was to provide an  
21 expeditious alternative to significant scientific agreement  
22 review, one that would not depend upon significant  
23 scientific agreement but would be, by the terms of the  
24 Senate and House reports, an alternative to it that would be  
25 a meaningful alternative.

1 FDA will err by trying to impose regulatory  
2 requirements on health claimants that exceed those expressly  
3 defined in the statute. Congress aimed to provide a less  
4 costly, streamlined alternative to significant scientific  
5 agreement. FDA's interim final rules in this case, I'm  
6 afraid, do the opposite.

7 The solution lies in faithful adherence to the  
8 statute, in defining the term authoritative statement only  
9 as the statute does, in favoring disclosure over  
10 suppression.

11 FDAMA Section 303 is thus not a redundancy. It is  
12 meant to be an alternative to significant scientific  
13 agreement review. It is meant to be an expeditious  
14 alternative to that review. Congress did not defer to FDA  
15 in FDAMA Section 303 as it did in FDCA Section 403(b), under  
16 significant scientific agreement rule.

17 Instead, Congress defines all of the essential  
18 terms and procedures to be followed in the statute itself.  
19 Those definitions and procedures are both necessary and  
20 sufficient, consistent with the congressional goal of  
21 creating a less costly and more efficient alternative to  
22 significant scientific agreement. FDA should withdraw its  
23 nine interim final rules and rely upon the statute and the  
24 Constitution, as defined by Pearson, as its guide.

25 Congress has defined the term authoritative

1 statement simply in the statute. FDA should not alter that  
2 definition. Congress deemed an authoritative statement to  
3 be any statement of a federal scientific body if the  
4 statement is published by that body and is not a statement  
5 of an employee of the body made in the individual capacity  
6 of that employee.

7 That is your starting point, that is your ending  
8 point if you mean to follow the intent of Congress.

9 Congress also defined the procedure to be  
10 followed. The statute contemplates the submission of only  
11 three items. FDA should not add to the list. FDA should  
12 not subtract from the list. FDA should follow the intent of  
13 Congress and follow the statutory directive.

14 Congress expects that claimants will file a notice  
15 of the claim, which shall include the exact words used in  
16 the claim in a concise description of the basis upon which  
17 the claimant has determined that the statement is published.  
18 In the case of a nutrient content claim, it must identify  
19 the nutrient level to which the claim refers. In the case  
20 of a health claim, it must identify the relationship between  
21 the nutrient and a disease to which the claim refers. And  
22 the claimant must provide a copy of the statement upon which  
23 the claim is based and provide a balanced representation of  
24 the scientific literature relating to the claim.

25 Congress thus expects FDA to approve claims under

1 FDAMA Section 303, to do so more prolifically than has been  
2 the history under the significant scientific agreement  
3 standard so long as they meet the statutory definition of  
4 authoritative statement and include all of the elements  
5 specified in the statute for filing with the notice.

6 And under Pearson, the discretion the agency has  
7 is in identifying reasonable disclaimers to avoid any  
8 potential to mislead. If our aim is to inform the public,  
9 this is the constitutional manner in which we can do so.

10 We supply the information, preliminary or not. We  
11 use disclaimers to characterize the level, quality and  
12 nature of the evidence. We do so succinctly and we do so in  
13 a manner that enables the average consumer to comprehend it,  
14 but we get the information out because under our First  
15 Amendment, regardless of the complexity of issues, our First  
16 Amendment commands us to have faith in the American people  
17 and in the individual judgment of citizens to make  
18 determinations as to what is best for them and as to what  
19 they believe and do not believe. Government is not to make  
20 that decision for us.

21 The constitutional command of Pearson is  
22 disclosure over suppression. The test for the agency is  
23 whether it will, in spirit and in substance, humbly and  
24 faithfully follow the statute and the Constitution, or will  
25 it endeavor to erect barriers to the dissemination of health