UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD AND DRUG ADMINISTRATION

FOOD ADVISORY COMMITTEE MEETING

Holiday Inn-Eisenhower Metro Center
2460 Eisenhower Avenue
Alexandria, Virginia

September 25, 1997
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C O N T E N T S

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P R O C E E D I N G S

(8:30 a.m.)

ADMINISTRATIVE

CHAIRMAN BRANDT: Can I get all the committee members around the table, please? Everybody else sit down so we can get moving. I am old and crotchety.

Okay. We welcome everybody to the Food Advisory Committee meeting. We seem to be missing some of our compatriots, but I guess they will show up eventually. You should have the agenda in your book. We are going to be updated on a lot of different things.

At this time, however, I think it would be a good idea if we go around the table and let everybody introduce themselves. I am Ed Brandt. I am a regents professor at the University of Oklahoma, Health Sciences Center, in Oklahoma City, and I have the power to turn off all the lights.

DR. LARSEN: I am Lynn Larsen the executive secretary of the Advisory Committee. A note about the mikes; he has got them set up so that only two mikes can be on at any one time and you need to turn it on and off at your own mike. As Dr. Brandt said, he can turn off all of our mikes.

DR. HARLANDER: My name is Susan Harlander. I am a vice president at the Pillsbury Company in the Meals Division, Research, Development and Agricultural Research.

DR. BLACKBURN: Henry Blackburn, professor in the Public Health, Division of Epidemiology, University of Minnesota at Minneapolis.

DR. CHASSY: Bruce Chassy, head of Food Science and Human Nutrition at the University of Illinois, Urbana Champagne.

DR. FUKAGAWA: Naomi Fukagawa, associate professor of medicine, University of

Vermont.

MS. LEWIS: I am Chris Lewis with FDA's Office of Special Nutrition.

DR. WANG: I am Mary Wang, California Department of Health Services, Food and Drug Sciences. Thank you.

DR. CLANCY: I am Kate Clancy, the director of the Agriculture Policy Project at the Henry Wallace Institute for Alternative Agriculture.

DR. BENEDICT: I am Steve Benedict, Department of Microbiology, University of Kansas.

DR. RICHARDSON: I am Donna Richardson, director of Community Outreach for the Howard University Cancer Center.

DR. ASKEW: Wayne Askew, director of the Division of Foods and Nutrition, University of Utah.

DR. LARSEN: I have been asked to walk through your notebook a bit. In addition to the notebook, those of you on the committee, should have at the table some additional materials that we handed our this morning: a couple of brochures about the new Joint Institute for Food Safety and Applied Nutrition. That is a cooperative venture between the Federal Government, FDA, and the University of Maryland.

Late yesterday afternoon, through the good auspices of Donna Porter, we received a copy of the House Bill 2469 as it stood yesterday afternoon. You have a copy of that there and I will come back to that in a bit, what the significance of that is.

You also should have an executive summary of the research done by Dr. Levy. This was distributed at the Emerging Science Working Group session back in the winter. It provide some information on the results of the study that is associated with the material in Tab 5G of your notebook.

At the time the Wording Working Group was doing their task, we had the proposed -- or the material that is in your tab about that research. We did not have the full research report, so we wanted you to have at least this executive summary.

We do have some copies of the full research report back on the staff table, if you want to take a look at that, but that is about an inch thick so we decided not, at the last minute, to make copies for everyone at this time of that.

You also will have on the table some back-to-back copies of three press releases: one talks about the final dietary supplement rules published just this week; another announces FDA's strategy on increasing safety of juices, fresh juices; and a third talks about proposed legislation to improve food safety. I believe that is an Executive Branch proposal and it has not been provided to Congress yet as far as I know.

Harking back to the dietary supplement rules; there are six rules that published on Tuesday, five of them are actually dietary supplement rules. The sixth one is notification of compliance date, uniform compliance date, for labeling. I do have one set of those rules with me that we downloaded from the web.

You can access them on the web or if you are interested in getting copies from our copies we can send them to you after the meeting, just let the staff know that you need copies because you cannot get them any other way, at least not readily.

You should have a set of slides that will presented by Dr. Childs in her presentation tomorrow. Finally, members of the -- well, I was going to say, members of the Emerging Science and Research Incentive Working Groups, we have got some materials for you and we

haven't distributed them yet to the table. They will include an agenda and a task list for your activities tomorrow.

We have such a large audience, I am not sure this next notice really is needed. For the audience, at the staff or registration table I have put together a form that you can use to let us know if you wish to be placed on our electronic fax list, then when we have an Advisory Committee meeting coming up and we are about ready to publish the "Federal Register" document we can fax that notice to you and will get it ahead of the "Federal Register" notice. If you are interested you can go ahead and fill that out and we will put you on our list.

I was asked to, as I said, walk you through a bit of the notebook and explain a little bit about what is in here and why. Some of it is probably self-evident to you, but I will try to run through it fairly quickly.

I am going to start with Tab 4, which has material associated with the update topics that you will be hearing about, largely, this morning. The first, Tab 4.A., is a draft report of the Dietary Supplement Commission and Dr. Ken Fisher, the executive director of that commission, will make the presentation and comment on that proposal. Presumably, he will tell us how close they are to a final, if he can tell us anything about that at all.

The second, Tab 4.B., is some information on the National Academy Report on RDA's for Calcium, vitamin D and other related nutrients. Dr. Chris Lewis from our Office of Special Nutrition will speak to us on that issue. I note that we do have a typo in there someplace. We have not redesignated how these vitamins are called. They are still -- or the levels are still called "RDAs." I noticed we called them "RADs" in a couple of places. We haven't changed the irradiation of the vitamins.

Tab 4.C. is some material on the ephedra proposal. I believe what we have got is the extension of the comment period, the "Federal Register" notice about the extension of the comment period. All of you should have received a copy of that proposal some time ago. Dr. Beth Yetley should be arriving to tell us about that. She is the director of the Office of Special Nutrition.

Tab 4.D. is some information on the B12 fortification petition. This relates to the previous committee discussions on fortification of folic acid. As you will recall, one of the safety concerns there was masking a vitamin B12 deficiency. Dr. Jeanne Rader, the director of the Division of Science and Applied Technology in our Office of Food Labeling, has been a key scientist working on and overseeing both the folic B12 reviews and will address that issue.

FDA has been involved in a number -- or is involved in a number of international cooperative assistance efforts. One of those has been working with the country of Russia. Dr. John Vanderveen was a member of a delegation that went over there earlier this year to discuss fortification of food in Russia, and he will tell us a bit about that activity.

One of the other international activities that has been going on for a long time, FDA has been involved with for a considerable time, is the CODEX Alimentarius, which is a U.N. organization focusing on food safety and food standards in international trade. It operates through a number of committees, for example, Food Hygiene, Food Labeling and Dietary Supplement Committee.

Dr. Ed Scarbrough, who used to head up our Office of Food Labeling until about a month ago, is now the U.S. CODEX coordinator operating out of the USDA and he will provide a general overview of CODEX activities and issues. Dr. Yetley will talk about the Dietary Supplement Committee.

The food safety initiative, which was announced by the president back in January is a multimillion dollar effort that FDA, CDC, I believe NIH, and EPA are also involved in. It is intended to increase the effectiveness of microbial food safety efforts and to heighten the consumer and industry awareness of their roles.

Ms. Karen Carson will be here later this morning to address that issue for us. She is with our executive operations staff in CFSAN. There are a number of things going on this week. It has gotten to be very active in some of these areas. I hope that Karen is able to be here to talk to us about that.

I know the next person or the next issue, Senate Bill 830, we are going to have to delay the presentation on that one, at least I am convinced we will. The Senate bill itself passed last night, and if you picked up a copy of the "Post" this morning, you would have seen an article in the first section, a few pages back, on that bill. It is largely devoted to drugs and devices, but if enacted in the present form, it has several provisions that impact on foods.

For example, the way we process approval of health claims and the basis for that approval or what folks can use as the basis for their health claim, and that may have an impact on our whole Keystone activity, which is the primary business of the committee at this meeting.

It also has a fee-for-service notification system for use of indirect food additives, for example, food contact materials. The reason Mr. Lake, who is the director of our Office of Policy Planning and Strategic Initiatives, probably won't be here this morning to discuss that is because the House committee looking at the related House bill is going to markup this morning at 10:00.

He will probably have to attend that markup. If he gets done early enough, he will try to be here this afternoon to tell us what is going on. If that doesn't work, he guarantees me he will be here tomorrow morning, so we will have his presentation tomorrow morning to discuss these bills.

If he doesn't show up, we are going to put Donna Porter on the spot. She said yesterday she would be willing to make a few comments. So, we will see how that all pans out; but as I said, things are happening as we sit here, and it is hard to keep up with them.

The last issue is the Food Quality Protection Act of 1996. That addresses EPA regulation of pesticides. It did change some of the regulations that FDA had worked on in the past, particularly the microbial -- antimicrobials, I should say, when they are applied to foods and removes, technically removes, FDA's authority, moves that over to EPA on those products.

We have been in some discussions with EPA. Those discussions have gone back and forth, and we have asked Mr. Eugene Coleman, the director of Petition Control in the Office of Premarket Approval, to tell us what he can at this time. Since we set this up on the agenda, it has gone back and forth, how much he can tell us and what he can tell us and whether he can tell us anything. Hopefully, we will be able to learn a little bit more about that this afternoon.

The last four tabs of your notebook contain the minutes of four of the working group sessions that we held earlier this year. The working group chairs have been asked to provide a brief comment from their perspective on those meetings, not to recapitulate the minutes, but brief comments on the meetings from their perspective on where their committee is at and where they see it going.

Of course, two of the subgroups, working groups, will meet tomorrow when we adjourn the committee meeting. I believe Steve is looking towards the end of the day today to have a session of his working group.

Tab 7 also contains two additional documents: one is a summary of research that will be

described in the presentation tomorrow; it is another summary of Dr. Child's information. The other item there is a discussion draft for consideration by the Incentives Working Group, and this discussion draft was prepared by Jim Stanley of the working group.

Finally, backing up to Tab 5, this is the primary goal or work -- charge of the committee for this particular meeting. In there you have a draft report from the Health Claims Wording Working Group. They believe they have achieved a document that can now be discussed by the committee and then, presumably, approved by the committee and passed on to FDA with recommendations.

As a little charge, and you can go over this again this afternoon, but as a charge I would suggest that your task is to discuss this report and to come to some agreement on the disposition of the report and to deliver it to FDA as the committee's recommendations as the report stands, if you wish; or with specified changes; or if it is the committee's desire, you can return it to the working group with instructions for further work.

I think the working group would prefer the first, but obviously all of those options are up to you. The tab also provides the minutes, I should say, of the working group's member list and the working group committee charge, so you have some perspective as to what they were working from.

There were some key documents that the Health Claims Wording Working Group used in their deliberations and some of those have been included here. We did not provide you with everything. One of the materials there is the basis for the speech given by Dr. Shank. That item is included because it doesn't directly bear on the working group assignment, per se, but provides a lot of perspective on critical issues for the use of health claims, particularly with respect to a certain category of foods, as discussed there. I thought it seemed useful that the other working groups should have it as well, and so I would just use this opportunity to provide that to you for your edification as it were.

I think for this morning that takes care of my lengthy administrative comments.

Thank you.

CHAIRMAN BRANDT: Any questions by anybody on the committee?

Okay. You commented about the audience, and I remember well several audiences that were quite large, as a matter of fact, like BST and Flavor Saver Tomatoes and a few other things like that. So, it is kind of a thrill not to have that.

Dr. Fisher, would you bring us up to date on the Dietary Supplement Commission, which is under Tab 4?

UPDATE PRESENTATIONS

DIETARY SUPPLEMENT COMMISSION REPORT

DR. FISHER: Thank you.

I would just start off by saying that since Lynn has indicated that we have -- we do have the whole report or the executive summary in the tab. You have the executive summary and that is basically what I am going to talk about, so maybe I should just say are there any questions. I am good at that.

DR. LARSEN: Is your mike on?

DR. FISHER: I think so.

At the present time, where the commission is that they prepared their draft report and made it public on the 24th of June and requested one more round of public comment. We received over 400 comments in the period from June 24 through approximately the 13th of

August.

The commission met again on the 14th and 15th of August and reviewed a number of modifications that had been made to the draft report by the commission members, as well as took under consideration that many of the comments that had been received as a result of the draft report becoming public.

As I said, there were about 400, 450 comments that were received, approximately 250 to 300 of these were an orchestrated letter writing campaign by the International Advocates for Health Freedom that commented on the role of the Commission on Dietary Supplements and implied that there was some connection between CODEX and the commission.

The other 140 to 160 comments were received from citizens, from organizations, from both within the industry and outside the industry, and in many instances provided the commission with some additional perspectives on what they had to say.

I think it is fair to say that as a synopsis of most of the meaningful comments received is, would you please stop writing a report that sounds like a bureaucratic academic report, and, would you please put your recommendations and suggestions in clear, understandable, logical English, which is basically the process that we are involved in at the present time.

Our schedule, at the present time, is now to take the revisions of the draft report made by the commission on the basis of the comments and their review and to weave -- well, we have already done that, excuse me. We have done that, and we have another draft which is out for review by the seven commission members.

Those comments are due at the end of this week, at which point we will be putting together the final draft of the report. We had initially indicated that the report would be done by the end of September. As some of you know, me, I am an eternal optimist. We are now shooting for the end of October, and I suspect that we will see the Thanksgiving turkey on the table before we finish with the process of the final review. It will be done, and it will be available at the end of October or early November.

There is, of course, as you know, a process at the end of all of this where one has to get it printed by GPO and go through the exercise of releasing the report. Since the Dietary Supplement Health and Education Act says this report has to be delivered to the president, to Congress and to Secretary Shalala, one has to schedule the delivery of this report in an appropriate manner, which is something that is absolutely unbeknownst to me. I have discovered that it is unbeknownst to an awful lot of people as to how you do exactly that.

Maybe you might want to assist us, Dr. Brandt, since you probably know exactly how to do those kinds of things.

Anyway, let me go over some of the conclusions of the commission and just comment on what those conclusions are. I am basically using the draft report, and I will give you just a clue as to where some of the changes have been made.

If DSHEA doesn't do anything else, DSHEA defines a dietary supplement. If it doesn't do anything, it defines a dietary supplement as to what exactly a dietary supplement is. Of course, I am sure you have read this little note down here that says: "it can be a substance to supplement the diet by increasing the total dietary intake of that substance."

If you think about the logic of that language, you come to the conclusion that if it isn't there before and you take some more, you obviously have increased the intake and so one can say that this is pretty broad and open. But the law did define what a botanical -- or, excuse me, what a dietary supplement is.

It also limited and made some constraints about what exactly a dietary supplement should be. It is to be ingested, not taken by nasal or any other route, not a conventional food, it is not a sole item of a meal, and it is labeled as a dietary supplement.

The most important thing there that the commission, and the commission does agree with all of these and has made few, if any, comments about this other than to indicate that it concurs with these, is that it is labeled as a dietary supplement.

I think you can appreciate the fact that ascorbic acid, as an example, could be labeled as a food, it can be a food additive, it can be a grass food ingredient, it can be an indirect additive, it can be an over-the-counter drug, it can be a dietary supplement, and it, for that matter, could be a prescription drug.

The important reason for bringing up this example is that underlying all of this is that whatever is on the label describes the product and its regulatory status is related to what is on the label.

I think you probably know that Dr. Malden Nesheim, the provost emeritus of Cornell and imminent nutritionist, is the chairman of this panel. Its seven members fulfill the requirements of the law for diverse expertise.

Dr. Dickinson is scientific director for the Council for Responsible Nutrition; Dr. Farnsworth is one of the world's most imminent pharmacognosists. Margaret Gilhooley, professor of law at Seton Hall University and many years ago in the General Counsel's Office of FDA. Tony Podesta of Podesta Associates, another lawyer with expertise in the area of food and drug law. Rob McCaleb, the president of the Herb Research Foundation in Colorado. Shiriki Kumanyika, who was at Penn State when she was appointed but moved to the University of Illinois -- there is no connection, no conflict of interest there, they are in separate buildings, I believe -- who is also a well-known nutritionist.

One of the things that the commission did, even though it was not technically in its charge, and interestingly enough it has been criticized for, is that it early in its work determined that safety is a very important consideration for dietary supplements. It basically outlined, as you can read in the "Executive Summary," that yes, industry is responsible for safety assurances but industry is also responsible for providing warnings; there is a need to improve post-marketing surveillance systems; and FDA should take some swift enforcement action when necessary.

There has, I'm sure, I know there has, been some discussion of this group about the speed in which FDA has acted in certain cases where dietary supplements have been marketed and there has been a problem.

Of course, something I am sure that the government does not want to hear, and that is, if FDA is supposed to do what the law says it should do, then FDA either needs to change the way it marshals its resources or it will need additional resources. They don't like to hear that, but that is one thing the commission is saying.

With respect to health claims, the commission agreed that the definition of a health claim, that is in NLEA, is appropriate for both foods and dietary supplements, and there is nothing wrong with significant scientific agreement to make a health claim.

They did agree that, and there are some recommendations in the report, and these are being modified slightly. I am sorry I cannot tell you how they are being modified, but basically they are saying that the process of reaching scientific agreement needs to be opened more broadly, there needs to be more public input into that process, there needs to be greater use of expertise, and there needs to be more guidelines as to what "significant scientific agreement"

means. Of course, that is coming out of some of the work of this group.

Statements of nutritional support, one of the topics that took a great deal of time and effort on the part of the commission. The key phrase in the law and in the charge to the commission is "truthful not misleading and scientifically valid."

I don't think I need to tell this group that there can be some claims that are truthful, that are also misleading and not scientifically valid; there are some that can be not misleading, but false; and there are some that can be truthful, not misleading and have no scientific validity whatsoever.

That depends upon what kind of science that one is concerned with. The commission has made an effort to try and help define these as well as to define structure function statements and to separate health claims under NLEA from drug claims under the drug regulations and to talk specifically about statements of nutritional support in the sense that they do not mention "disease." They do not mention words like "cure," "mitigate," "treat," or "diagnose" and other words.

They have tried very hard in their text to try to indicate their thinking about the fact that statements of nutritional support are neither drug claims nor OTC claims. That is another section in the report that is being modified. There is a recommendation to FDA about providing additional guidance to manufacturers and consumers about what exactly FDA thinks a statement of nutritional support is.

That discussion lead to something which comes up a little bit later, and that is, how do you make a statement of nutritional support for a substance that has no nutritional value, but in fact is a dietary supplement that is being used for purposes other than nutrition. I will come back to that in a minute.

Another topic of great discussion was what should be in the letter of notification. If you will look at what was published in "The Federal Register" on Tuesday, you will find that FDA has published what they think ought to be in the letter of notification.

The commission has some additional suggestions, and one of the major differences is more information about the producer of the product; the second is if it is a botanical product, the Latin name needs to be specified.

The FDA publication yesterday indicated, one can use a secondary reference such as "Herbs of Commerce" as a source document and you don't have to have the Latin name in there if it listed in "Herbs of Commerce." I would hate to ask everybody who has ever read "Herbs of Commerce" to stand for a minute, because I suspect there is only three people in the room that have ever read "Herbs of Commerce," not a very enlightening book.

There are also some changes, and this was in the draft report, with respect to contraindications and warnings and also some changes about the summaries of evidence. This suggestion, in the draft report, that a summary of evidence of safety and efficacy should be in the notification letter, as you might expect, raised a large number of points, a large number of comments particularly from industry.

That section is being modified. Again, I wish I could tell you, but I cannot, mainly because I have not been in the office for two days and I know that it has probably been changed since I was there on Monday. Since we have a very active commission who have an interminable use of E-mail, pencil, paper, word processors, and minds always working.

The same thing is true of the substantiation files. There are some suggestions that even though the substantiation files, the law says the substantiation files need to be -- the manufacturer

needs to say they have a substantiation file, the commission has gone on to suggest that there ought to be certain things in the substantiation file.

Again, this raised a lot of questions on the part of a number of people from industry because they said, well, if we say we had substantiation files, why do we have to say what we have in there.

The commission's response, which was in the report, basically says, these are the kinds of things you ought to have in there.

The issue about publications being used in connection with sales is a very difficult one, because the law says that the publications have to be balanced. The best example I can give you of the dilemma of the discussions of the commission is that in the Rockville area there is a health food store which I frequent on a regular basis.

Over one of the display racks it says "Dietary Supplements" and then underneath it says "Balanced Literature" and the rack is empty, and then there is arrow that says "Information about these supplements over there" and it is on another rack. The reason is the law says that you have to separate the balance statements in the publications from the physical place of sale.

In this store as you go in, the dietary supplements with this literature rack is on the right-hand side, just past the cash register, the literature rack is on the left-hand side of the store, and that is where you can read all about all the supplements that are in there, and there is nothing written that contains any balance presentation.

Now, that is a little facetious. I think they are pretty smart to do that. There are several problems with this area that the commission wrestled with. How does the wholesaler or the mail-order company handle preparing balanced information? It is not a retail sales outlet.

Secondly, what constitutes a balanced presentation about a dietary supplement? Who is to judge that it is balanced? Does the Ford Motor Company and the Ford dealership put up a sign that basically says, the National Transportation Safety Board has determined that the rear hatch of all of our station wagons is a safety hazard if you put your children in the back seat? That is not true; I guess it was Plymouth.

Obviously, the Plymouth/Chrysler dealers don't have that sign up there. Why should the dietary supplement manufacturers have to have, and retailers have, such signs and such balance presentations in their literature? The commission's recommendation is that there needs to be an awful lot of proactive monitoring and there has not been that much experience yet.

There are five general conclusions, or five general statements, that are in the law suggesting that: this literature has to be neither false nor misleading, does not promote one product by brand name, does present a balanced view, is physically separated, and does not have any labels or anything attached to it. The commission's recommendation is that it is going to take considerable time to see how that is going to shake out, and they are suggesting proactive monitoring.

Perhaps, the biggest issue that the commission faced up to and spent, I think, a significant amount of time debating is that it is no secret from anybody and it is the real world to indicate that there are a number of dietary supplements that are not used for nutritional purposes. They are, in fact, used for prevention and treatment of disease; they have been since early time.

The literature that survives from the 14th, 15th and 16th century primarily are herbals. There has been, in every culture known to man for years and years, the use of plant products, for the most part, and now and even then animal products for medicinal purposes.

The commission does not have any desire to say that you should not be able to market a

dietary supplement, a botanical as a dietary supplement, or anything such as an animal product and then more recently we have things like enzymes and hormones and the like. As long as they meet the requirements of DSHEA, it is perfectly okay, as far as the commission is concerned, to market these as dietary supplements.

However, the commission is reminding everybody that if you make a preventive or a therapeutic claim, then you are not marketing a dietary supplement. If you are marketing it for a medicinal use, you really need another regulatory route in which to market that material. That most logical route there, in this country at this time, under our regulatory system, 4is to have some way to market this as an over-the-counter drug.

If you want to market, for example, Feverfew or St. John's Wort -- if you want to market St. John's Wort, for example, and say that it will give you a feeling of well-being, that is fine, label it as a dietary supplement. If you want to put on the label, "Helps treat depression," then the commission is recommending that it should be marketed as an over-the-counter drug. That created an awful lot of discussion.

There are some suggestions about additional research that are needed. There are also some suggestions about the fact that the nutritionists and dietitians and other people in public health need to be a little bit more knowledgeable about dietary supplements in terms of what they suggest to their clientele.

There is a recommendation that there should be an expert advisory committee on dietary supplement labeling. The suggestion is it would be established by industry, but the recommendation does not prescribe how. The models are the Cosmetic Ingredient Review Panel of the Cosmetic Toiletries and Fragrance Association and the FEMA, Flavor Extract Manufacturers Expert Panel on Flavors. Those were the two examples that the commission pointed to as possible routes of how this ought to be done.

Then I suspect, and one that is dear to the hearts of some of you, and that is, there needs to be more research on dietary supplements in terms of the relationships between dietary supplements and maintenance of health and avoidance of disease and there should be continued support for research.

One of the things, interestingly enough, the commission has a rather strong recommendation for in there says that Congress should support the Office of Dietary Supplements at NIH in a manner that DSHEA specified, and that is, at least a minimum appropriated amount of $5 million a year. The Office of Dietary Supplements has since its inception been getting along on less than $1 million a year and has no research funding on its own.

One of the comments received from the Hill was that, commissions do not tell Congress what to do. There is also a comment in the report that says the commission is an independent agency and was given the authority to make any recommendations that it wanted to.

One of its recommendations is there needed to be more research; more federal agencies should get involved in research. The issue of incentives, I will be honest with you and say I was involved in the "Keystone" report. As Jim knows and Donna knows, most of what is in the commission's report about incentives is taken out of the "Keystone" report.

So, if your incentives group has any more suggestions, I am sure the commission would be happy to at least look at that and incorporate that information in there.

That is about where we are. I hope that we complete this process in the next 30 to 60 days and make the report available. As you know, the secretary has 90 days to announce in "The

Federal Register" whether or not there will be any changes in regulations, based on the commission's recommendations. Then there is a two-year period when all of the recommendations -- excuse me -- all of the proposed regulatory changes have to be finalized.

The other thing I will leave you with is that in the charter of the commission, as an independent agency, there is a phrase that says that once the report is delivered to the president and to Congress and to the secretary, the commission will go out of existence.

One of the folks in the General Counsel's Office at HHS said, who wrote this charter?

I said, "I did." They said, well, we can't have this. We can't have the commission going out of business when its report is delivered because there will be a lot of follow through. I said, "That's not our problem. That's what the charter says."

I will ask questions, I guess, after we have the rest of this.

CHAIRMAN BRANDT: Yes. If you will stay around, then we will have questions after we hear from other folks. I should have pointed out that Dr. Fisher is the Executive Director of the Dietary Supplement Commission. I should also have pointed out that Professor Cohen is also an alumnus of this distinguished committee, so I apologize for not saying that.

Dr. Lewis is going to give us a report on the National Academy of Sciences' report on calcium and other stuff.

NAS RDA REPORT ON CALCIUM, VITAMIN D, {IOn}ET CETERA{IOff}

DR. LEWIS: Thank you, and good morning. I assume this is on. In the next few minutes, I will try to briefly summarize a report from the Food & Nutrition Board Institute of Medicine, National Academy of Sciences. The report deals with recommended intake levels for calcium and related nutrients. It was issued in a prepublication form about a month ago, and I think beginning today it now has been officially printed and is being distributed. It represents about a year and a half's worth of work on the part of the Academy, and it does establish new recommended intakes for calcium and four other nutrients.

If I could have the first overhead, please, which is again the report itself.

The second overhead, the last revision to the recommended dietary allowances, which this report is considered to be a follow up to, the last revision occurred in 1989. It was a process whereby all 19 nutrients for which RDAs had been set were reviewed. The entire report was issued as an entire book, so all 19 were updated at the same time.

In 1989, after they issued this report, the Academy decided to take a hard look at how they had been developing these so-called "allowances." They evaluated the entire process. This began in I think it was June 1993 through 1994. They looked a great deal at how they had been doing business and decided they wanted to do it a different way. They developed a revised approach to establish these reference intakes. I will talk more about that in a minute.

The other two important points about this new report is that it does reflect for the first time a very extensive collaboration with Canada. This new approach is a joint effort with the Canadians, and the values are intended to apply to persons both in the U.S. and in Canada.

Another unique aspect of this report is that it consists of a review done on the basis of nutrient groupings. It is very expensive to do all 19 at the same time and also very cumbersome. Funding, as in all things, is becoming increasingly difficult.

They started by seeking funding for what might be considered to be functional groups of nutrients. The first one funded was the calcium grouping, nutrient grouping. The funds came from NIH, USDA, and FDA.

Can I have the next slide, please?

This functional grouping that was reviewed and was issued last month included calcium, phosphorous, magnesium, vitamin D, and fluoride. Those were the five nutrients reviewed in this initial report.

Can I have the next one, please?

Now, the report goes into some detail as to how they implemented their proposed revised approach. It indicates that nutrient requirements are to be based on optimizing health. In the past, as the report indicates, the emphasis has been largely on preventing deficiency. Along these same lines, the set does consider the factor of reducing chronic disease risk as well as preventing deficiency.

Also, for the first time the Academy examined, in greater detail at least, the need for establishing the safe upper limit of intake. They indicate that because of the increased practice of fortifying foods and because of the use, the widespread use, of dietary supplements there was a need to take a look at these safe upper limits.

Could I have the next slide, please?

Now, terminology is something that we are all trying to get our arms around it at this point, and I think one of the key points is that the RDIs, the "dietary reference intakes," do in general replace the RDAs. The RDIs are more or less a set of different types of recommended intakes. They still do have a recommended dietary allowance; that is, part of the RDIs do include the concept of an RDA.

The RDA covers the nutrient needs of most healthy persons within the age group and in general is established the same way as RDAs have been established before when possible doing two standard deviations above the average requirement. That is the third bullet down there, the estimated average requirement, the "EAR." They take the EAR to develop the RDA. The EAR, as I understand it, meets 50 percent of the requirements in the group. It is more or less a median.

If there is a lack of scientific data to set an EAR, the Academy will establish what is known as an adequate intake, an "AI." This value is more likely to be based on observational and intake data, and so therefore is a somewhat softer number.

Then, lastly, of course is the so-called "UL," the tolerable "upper intake level." As described, this is the maximum level unlikely to pose a risk in almost all persons in the population. The Academy goes to a great deal of effort to emphasize that this is not a recommended intake, and there is no implication of benefit for these levels, rather it is a safety issue.

If I could have the next slide, please?

I believe you all have handouts now that talk about the DRIs that have been issued in this report. In the case of calcium, they have established an AI, and adequate intake, suggesting that there were not sufficient data to establish an EAR and therefore an RDA.

The endpoint they used for determining their intake levels were based on the concept of maximal calcium retention, which you can read largely as an issue of bone density, bone mass.

For phosphorous, they did establish an RDA; although, for infants they did do an AI. The phosphorous value, unlike in the past, has not been derived relative to calcium. It does, however, base its conclusions on supporting normal bone growth.

In the case of magnesium, again we have an RDA and the endpoint was largely balanced studies. For both vitamin D and fluoride, we have AIs, vitamin D being based on serum levels and fluoride based on caries prevention.

Could I have the next?

The handout that you have I think on one side gives you the RDAs and AIs established now in 1997 and on the flip side gives you the old RDA values from 1989. One of the first differences you might notice is the fact that the age groupings have varied. The Academy reports that having looked more closely at physiological stages of development they feel that this set of age groupings is more appropriate, based on more evidence.

In the case of calcium, the values issued last month are generally higher, in fact in almost all cases higher. In one case, it has moved from 800 to 1,000 milligrams and then the highest has moved from 1,200 to 1,300 milligrams; that is the adolescents.

It is interesting to note that the value for infants has actually decreased, but the Academy this time has based the nutrient requirements for infants on the values found in human milk.

In the case of phosphorous, some have gone up and some have gone down. The changes are not fairly large, however.

Then the second slide?

In the case of magnesium, again some values have gone up, some have gone down, most are somewhat higher but there really isn't a large set of differences between the two.

In the case of vitamin D, again some up, some down. I think it is important to note that there is a higher recommended level for persons 50 years or more, compared to the previous 1989 revision.

In the case of fluoride, we did not have an RDA in the past; we had an ESADDI, "estimated adequate safe and adequate daily dietary intake." But considering the fact that fluoride was done in ranges and looking at the values we have here, there has effectively been no change for fluoride.

May I have the next slide, please?

A lot of people have taken a close look at the UL values, the upper limit values. In the case of calcium, they could not establish one for persons less than a year of age, but 2,500 milligrams is the safe upper limit for calcium for all the other age groups.

The ranges that you see here are not ranges for the values themselves, but they reflect the age groups. In the case of phosphorous, the youngest age group is 3 grams and the older, larger age groups, if you will, are four. In the case of magnesium, depending on age group, it ranges between 65 and 350 milligrams, vitamin D is 25 to 50 micrograms, and then you can see fluoride is a very wide range of .7 to 10.

Okay. In terms of what happens next, if I could have the next slide?

We did receive the report in a prepublication copy about a month ago, and we are actively reviewing it. As I mentioned FDA was one of the funders of the report. At this point, we have not decided, nor is it clear, what type of impact or what type of changes this might mean for us.

Certainly, one of the questions that is always asked is, does this mean that it will be necessary to change the reference labels, reference values, for the food label. Of course, we have not yet reached a decision on that. If there is a need to change reference values based on this report or others, it certainly is subject to notice and comment rule making, so nothing would be done without a considerable amount of open public comment.

Probably, one of the key questions we have to think about is the fact that the label reference value at this point is 1,000 milligrams. The highest value in this report is 13. If you continue to consider the need for the reference value on the label to be the highest value, it means about a 300 milligram change as far as the reference value.

We have to balance that against the cost to the industry and ultimately consumers for

changing the food label, as well as the fact that because the Academy is doing this in groupings of nutrients, as we will talk about in a minute, we have another report on folate and B vitamins coming due next spring.

So, there is some interest and concern about piecemeal changes as opposed to larger perhaps more combined changes in the future. At this point, as I did mention, we are reviewing the report and no decisions have yet been made.

If I could have the last slide, please?

I suppose an important question is, What is next for the Academy? They do at this point have funding to consider folate and certain related B vitamins. That is the next nutrient functional group that will be out there. If they are able to hold their schedule, they report to us that they will be able to present a report probably in the spring of 1998.

In addition, at this time funding is being sought and has been found in part for review of the so-called "dietary antioxidant nutrients." What exactly these involve is not clear, but it would certainly be nutrients such as vitamin A, vitamin E and vitamin C. Again, that particular task order has not been finalized, so obviously no date as to when it might happen is clear at this point.

Yesterday, the Academy did present the report officially in a symposium, a public symposium. I suppose in many ways, as far as how the academic and consumer groups and what not will respond to the report, the jury is still out. I think for a number of people the use of an AI instead of an RDA for calcium was a little bit of a surprise, and they need to think through the ramifications of that.

I think what was perhaps brought out yesterday at the public meeting -- or was it Tuesday, I guess, at the public meeting -- was the fact that we now have quite a bit of terminology running around.

We have RDIs, RDAs, EARs, AIs, and ULs and that perhaps we need to consider ways both to think about what is the most useful approach in terms of terminology and also better ways on how we get a handle on using these various subfractions of what is now known as the "dietary reference intakes."

The handout that you have, I think, gives you all the information separate from the report. I do understand the report, if not available soon, will be available very soon.

Thank you.

CHAIRMAN BRANDT: Thank you very much. You are going to stay for a while with us?

DR. LEWIS: I will stay.

CHAIRMAN BRANDT: Now we have our good friend Dr. Elizabeth Yetley, who has been with this committee on a number of occasions, who is going to talk about ephedra.

EPHEDRA PROPOSAL

DR. YETLEY: Maybe I could have someone help with overheads also?

This is one of those issues like folic acid, which seems to go on and on and on and on, but we continue to make progress.

If I can have the first overhead?

Maybe you could go just to the second one. It was just a title. Just go on to the second one.

Just to give you a little bit of reminder, since a number of you have been involved in several steps of this process, what has the process been to date. In October 1995, we did convene

an ad hoc working group under the umbrella of the Food Advisory Committee to look at what we saw as an emerging problem. At that point in time, we had over 300 reports of adverse events and a fair amount of information on products in the marketplace, and we wanted to get some read on the situation.

As we were working with the conclusions and recommendations of that group, which were somewhat difficult for us to deal with because there was not always consistency between some of your recommendations and what the adverse events were showing us, within a few months we started to have a very rapid increase in the number of adverse events. It almost doubled over the next six months.

We had the deaths of two young men reported on these products: one a young man reported on a street drug alternative, a single very high dose of the product; and the other was in a young man who had been using a bodybuilding product for several years, a very low level, chronic exposure which had resulted in chronic toxicity.

Given the new information, the vastly changing situation, we reconvened our working group along with the full Foods Advisory Group in August 1996. I think we had a very fruitful discussion. We got a number of recommendations, and at that time we started to work on a proposed rule.

The proposed rule was finally published in June 1997. We gave it a 75 day comment period. We have just extended that comment period for another 75 days, and I will talk about that in a few minutes.

Next slide, please?

For those of you that are not familiar with the ephedrine alkaloid containing dietary supplements, let me give you just some brief overview. The common names for the botanical sources of the ephedrine alkaloids are such things as ma huang, ephedra, Chinese ephedra, epitonin. There are other botanical sources besides these, but these are the most common.

The botanical sources provide a variety and a mixture of ephedrine alkaloids. You can see these on the second bullet: Ephedrine, pseudoephedrine, which you of course recognize from OTC drug products. Each of these has its own unique biological effects, and obviously there are some interactions.

Just as a reminder, these ephedrine alkaloids chemically and physiologically act and look like chemical stimulants. They have an amphetamine-like structure as well as an amphetamine-like effect.

Next slide, please?

In preparation for our August Advisory Committee meeting as well as for the proposed rule, we did find the need to find out what these products were in the marketplace. There wasn't any registration or listing of them. We did identify eventually 150 marketed products. We got the information from those products in terms of label information, ingredient information and what not.

Most of those products contained the ephedrine ingredient as a concentrated extract. Most of those products contained a number of other ingredients which could have, and probably do have, biological activity. There, of course, was the question as to what interactions these might have.

The median number of ingredients in these products was over 20. On analysis of these products, where we looked at the total ephedrine alkaloid levels they ranged all the way from trace to 110 milligrams per serving, and we saw all kinds of products within that range.

Street drug alternatives ranged from trace to 110, as did bodybuilding products, as did weight loss products so that was not a differentiating factor. The claims of course, the intended use according to the manufacturer's claims, were for weight loss, bodybuilding, energy, mental concentration, sexual sensations, and so on.

Interestingly, 85 percent of the products that we looked at already had warning labels about possible contraindications for use or possible adverse effect. The adverse effects that we had seen had occurred with products that had already had warning statements on them.

The next slide, please?

I indicated at the time of our Advisory Committee meeting we had over 800 reports of adverse events associated with 100 different supplement products. The vast majority of these were in young, healthy adults and young women who were asymptomatic prior to the events that they had, and even after they had injuries and illnesses they tended to have normal coronary arteries and what not.

The effects, adverse effects, were primarily cardiovascular and nervous system effects. The first bullet under that gives you the less clinically serious symptoms: the irregular heart rhythms, blood pressure rises and what not. In the more severe cases, we saw heart attack, stroke, psychosis, seizure, and death; again, predominantly in young adults for whom we would not expect such serious injuries and illnesses.

Next slide, please?

Based on the literature we had searched, on the adverse event reports we had, on the advice and recommendations and discussions from the Advisory Committee, we did then publish a proposed rule. I will go quickly through the provisions of that rule.

First of all, we proposed that a dietary supplement product containing ephedrine alkaloids would be adulterated if it contained on a per serving basis 8 milligrams or more of total ephedrine alkaloids; or if the labeling would suggest a use such that the consumer would take 8 milligrams or more within a six- hour period or more than 24 milligrams in a day.

We also proposed that there be the recommendation not to use the products for more than seven days. This again was based on several factors, the traditional use, as we understood it, was primarily for short-term use. This was certainly discussed at our Advisory Committee meeting. The drug use, the authorized drug uses, tend to be for short-term use, and over 60 percent of our adverse events occurred in users who had used the products for more than a week.

Another proposed provision was that we propose to prohibit the combination of an ephedrine alkaloid source with a stimulant that could act synergistically with it. We specifically gave examples of caffeine and Yohimbe and we ask about other possible interactions that might have adverse effects.

Another proposed provision was that we propose to prohibit any claims that encourage long-term use. Again, this was the idea that most of the serious injuries and illnesses had been associated with long-term use.

Our Advisory Committee had discussed the fact that they were not aware of data to support benefit claims for weight loss and bodybuilding and what not, and so we proposed that these types of claims would be associated with unsafe use as we knew it and that they would be prohibited.

Next slide, please?

Additionally, for those products that had claims that would encourage more short-term use for energy for an athletic performance, where that person might be just running race or

something and then taking it at that time, we also proposed that it have a warning statement that they not take more than the recommended dose. So, it would not encourage excessive consumption, which of course is what we had seen in some of the cases.

We also proposed that all of the products contain a specific warning statement. The wording of this warning statement is very long, and we hope we get some good comments to help us shorten it.

We tried to focus on that type of information that we felt would be most useful to the consumer to identify those diseases or those medications that a consumer would be taking that the consumer could self-diagnose the risk. If the consumer were hypertensive, he would know that, whereas some of the other conditions the consumer might not be able to self-identify. So, we tried to just focus on those that had meaning for the consumer.

We felt thought that if the consumer was unaware of the risk that he should be warned as to what the early symptoms of risk were -- the headache, the general malaise, the dizziness and what not -- and recommend that they stop of they have those and consult with their physician so they knew what to do.

We recommended that this warning statement start with the word "warning" so that it would catch the attention of the consumer, and so on and so forth. We tried to make this something that the consumer had enough information to take action about.

Finally, we articulated a policy that we would like comment on, and that policy suggestion that we put out in the document was that we would like to find that street drug alternatives are drugs and do not come under the scope of the dietary supplement or under the scope of the DSHEA.

We did not feel that they were intended to supplement the diet; their intended use was radiational, not what Ken talked about in terms of supplementation of the diet.

Last slide, please?

We have just recently extended the comment period. There were a couple of documents, one came out on August 20 and one came out on September 18, and there were a number of reasons that sort of converge to convince us that this was an appropriate action.

We had discovered that on a few medical records that were in the docket. The contractor had failed to Xerox the back side where there was writing on the back side. That was not very many. Interestingly, no one noticed it, no one brought it to our attention. We happened to find it ourselves.

Then in correcting that, there were a number of other things that would help, we felt, with making the docket more usable. The contractor had pulled product labels which were in the files. Those are handy to have when you go through those files. The information is there in other forms, so we have reinserted those. There were a few redacting errors.

There was a great deal of concern from the small business community and the Small Business Administration that the size of this docket was overwhelming to the small business community. There are a number of small businesses in this particular area.

There was concern from the docket management side that the docket had grown sort of by leaps and bounds. We had put adverse events reports in the docket at the October working group in 1995. We reput them there with updates if we had them in August of last year, and then we reinserted them to support the docket.

So, here you had the same errors packaged three different times. Oftentimes, they had grown because we had updated them as they went. It was very confusing to users of the docket

to have the same number three times, and they didn't know which one to do. We have consolidated all of those into one, made it much more usable in terms of indexing and guides and what not.

We also have added new information that became available to us subsequent to the original publication of the proposal. We obviously did not rely upon that, but we felt that because we had it, it was useful. We did have a number of new adverse event reports; I think there is about 70. We did have additional information come in on the chemical analysis on a number of the consumer complaint samples, and so we put those out there for people who are interested.

At this point -- slide off, please -- we have as of yesterday 267 volumes in this docket. I got a listing. These are one-liner listings of the docket (indicating). I got this in early September. You can see how large it already is and the major commentators have not yet submitted them.

We have had a number, thousands, of letters from consumers. Many of them are either form letters or they are letters that obviously are following some instructions. They are terribly concerned about the fact that they believe we are going to make ephedra unavailable to them or that we are basing our decision on an anti-supplement mode, rather than on the science and the data.

We have a few, a very few comments, from health professionals. We have a few comments from victims some of whom we were aware of, some of whom we were not. But there are many, many, many pages to go through as we start to review this docket.

CHAIRMAN BRANDT: Okay. Thank you very much.

Now questions for any of the three presenters from anybody? Yes, sir, go ahead.

DR. BLACKBURN: I would just like to comment. I think there are only a couple of us who have been here throughout all the proceedings on Ephedra and agree with you on the ambivalence and ambiguity of our recommendations to you and really congratulate the group that came up with such a concise and strong report, and I hope we will all have the background to stick behind your report in the face of these comments.

CHAIRMAN BRANDT: Also, I have been advised that you need to say your name before you comment. That is my fault, not yours, because otherwise we are not going to know who is talking. All right. Other questions, comments from anybody on the committee?

Yes, sir?

DR. CHASSY: Yes. It's Bruce Chassy. I guess a question on the Supplement Commission. I notice that there was a requirement for I guess the documentation for safety and efficacy. What does "efficacy" mean in that context? Did the commission talk about that?

DR. FISHER: The context that the commission used the word "efficacy" is effectiveness or benefit from use.

DR. CHASSY: What is "sufficient documentation" or evidence?

DR. FISHER: I am hedging, Dr. Chassy. I am not hedging I am just selecting my words carefully. You recognize, I am sure, that efficacy and benefit when you are talking about a drug relies primarily on double-blind clinical studies.

Benefit of food is an inherent quality of a food because a food provides nutrients and energy. With dietary supplements that contain nutrients, clearly the benefit is the provision for nutrients that may or may not be present in the diet in sufficient quantities to meet the needs of the individual.

There also is in the dietary supplement area the considerable body of information that involves long history of use, traditional use, anecdotal information, and the like which is insufficient for drug claims, but yet that body of knowledge exists.

I believe it is fair to say that the commission is of the opinion that that body of evidence should be taken into account. That was one of the issues that lead to the suggestion that there be an expert advisory committee looking at label claims that would, in their process of review, look at this body of knowledge and make some type of public statement in some kind of report about a dietary supplement somewhat analogous to the reports that come out of the cosmetic ingredient review or those that come out of the FEMA review or the reports, which obviously I know a little bit more about, and that is, the report of the review of the substances that were generally recognized as safe.

For example, review of the composition, a review of the chemical composition, physical characteristics, consumer exposure, the biological information that comes from in vitro studies, animal studies, human exposure, and clinical studies. Now, did the commission come to some discreet, clear little chart? The answer is no.

CHAIRMAN BRANDT: Other questions or comments? Yes, ma'am, Dr. Clancy?

DR. CLANCY: I noticed -- Kate Clancy -- that one place in the report it says that if proprietary research is the source of some of the information that that has to be noted. I have a whole bunch of questions, but I will ask one first and I may not have any questions after that. Is there much use of proprietary information as the basis for either claims or statements on labels?

DR. FISHER: For dietary supplements?

DR. CLANCY: Yes.

DR. FISHER: For some dietary supplements there is a body of both long history of use as well as clinical study, and some of that is proprietary, yes.

DR. CLANCY: That being the case, how is proprietary information handled in terms of any kind of FDA or even commission thought or FDA oversight in terms of claims and marketing?

DR. FISHER: I can't answer for FDA. I do know that in the review of prescription drugs proprietary information can be reviewed, is considered in the review, but remains a part of the docket that is not open to public inspection.

Isn't that correct, Chris?

That's right, you all are on the food side. With dietary supplements, I think the commission was thinking along the same lines. Part of the thinking of the commission in this area is spurred by an issue which you will discuss later, and that is, there are very few incentives for the dietary supplement industry to do clinical research. Because once they do that research in the present regulatory climate and marketplace, that research becomes a matter of public knowledge, and therefore all competitors would have knowledge of the clinical research.

DR. CLANCY: That is exactly the reason I am bringing it up right now, because I have a lot of concern about that. So I have another question, and that is; is there any feeling about what percentage of the total amount of evidence given for a claim could be proprietary? Is there any cutoff point? Could it become a majority of the evidence that was proprietary information on which a claim was being based or a marketing plan?

DR. FISHER: There was some discussion of that, but there is nothing in the conclusions and recommendations about the percentage of evidence.

There is a hierarchy developed about which is I would think is consistent with what has been proposed by a number of organizations. You have anecdotal information; you have history of use, you have history of use in many cultures than you have information from use under noncontrolled conditions; and you have in vitro studies and then you have animal studies and then you have human studies. Some of those human studies extend to the double-blind placebo control type as "the gold standard."

If you are asking me is the commission aware of any double-blind placebo control studies that have been done on dietary supplements that are on the market, the answer is, yes, there are a few. The two that I am thinking of right now are, in fact, proprietary.

DR. CLANCY: One last question. That is not very many. But if there were to be more, how would the public be made aware of how much of the claim base was proprietary information and how would the statements that the commission is asking for with regard to the safety and efficacy statements, how would those be written if some of that was coming out of proprietary data?

DR. FISHER: That is a good question which I will ask the commission next week. I honestly can't answer you.

DR. CLANCY: Okay.

DR. FISHER: I think one thing I did not say, when I made the presentation, is much of the thinking of the commission is guided by the phrase "in the charge to the commission" that relates to the fact that the commission is supposed to look at the manner in which the consumer is provided with adequate information in order to make informed health care choices for themselves and for their family. {IOn}{IOff}Ipso facto{IOn}{IOff}, that means that all parties should provide as much information as they possibly can so the consumer can make a decision.

DR. CLANCY: Exactly. I mean, that is the basis for my question.

DR. FISHER: I realize that.

CHAIRMAN BRANDT: Okay. Any other questions or comments? Yes, go ahead.

DR. ASKEW: Wayne Askew. I have a question for Dr. Lewis with regard to the RDAs and dietary reference intake values. I, too, share the concern that perhaps we are getting this whole business so complicated that these values that they come up with are going to be less useful because the average person will not be able to understand what they mean. Did they state what the difference between the AI and the ESSAI was that we used to use?

DR. LEWIS: There is not a lengthy discussion in the report. I think there was a feeling, as I read the report, that there was some threshold that could not be defined and they have done away with ESADDI. Where AI would end and an ESADDI, if it were to exist, is not clear from reading the report. My sense from how I have seen the internal discussions is that an AI is somewhat stronger than an ESADDI, but where exactly is not articulated. It might vary nutrient to nutrient.

DR. ASKEW: Well, that is my feeling too. The fact that they came out with an AI instead of an RDA for calcium I understand the thinking that went into it, but we basically had an RDA established for calcium and now we are saying, well, we are less certain but we think it is more. I think that is just a little confusing.

DR. LEWIS: We have talked to the Academy about some ways, perhaps, of clarifying both what these different terms mean and how they might be used. If you do read the report in terms of calcium, their endpoint is now what they are calling "maximal calcium retention."

There is quite a bit of discussion about the fact that you cannot measure calcium directly,

some serum measure or whatever, and therefore the available studies are less clear than they would have liked for an RDA.

CHAIRMAN BRANDT: Okay. We have time for one more question. Dr. Benedict?

DR. BENEDICT: This is Steve Benedict. I would like to ask Dr. Yetley, with respect to what I read, that is very nice on the ma huang, but the thing that I didn't see addressed, perhaps I missed it, is the noninformable consumer, like a 16-year-old child, and I didn't see any protection in there for those individuals. I am just wondering what the nature of the discussion was and whether anything else could be considered at this late date.

DR. YETLEY: Well, certainly you could give comments to the docket to that effect. We did, in fact, raise it in the preamble and ask for a comment on that particular issue. There has been a number of reports of abuse in teenage adolescents, but they are primarily with the drug products, with the ephedrine-containing and pseudoephedrine-containing drug products.

We had almost none of those reports in our docket on the food side, and so that did not give us a very strong basis on which to make that kin of a proposal. However, it was an issue that had been raised by our committee.

It was an issue that had been proposed to be addressed by the industry, and so we did ask for comments specifically on it, because it was sort of one of those things that we lacked a lot of evidence, but yet it was a concern that had been raised and appeared to be a real concern.

DR. BENEDICT: Thank you.

CHAIRMAN BRANDT: Okay.

DR. CHASSY: This is Bruce Chassy. Just kind of following up on that question, How did you deal with the notion that people might well be taking some of these products to a specific pharmacological endpoint, and therefore might ignore the recommended dosage looking for a desired effect? Then, quickly, have you looked at what all of this discussion for the last two years has done to the marketplace, the products that are now out there?

DR. YETLEY: If you go to some of the health food stores like Ken Fisher goes to, some of the products that we had identified in our survey a couple of years ago as containing ephedrine alkaloids no longer list those ingredients on the ingredient list, so presumably they are not there. At the same time, you have new products being introduced. So, I don't have a good sense of the marketplace, but there certainly still are products there.

Your first question was relative to the issue --

DR. CHASSY: Of recommended dosage.

DR. YETLEY: Oh, and the possibility that if people would not follow -- or if this doesn't work, what then, I think is the issue.

DR. CHASSY: Let me clarify. If people are taking this for a specific feeling or anorectic effect or whatever and they don't get it from an 8-milligram tablet, why are they not going to take three or four or five tablets?

DR. YETLEY: That is, obviously, an issue that is a concern. One of the discussions that we had in the preamble was that very discussion, and a warning on our part that if this doesn't have the desired effect once implemented, then we might need to come back and revisit and make another change. I think at the same time using the data we had, in terms of use patterns and effects of those use patterns, we have tried to be as consistent as we could with what the data was that we had.

CHAIRMAN BRANDT: Okay. I love that term "noninformable consumers." I always thought when my sons were 16 they were noninformable on a lot of things.

Dr. Rader, vitamin B12 fortification.

VITAMIN B12 FORTIFICATION

DR. RADER: Thank you.

I will operate on the theory that brevity is the soul of wit, and I have only overhead. I think I can talk you through this issue that we have or just a topic that you may or may not have any familiarity with.

Last August, we received a citizens petition that requested that we cofortify every food that was to be fortified with folic acid with a specified amount of vitamin B12, and that amount was given as a minimum 25 micrograms per 100 grams of the folic-fortified foods. The petition sought to require this in every case where folic acid was in a cereal-grain component of a food or was in the cereal grain itself as the sole ingredient of a food.

The second part of the petition requested that we take from the market any supplements that contained folic acid that didn't contain B12 or that had folic acid in B12 but had any other vitamins and minerals.

This was a very complicated request, but their petitioner wanted B12 in ever supplement containing folic acid and then in that universe then removing everything where other vitamins and minerals of any type were also included with the two major B vitamins. Now, the justifications for these two requested activities, the first one was the petitioner --

DR. LARSEN: Excuse me a second, Jeanne.

DR. RADER: I'm sorry.

DR. LARSEN: Can you bend the microphone down a little bit? Because when you turn towards the screen, we can't hear you.

DR. RADER: Oh, I'm talking to the ceiling.

DR. LARSEN: Yes.

DR. RADER: I'm sorry. The justifications were that our fortification program was going to cause nerve damage, due to folate mass pernicious anemia in certain groups of the population. The groups identified were elderly Americans, which unfortunately were people over 50, which probably includes most of us in the room, and young African-American women in whom pernicious anemia has an earlier age of onset.

The second, the justification for the supplement change was some data from in vitro studies that in the presence of some components of dietary supplements, predominantly iron and/or vitamin C, that folic acid and B12 might be destroyed or turned into inactive ingredients. So, there were two requests and two justifications.

Now, let me skip down to a minute to the FDA actions. We have 180 day statutory limit in which we are supposed to respond to a petitioner, a citizen's petition. In June of this year, which was after our 180 days, we had to inform the petitioner, that due to resource constraints and other priorities, we had not been able to reach a decision on the petition. The notification went out in June, we are now in September, and we have still not reached a decision on this.

Several things to consider: one is as Chris and Beth both mentioned, the IOM is now working on folic acid, B12 and other B vitamins as part of their second review of nutrient requirements. So, some of the issues raised in the petition are, in fact, going to be part of their review and we are expecting the report by next spring.

Some considerations when dealing just in general terms with a petition of this type are, obviously, do we believe our fortification will cause the damage that the petitioner cited.

For those of you who worked with us a number of years ago on the Folic Acid

Subcommittee, you remember we spent enormous lengths going over safety data. The final regulations proposed and have in effect an upper limit of safe intake such that the fortification is not thought to cause injury on any kind of a scale such as that proposed.

There is a safe upper limit of intake on the fortification. We have set the fortification low enough to avoid injury to a number of groups who potentially might be at risk of excess of intake. Those that we identified as potentially at risk aren't just those that have a vitamin B12 problem.

There were other groups, if you will remember, that we looked at. But the safe upper limit of intake was put in place and the level set low enough to protect a wide range of potential problems that would arise from a much higher level.

Also, we are going to be looking at whether the fortification in that level might be appropriate. The curious thing about the fusibility, again going back, those of you who remember the folic acid remember there was enormous amounts of fusibility data in place at the time we went forward with our folic acid fortification.

We did a literature search on comparable studies with B12. We found one paper in the Japanese literature where a group put vitamin B12 into a meat product. In terms of the fusibility of doing this, we have virtually no information on what would happen to vitamin B12 in terms of what would happen to the amount, whatever amount was put in the foods; what is the appropriate vehicle, are cereal grains an appropriate vehicle for a vitamin that normally is not found in plant products; what are the effects of processing; what about stability. We have virtually no information on this whatsoever. We have a wide range of issues to look at. As I said, the decision is still pending.

Thank you.

CHAIRMAN BRANDT: Thank you very much. Now fortification in Russia, Dr. Vanderveen.

FORTIFICATION IN RUSSIA

DR. VANDERVEEN: I, too, will try to make my comments brief to bring you back into time. Just a little chronology, there is a small handout that is coming around. In the fall of 1996, there was a request for assistance on iodine fortification under the Gore Commission process.

It was stated that Chernobyl had a high rate -- the Chernobyl area that was in Russia and also perhaps the Ukraine had a high rate of thyroid cancer, especially among young children. It was found that widespread iodine deficiency existed in those areas, and that the high iodine, 131, was being taken up very, very rapidly by these children and resulting later in what they called irrio-active iodide caused cancer.

By January, however, it became clear, and let me say that responsibility was given to CDC to work on, but by January 1997 it became clear that the Russians were interested in more than just iodine. They were interested in broad nutrient fortification.

By February, and you have a little handout now, we had a meeting on the 3d and 4th of February in which a number of Russian scientists came here along with their minister of health and representatives from the United States, Russia, UNICEF, WHO, World Bank, food, health, and commodity industries together with nongovernment individuals and had a two day meeting on this subject.

It turned out that the Russians had a perfectly well formed agenda and wanted to only talk about four nutrients: they were iron, selenium, fluoride, and iodine. We agreed to form a cooperative effort, and that is the statement that was signed by our secretary and also by their

minister of health, I should say.

USAID made some funding available to start working on an effort, and we began a planning of a workshop in Moscow to take care of that. A meeting was planned and hosted by the Russians in the late March, early April time frame. The attendance was over 400 people.

It was entirely a Russian show. There were five of us that were sent over to participate. We did make a statement about this cooperative effort, but it was really an opportunity for us to learn about the Russian experience at that point in time.

It was quite clear that anemia was widespread, reported by the Russians in their limited surveys to be as much as a third of the pregnant women were suffering very severe anemia, B vitamins, including vitamin B12, and vitamin C deficiencies existed rather broadly they claimed. The evidence was less clear on that point, and no further discussion of that, I must admit, has taken place since.

There is decreased height in children. Their data on anthropological measurements indicates that children are shorter presently than they were in previous years, primarily due to inadequate protein and calories. Severe problems with dental health; there is no fluoridation occurring presently in the Soviet Union. There was widespread goiter. In addition, there was some cretinism among young infants that were in certain parts of the Soviet Union, and there is no iodine fortification that is occurring.

In addition, there were nine children deaths the previous year due to Kashan's disease, and that was an indication of selenium deficiency. That was backed up by some limited data on biochemical measures for selenium deficiency. It was decided, of course, to concentrate, as I said earlier, on the four nutrients: Iron, selenium, iodine, and fluoride.

Let me say next that we therefore decided that there should be a plan put together and the Russians invited us back for a joint workshop in which experts from the United States participated, and I might make comment that other countries did participate as well. This workshop took place in late June, early July in which we sent 20 individuals from the United States and from some other countries there to work.

Dr. Yetley and I attended for the FDA. We had specific comments by the Russians as to what they were planning to do, and again a review of the status of these four nutrients. The iodine was the furthest along in their thinking. They had a rather well-planned, well-thought-out -- maybe Beth would like to make some comments on that. I think she did attend that particular area.

We broke up into workshops on these after their presentations took place. It was the furthest along. They had a meeting of all their health officials throughout Russia, and they had agreed that iodization of salt and other efforts should be undertaken to eliminate the difficult problem they had with iodine deficiency in that country.

I might just mention that they did have iodine fortification some years ago apparently. I am not quite sure why they quit, except for the fact that they have given various excuses such as the quality of nutrients that were being added were inferior and caused problems. They did not have the money to continue doing it. There was no longer a problem so they quit. You know, I got a lot of these different reasons why they quit, but fortification was stopped.

Now they are waiting for legislation to implement it nationally; although, we indicated that there is not legislation in this country and many other parts of the world to require fortification of, to add iodine to salt or other activities. They felt they needed national legislation to force this matter along, and perhaps they are right on that issue.

Secondly, I will just address the issue of fluoride. That is also making progress. The Colgate Company has entered into a partnership over there, and has brought technology for adding fluoride to dentifrice; although they had this knowledge, the quality, again of materials to be added and the products that were being imported, was inferior in this regard.

Dental caries, again a very, very serious problem. There are hardly any children in grade school that do not have significant caries. Again, there was a reason to want to move in this general area.

We have now decided to do a demonstration project in Russia of a small community water supply in which we would purchase equipment and bring it over there and show them how to do fluoridation of their water supply. Again, the questions surrounding that are up in the air.

Next I will talk about iron. I did participate in the iron activities. Even though they have serious iron problems, they had not come to grips to what to do. They wanted to do a whole host of research projects including development of supplements, development of materials to be added to foods.

They wanted to look more closely at why they had the problem of iron deficiency in young children and adults. We pressed hard to try to tell them look, that technology is there; this is well known how to do fortification of iron; it has been successful in large parts of the world. We eventually got them to agree to put together a protocol to start a demonstration project on fortification of iron.

Let me say further that, at a later time, I did visit a flower mill. The millers are perfectly willing to get on with it if the resources are there to start fortification. We also indicated that Russia certainly is capable of putting together a high quality iron fortificant that could be added to foods and they have the opportunity to do that. The technology is there, et cetera, et cetera.

We are waiting to see what their demonstration project is going to be. I am told that it will probably be very long before we see it. Nevertheless, we are continuing to press them on this issue.

Selenium, the last issue. Orville Vendor, from the U.S. Department of Agriculture was our senior representative on this issue. This is less defined than any of them. There is, indeed, some indication that Kashan disease does exist around the Lake Bacall area of Russia and is something that needs to be addressed. Our present thought is perhaps we ought to send wheat from North Dakota and South Dakota over there, since it is high in selenium and that would help solve the problem.

In fact, we have talked to the Foreign Agriculture Service of this government. There are monies to try to do a demonstration project of bringing wheat over there and working on that. They do have some other opportunities, a high yeast selenium product that is being made.

I just have some observations I want to quickly indicate. Many of you have already been to Russia and know these things, but it was an eye-opener for me. The Russians are very limited in resources. I was appalled at the Institute of Nutrition's resources. You are dealing with a building that is a couple hundred years old and has not been repaired in over 50 years. It is really a very, very difficult situation. However, people are very bright and very capable and they know what to do; it is a matter of being organized to do it.

Secondly, there is a lack of understanding of how industry could be encouraged to do many of these things. The concept of letting industry make a claim for their food that it is fortified was a bit difficult to get across; however, we are starting to see that.

The next thing, all fortified foods in the Soviet Union must be approved by the ministry

of health on a one-by-one basis. It is a shocking situation at this point in time. They have no regulations that are broad. What they do is, a person comes in and submits an application for fortification. It is worked on and approved, and then he may sell that application to other individuals so that they can make the same, identical product.

Clearly, that has to ease up, and we told them that, the ministry of health told them that. They said the problem they had is when Glasnos came and everybody started shipping products into the country this is the only way they could control and keep things there.

Thirdly, medical monitoring, there is very little of it done presently in the Soviet Union in an organized fashion. However, during pregnancy and infant nutrition examinations, they have a golden opportunity because it is required that every woman be seen every month and can follow these and recommend therapeutic means to deal with iron deficiency and other aspects, and the same with infants.

Infants must be seen certain times during the first year of life, and as a consequence there is a great opportunity to deal with that. We told them that, and they are very interested in putting together surveillance systems because these pediatricians are government hires and they can deal with it from that perspective.

Those are my comments. Any comments and suggestions you have I would appreciate.

Thank you.

CHAIRMAN BRANDT: Thank you very much. Are there comments or questions?

Okay. Seeing none, we will now take a 15 minute break. I would advise the members of this committee that Room 417 is where all the goodies are.

(Recess)

CHAIRMAN BRANDT: Okay. We are about ready to start everybody. We are going to begin with the CODEX. To discuss the general aspects of the CODEX, Dr. Ed Scarbrough, who is from the U.S. Department of Agriculture, please begin, sir.

CODEX - GENERAL

DR. SCARBROUGH: Okay. Thank you very much. First of all, I apologize I don't have any overheads or slides. I just haven't had time yet to gin up my self-promotion mill, so I will rectify that very quickly.

What I wanted to do, very briefly this morning, is try to give you an indication of why CODEX is important to this committee and important, we think, in the overall U.S. trade and food safety area. A little bit of background on exactly what CODEX is because many of you may not be familiar with the organization.

Beth is going to then talk a little bit about a couple of our activities in the CODEX. I think that dovetails very well with what I am saying, because it gives an example of how CODEX works and some of the issues that we deal with, and then end up with some of the ongoing initiatives in the CODEX office and ideas on how you might more fully participate in CODEX activities.

Now, the Uruguay Round of discussions on the general agreement of tariffs and trades that concluded in 1994 lead to the establishment of the World Trade Organization as the recognized body for settling international trade disputes.

That same round of discussion, however, lead to adoption by the member companies' countries of two important sets of agreements. These agreements are referred to in shorthand as the SPS agreements and the TBT agreements. SPS, "sanitary and phydosanitary" agreements -- "Sanitary" refers to human health and animal health, "phydosanitary" to plant health -- are

agreements that the SPS recognizes, or the WTO recognizes, as being justified for countries to institute to protect the health and safety of their consumers, their livestock, their wildlife, and their plants including important food crops.

The countries who signed the SPS agreements also agreed that these measures should not be used as unjustified barriers to trade, and they also agreed that they should be no more restrictive than necessary to achieve the appropriate levels of protection.

That is a key phrase in the SPS agreement because, what is the appropriate level of protection? The SPS agreements then specifically reference international standards, such as CODEX standards, as representing international consensus of what is an appropriate level of protection.

So, the CODEX Alementarius has been formally recognized by the World Trade Organization as a body that is setting international standards that have some validity as benchmarks or reference points in international trade disputes.

The technical barriers to trade agreement covers other kinds of measures that are not food safety or sanitary/phytosanitary. Those agreements don't specifically reference CODEX, but they do refer generally to international standards. The use of CODEX under the TBT agreement is not nearly so clear or specific as under the SPS agreement.

Well, now that this body has been recognized by the World Trade Organization, what is CODEX Alimentarius? Well, CODEX Alimentarius is the joint food standards program of the Food and Agriculture Organization and the World Health Organization of the United Nations. It was established 35 years ago with the express purpose of facilitating international trade and helping to protect the health of consumers through the establishment of international food standards, codes of practice and other guidelines.

CODEX Alimentarius Commission is currently composed of 158 member countries. It meets every two years and adopts draft and final standards, guidelines, codes of practices and assigns new work to CODEX committees. It is the CODEX committees that do the work of developing standards, guidelines, recommendations, {IOn}et cetera{IOff}.

The commission has set up two kinds of committees. There are 18 commodity committees. These are committees that deal with specific food types: committees on milk and milk products, fish and fishery products, fresh fruits and vegetables, processed fruits and vegetables, nutrition and foods for special dietary use that Beth will talk about in a minute is a commodity committee.

In CODEX terms, it is thought of as a vertical committee dealing with a specific commodity. A number of those committees are adjourned at the present, but the still active ones generate quite a bit of work.

CODEX has also established eight horizontal committees or general subject matter committees. These include food hygiene, food additives and contaminants, food labeling, pesticide residues, residues of veterinary drugs and foods, methods of analysis and sampling, the CODEX Committee on Food Import/Export Certification Systems, and the CODEX Committee on General Principles.

These general subject committees establish criteria, then, that are applicable to all commodities and then they evaluate requests from the commodity committees to afford variable treatment to a specific commodity.

Now, the CODEX Commission, which meets every two years, determines the need for a standard or new work and assigns the drafting of that work to a specific committee. Once that

happens that sets in motion an eight step process that all of these CODEX documents go through.

I will not bore you with the eight steps, but the important point to raise is that in those eight steps, the standards are reviewed twice by the commission and are reviewed twice by member countries. In the United States, that means that all of the CODEX documents are made available for public comment -- including comment by the food industry, trade associations and consumer groups -- two times before they are developed.

Now, the CODEX standards or text, and I think this is very important to note, are not equivalent to national legislation or regulations. They are simply recommendations of the FAO/WHO to the national governments. They cannot take the force of law, unless there is action by an appropriate legislative body in the member country.

A member country cannot enforce a CODEX standard, unless it has adopted that as a standard in the country. However, the CODEX standards do have value as reference points under the international trade agreements. That was what I was speaking of initially.

These, as I said, are considered by WTO to represent international consensus regarding the requirements for protecting human health from food borne risk. A member state's food safety measures are considered justified and in accordance with the SPS if they are based on CODEX standards and related text.

The adoption of a CODEX standard is not mandatory, but failure to apply a CODEX standard by a member state creates the potential for a trade dispute if that state then applies a more restrictive barrier to trade than is necessary to achieve the level of protection afforded by the CODEX standard.

As I mentioned as I started out, the relevance of CODEX standard to the technical barriers to trade agreement has not been established simply because it has not been an issue in any of the trade disputes to date. So, that is a very brief lesson on CODEX and how CODEX is organized and operates.

As Lynn and Dr. Brandt indicated, I have recently moved from FDA to take the position of U.S. Manager of CODEX. We are just getting started with a two year program aimed at having the United States in a very good position at the next commission meeting, to have our viewpoints seriously considered by the commission and by other member states.

Toward that end, we have kicked off a program of nine initiatives. Let me just very briefly indicate what is on our plate. First, we want the CODEX itself to define the role of CODEX standards in the SPS agreements, rather than have SPS tell CODEX how the standards should work.

We see risk analysis as a very important point underlying all of the CODEX food safety measures, and we have started a program to ensure a consistent risk analysis approach across all of the CODEX Committees.

We are developing guidelines for the CODEX delegation so that all committee delegations are operating by the same ground rules. We have instituted a program of delegate training, so that our delegates who represent the United States not only know the CODEX procedures and know the trade agreements, but also have some training in negotiation strategy and how to deal with this international arena that so many of us are very new to.

One of the things, and perhaps Beth will bring this out, is that the CODEX Committee chair has a tremendous amount of power in determining how work goes within that specific committee. We are developing guidelines for committee chairs generally so that all chairs are operating from the same set of guidelines.

The CODEX Committee on General Principles is a key CODEX Committee that meets every two years in Paris. We see that upcoming meeting as being a key meeting to establishing how CODEX will operate in the future.

CODEX is staffed by a secretariat in FAO in Rome. FAO, like all other U.N. organizations, is having budget difficulties. One of the ways that FAO has addressed the budget difficulties is to cut down on the size of CODEX meetings and the length of CODEX meetings and to discourage any working groups, and yet in the past the working groups have been some of our most effective means of advancing text through CODEX.

We have established an initiative within the U.S. CODEX office to advise or bring our recommendations on Rome on the appropriate role of working groups and how they may be more efficiently and economically handled. We need to look at CODEX under the TBT agreements and see how and where CODEX standards fit into that.

Our final initiative, and one that is perhaps the most important, we want to increase the participation of nongovernment organizations -- consumers, trade associations and professional groups -- in the CODEX process.

One of the ways we are trying to help participation in CODEX, and in your briefing book, is that the CODEX office has established a web page. That web page is updated practically every week. All of the activities of CODEX go up, the meetings that we have, the documents that are being developed. The web page affords a link into the FAO site in Rome so that anything that comes out of Rome is immediately available through our home page at USDA.

The briefing book gives a home page or a worldwide web address. If you want to get into the U.S. CODEX home page, you simply can go in through the worldwide web, "USDA.GOV," click on "Agencies," and under the Food Safety Inspection Service, "FSIS," you will find CODEX. Click on "CODEX" and you are into our home page with a tremendous amount of hot, up to the minute information.

We also have provided, in your briefing book, the U.S. CODEX office address, telephone number, fax number, and our AOL E-mail address. If you have any questions or want any further information on a specific issue or just want more information on CODEX in general, please feel free to call us or send us a letter at the U.S. CODEX office because we are very anxious to increase participation by all groups in what we see as an increasingly important U.S. trade and food safety issue.

Thank you.

CHAIRMAN BRANDT: Thank you. Now we will discuss the dietary supplements aspect of CODEX. Dr. Yetley?

DIETARY SUPPLEMENTS

DR. YETLEY: Thank you.

I am not quite sure why supplements were picked on particularly as an example, except that once again Bill Clinton and I are the daily recipients of many letters of objection as to what is happening with this vitamin/mineral supplement document.

I am the U.S. delegate to the Committee on Nutrition and Food for Special Dietary Use of the CODEX. This is a horizontal committee that deals with technical issues, with scientific issues related to nutrition.

At our October 1995 meeting, which is held in Germany and the German delegate is the chair of those meetings, the German Government indicated that they were going to put forth a proposal for standards for vitamin and mineral supplements.

As part of this proposal, they would have a philosophical statement as to the need and appropriate use of supplements, vitamin and mineral supplements. They would list exactly which nutrients could be allowed to be added to these. They would set a minimum level; they have now proposed 15 percent of the RDI. They would set a maximum limit, which right now is proposed at 100 percent of the RDI. They would have a positive list of allowable ingredients. And, they would allow for the same kind of labeling claims you have for food claims, and under CODEX this would not include health claims.

At that first meeting where they flagged or gave this information that they intended to do this, there was a lot of opposition to this including the U.S. Government's, since it is, of course is inconsistent with both our Proxmire amendments as well as our DSHEA. The group decided, however, to go ahead.

In October 1996, a year later, the German delegation did have a formal proposal in front of us. It was a very contentious discussion. The majority of the countries were in favor of this document. It was opposed, however, by the U.S., by the Canadian Government, by the U.K., and by the Japanese.

It was at its first step of discussion, the step 3 step, as Ed has indicated. There was so much contention about so many parts of this document that a large number of the document is in so-called "square brackets," which means that we could not agree as to what position we should take.

The German chairman, however, again Ed's point, I guess that the chairman can be very powerful, decided that this was such an important issue, despite the fact that there was no consensus, that the decision was made to fast track it forward, and they promoted it to a step five.

It then went before the commission this past June. We worked with Tom Billy and the other members of the U.S. delegation, Fred Shank, at which time the U.S. went forward along with Canada with a position that said, "Our preference is that you drop this. This is something that should be handled by national governments. If you don't, however, we suggest that you go back to step 3."

They were successful in getting it moved backward to step 3. The committee was asked to relook at it again in step 3 and also to reexamine whether or not it is needed. It has, however, really alarmed a number of consumer advocacy groups for the supplement industry. That is why we have had the write-in campaign, and it is of course viewed by the supplement industry itself as a potentially serious trade barrier if they want to export their vitamin/mineral products to other countries in the world.

We have suggested, the Canadian and U.S. Government has suggested, that, if they decide to go forward with setting upper limits, that they use a risk assessment approach rather than just some percentage of the RDI. I think that will be one of the more contentious issues next year at our meeting, which will be in Berlin, I think it is in October, a year from now.

We do have opportunity to comment on the current draft. I think those comments have to be in in January so we will be sending out the current draft very, very shortly asking for comments. We may have a public meeting to see where to go with it.

The other document that was equally controversial was one that had been proposed by the Canadian Government to look at botanicals that would be used as food products, as dietary supplements under food jurisdictions.

Basically, what this proposed is that we have a positive list or we have a list of botanicals that would not be allowed in foods because of their potential safety concerns.

At our last meeting, this was referred to WHO for consideration for an expert consultation. That created quite a firestorm and quite a backlash from consumer advocate groups. That issue came up before the commission. The commission on that particular issue last June did drop that proposal, so that now is off the books.

CHAIRMAN BRANDT: Okay. Thank you very much. Now Ms. Karen Carson will tell us about the Food Safety Initiative. How many of you attended that meeting, that was held here in Washington, on the committee?

I know I was. Yes, several of us did. Okay. Where are you? Oh, there you are.

FOOD SAFETY INITIATIVE

MS. CARSON: I have got some slides. Is it on? I've got to click this.

CHAIRMAN BRANDT: Bring that microphone down a bit, would you, before you start talking? Yes, thanks.

MS. CARSON: Okay?

CHAIRMAN BRANDT: Yeah.

MS. CARSON: Okay.

Some of these slides you may have already seen, and I am just putting them up to remind you what the Food Safety Initiative purpose was, and some of the planned activities and then I am going to talk about the status, what we are doing in some of the areas.

This is the goal of the Food Safety Initiative, to reduce food borne illness and the problem, what we are trying to fix. I am going to go quickly through these and not really dwell on them.

The six areas of the Food Safety Initiative: surveillance, coordination, risk assessment, research, education, inspections.

In the surveillance area, the problem is that passive systems are a major problem. The large numbers of food borne illnesses that we see reported, is it real, is it bigger, or is it smaller? The recommendation is that we establish a new safety early warning system to enhance surveillance of food borne diseases.

The first activity that was planned was to add a couple of sites to the CDC's food net site that is supported by FDA and USDA. Two sites have been added in Baltimore and Rochester, New York, in those counties, in those areas. That makes the total number of sites now seven. The others are in Northern California, Oregon, Minnesota, Connecticut, and the metro Atlanta area. One more site will be added next year, and that was in CDC's budget for FY'98.

Modernizing public health laboratories is one of the activities that was planned. A protocol has been developed for collecting and testing stool and serum samples to determine other types of e coli sero types that are pathogenic. That has been done, and creating a national electronic network for DNA fingerprint comparisons.

We are in the process, "we" being FDA, are in the process, of becoming hooked up. All the computer connections are being put in place now. That of course will be extended to states and other agencies that need that information.

Increasing national surveillance for antimicrobial resistance, monitoring for human isolates from humans and animals to include camplobactore, that has been expanded. Some of these activities, when I am telling you what the status is of these activities, we have a tracking system in place.

It is a very simple tracking system where we are keeping track of CDC's activities, USDA's, FDA's. We update that weekly, biweekly, at least monthly. This is a very huge

endeavor obviously. When I tell you what the status is, there may be other things going on and we just have not gotten into the system yet.

Coordination, an important area, the problem being that state and local governments' and the federal government's communication may not be as good as they could be. Efforts are coordinating particularly large outbreaks that involve both federal and state levels may not be as good as they could be so that the outbreak isn't responded to as quickly or as effectively as possible.

The recommendation is to improve coordinated management of the interstate food borne outbreaks. We have formed a food borne outbreak response coordination group. That involves representatives of CDC, EPA, USDA, and -- boy, my mind is going today -- CDC, USDA and FDA. In USDA Katherine Wotecky is the representative, and in our agency the commissioner's office is involved, the Center for Food Safety people are involved and HHS is involved.

This group, the purpose of it is to look at how responses are responded to, I mean, how outbreaks are responded to, the effectiveness. In order to move that forward, that consideration forward, they formed a smaller group to look at a test case, a so-called "test case."

We have chosen hepatitis A in frozen strawberries. That outbreak because it involved several states, several state agencies and several federal agencies they are looking at how communications occurred, what other kinds of interactions occurred, what works well, what didn't work as well as it could have, and what kind of recommendations can be made to improve. That is in process right now.

Research, a very important area, a major concern. There is a nice quote. We have got a lot of agencies involved in spending a lot of money on research and there is no real coordination. The problem is that we have these new pathogens. We have pathogens, of course, adapting to their environments and adapting to preventive technologies that we have used in the past. We need to find out better ways to deal with these.

This is a recommendation. We do have quite a bit of research going on, obviously, in ARS and USDA. USDA, for example, is doing research on irradiation and its use in fresh fruits and vegetables. Methods development, of course, is ongoing particularly in the cyclospore area.

Strategic planning for the research area, I am going to hit a little bit more on that later when I talk about strategic planning in general. We are looking at various ways to do this, so that the strategic planning will specifically be targeted to research.

In the risk assessment area, the problem is we need to characterize the nature and the magnitude of risk to humans and we need to develop methods that are specifically useful for microbial risk assessment. It is far less developed for microbes than it is for chemical contaminants. The recommendation is to develop models for improving risk assessment.

One of the first activities that we had on our agenda was to establish a risk assessment consortium. We are going to do this at the Joint Institute for Food Safety and Technology at the University of Maryland. We are in the process of doing this, of establishing this center.

We have formed, in house, a risk assessment team and an advisory group and interagency participants; that is, representatives of other agencies have been contacted. There is a meeting planned. These are the membership that we have identified as being essential to this consortium. We are planning a meeting in late October, early November to start setting out exactly how and what the consortium is going to do.

These are the other two major areas that we will be looking at in the risk assessment. In the inspections area, this is the problem, too few inspectors, too much work to do and we inspect

on the average only once ever 10 years.

In the status area, in HACCP we have published a notice of intent in the juice area that lays out three things that we are going to propose: mandatory HACCP, that we are going to have an education program for industry and consumers, and in the interim there will be warning labels on products that are not pasteurized or have some sort of a step that will give the equivalent protection of pasteurization.

In the education area, this is probably the area where the most activity has gone on. The problem, of course, is that people are not aware, or as aware as they should be of the sources of contamination: where products, how products get contaminated and how they can prevent that by safe food handling.

There is more definition of the problem and the recommendation is to target education and messages to target two groups, consumers specifically to start off, to change their unsafe food handling behaviors.

Right now, the emphasis, the majority of the activity is in the consumer area. On May 12, the Food Safety Education Partnership was formed. It is a partnership of industry, consumer groups, state groups, and federal agencies with the object of changing consumer unsafe food handling behaviors. The industry has committed more than $600,000 to this effort, to the agencies and the consumer groups; the state groups have committed technical assistance.

The money from the partnership is being used to develop the campaign slogan, that has been done, and educational materials to go along with it. There was a conference for educators, this was not part of the partnership, in June that Hillary Clinton attended.

September, this month, is promoting that as the "National Food Safety Month." That is sort of piggybacking on the National Restaurant Association, they have declared this "National Food Safety Month" in the past, and we are piggybacking on that and promoting it. Then a national food safety campaign aimed at consumers will be launched later this fall.

Research to identify barriers to why messages are not getting through to consumers and other groups about safe food handling behaviors, that was used to develop the slogan and the materials that will be used in the consumer campaign that will be launched later this fall. However, that needs to go on. We need more of that kind of research.

Under expanding existing information systems, a list server has been established. That is the address (indicating). Improving veterinary and producer, these other groups that education will be targeted to, these are later in the initiative. These have been scheduled for later or long-term activities, and I think you will be seeing those come up in the plans for the next step in the Food Safety Initiative.

Strategic planning, this is an overall strategic planning process for the entire Food Safety Initiative. We have started work on this. We have started laying out options for a process, to begin with a process for strategic planning that will be effective, give us a long-term view of what food safety needs are in the future 5 to 10 years down the road, and then for actually carrying out the process. This strategic planning process has already begun too.

Any questions?

DR. HARLANDER: The strategic planning process involves all of the federal agencies that are involved in this Food Safety Initiative?

MS. CARSON: At this point, the process itself will not just involve the agencies; it has got to be a very public process. What we are doing right now is just trying to lay out the options for a process that will get the largest input from the greatest -- the broad scope of people

concerned about food safety industry and everybody else.

CHAIRMAN BRANDT: Other questions?

DR. CLANCY: Yes. None of this deals with prevention. Kate Clancy. None of this plan deals with any kind of prevention of the contamination in the first place.

MS. CARSON: No, that is not true.

DR. CLANCY: Okay. Well, I have not seen much of it. Is there a document that articulates all of the activities that are out there, particularly within USDA, that would prevent contamination in the first place with these activities?

MS. CARSON: No.

DR. CLANCY: Do you have anything that describes that?

MS. CARSON: No, not what you are describing at this point.

DR. CLANCY: Okay.

MS. CARSON: You have to realize we are in the starting stages of the Food Safety Initiative. What I am describing here are things we have done with the money we had in our budgets for '97. We will really see more activity with an FY'98 funding, which is October 1. The prevention part, there is prevention all the way. The consumer education is a prevention type.

DR. CLANCY: No. I only mean specifically prevention not of disease, but of the contamination of the foods in the first place.

MS. CARSON: Well, that is what I am saying, education is part of prevention. You have to tell people how those things become contaminated so that they can prevent it; they can have an active part in preventing it. The research part is prevention part. There is a whole area of the research that is preventive technologies.

DR. CLANCY: In terms of production?

MS. CARSON: In terms of processing, production, distribution, everything. Of course, we will be looking at that because prevention is an extremely important -- it is one of the biggest parts of the Food Safety Initiative. So, yes, it is in there.

CHAIRMAN BRANDT: Other questions or comments? Dr. Wang?

DR. WANG: Mary Wang. In the national Food Safety Initiative, the inspection, I view that also as prevention.

MS. CARSON: Yes, that's true.

DR. WANG: The implementing has a type of inspection. Thank you.

MS. CARSON: Surveillance is prevention, too, insofar as we use that data -- it gives us information about where contamination is occurring, what types of products are becoming contaminated, what they are becoming contaminated with so that we can go back, use that information to then guide our prevention, a research that is aimed at prevention and the education that is aimed at prevention. There is prevention in every part.

DR. CLANCY: I would maybe suggest that you even elaborate it more than you have when you are presenting this to consumers, because it does not leap out at you at all that the prevention is there. That is not any kind of language that I have seen coming out of the reports on it, and I think it would be much more effective to use more of that language and to highlight where the prevention of the contamination in the first place at the level of production and processing could occur before it gets into the House.

MS. CARSON: That is a good suggestion, okay.

CHAIRMAN BRANDT: Any other questions? I'm sorry. Ms. Richardson?

DR. RICHARDSON: Maybe I missed it, but what role does enforcement of existing regulations play?

MS. CARSON: Give me a moment to think here. When we went into this, in the inspections area in particular, that did come up, should we increase inspections and enforce more. The decision, essentially, was not that we needed to enforce better. We needed to get people the information they need and then we had to develop the enforcement tools such as HACCPs so that we could enforce better rather than more. Does that make sense?

DR. RICHARDSON: Yes, that makes sense. I guess my concern is that it is sort of silent in that it is part of inspection and in prevention and that there is not a real articulation that there is going to be aggressive, better enforcement.

MS. CARSON: No, those words aren't in there, but that is the aim of things like HACCP, to be more effective in the systems that we are using to enforce with, and to help industry and those people with systems that will provide a safer product at the end and be easier -- not easier to comply, but our object was -- I guess I don't know any way to say it better, but it is to enforce better rather than to go out there and simply hammer people with inspections, a number of inspections. In the long run, that does not do anything. We are developing a HACCP system and putting them in place, so the industries using those will be more effective.

DR. RICHARDSON: Would I be wrong in saying that what you are looking at is more voluntary compliance?

MS. CARSON: No, that would not be voluntary compliance, because once we have HACCP systems in place we enforce those HACCP systems, no voluntaryism.

DR. RICHARDSON: Thank you.

CHAIRMAN BRANDT: Dr. Benedict?

DR. BENEDICT: Steve Benedict. As I recall from the meeting, there were some really exciting concepts discussed with respect to research and some specific things include, ecological concerns at the farm, stress levels on animals during shipping -- a whole host of really exciting concepts.

I am wondering what is the status of directing these research interests and why haven't we seen RFA's and publications suggesting that there will be money available to do this?

MS. CARSON: Well, most of those activities were targeted for 1998 and 1999 were long-term, and we are just now getting into the point where we have the funding to do this. I mean, we would have gotten in a little trouble if we had put on these with no money.

CHAIRMAN BRANDT: Any other comments or questions about any of these presentations?

Okay. The Senate Bill 830 discussion will not be held this morning, it may be this afternoon, it may be tomorrow, it may be never. It is in your book.

We are going to adjourn for lunch in just a moment. But, since Dr. Blackburn opened our meeting with a comment about my age, I am going to tell you a joke that I actually heard on the news as a true story. It turned out a gentleman who was in his early seventies decided to take up jogging for the first time, and people were really fascinated.

A reporter decided to do a feature story and was talking to this gentleman, he said, what advice would you give others your age who want to take up jogging?

He said, they should do exactly as I did. Start slow and then taper off.

I have 11:31, we are adjourned for lunch. Please be back at 1:00 because that is when I am going to start.

(Whereupon, at 11:31 a.m, a luncheon recess was taken.)

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

(1:00 p.m.)

FQPA JURISDICTIONAL DISCUSSIONS

MR. COLEMAN: Mr. Chairman ladies and gentleman, I am on your schedule to provide you with an update on the discussions between EPA and the Food and Drug Administration concerning the Food Quality Protection Act. I don't know how much of an update I can give you at this time on our discussions with the EPA, but I would like to start off our little discussion by saying a word or two about FQPA.

It is my interpretation and I would admit that it has been colored by discussions with others that the significance of the FQPA with regard to how FDA has regulated the use of antimicrobials on food and food processing is that the use of antimicrobials in processed food did not change under FQPA.

However, with regard to the indirect uses of antimicrobials that is on packaging materials and hard surfaces and that sort of thing, these uses which were regulated by FDA as food additives, it is my judgment that these are now considered pesticidal uses, which would make them subject to EPA's regulation.

That is Eugene Coleman's interpretation. I would like to caution you this afternoon that whatever I say needs to be considered as being tentative as best, because these negotiations, the negotiations with EPA, are continuing. It has not only to do with how we might regulate certain antimicrobial uses, but also how we actually interpret the FQPA as it affects our operations. Let me push that little caveat forward for your benefit.

Insofar as the discussions with EPA are concerned, I think that the most I can say at this time is that they are continuing. We anticipate, sometime this fall, publishing a joint notice that will be published in the "Federal Register" that will lay out for you any agreements that we have reached during the course of these several months in our many discussions and meetings, not only will that notice spell out for you exactly what the agreements are, but it will also spell out, hopefully, the underlying legal theories.

There is a good deal of discussion going on as we meet from day to day about exactly what this actually means with respect to our particular -- at least what we have done in the past compared to what we think we will be doing in the future with regard to the FQPA.

I don't know that that really satisfies the purpose for why I am here, but I think I will stop at this point and ask that you present to me any questions that you might have. Perhaps, I can respond to those.

CHAIRMAN BRANDT: Are there questions from anybody?

In any event, negotiations are still underway on the treaty?

MR. COLEMAN: That's right, sir.

CHAIRMAN BRANDT: Okay. Between FDA and EPA. Okay. No questions?

Okay. Thank you very much, sir. We appreciate very much your being here.

DR. LARSEN: When we first asked Gene to come, maybe I should probably make a comment about this, because we seriously thought that the thing, the negotiations, would have been further along and he would have been able to say more, obviously it didn't come to fruition. In fact, some of the things he even thought he could say originally he can't say at the moment. I apologize that we cannot tell you more about it, but I thank Gene for taking the time to come to even spend five minutes with us to at least let you know that we are in negotiations.

REPORTS BY WG CHAIRS FOR
SSA, INCENTIVES, ES AND META

CHAIRMAN BRANDT: Okay. We are now going to turn to reports of working groups. We have allocated approximately five minutes for each working group. The first one is chair of SSA, which is not Social Security Administration, but is "Significant Scientific Agreement."

Dr. Benedict?

DR. BENEDICT: Well, this may take a lot less than five minutes. This is Steve Benedict.

The working group was Significant Scientific Agreement Totality of Evidence, and our charge has been to develop general principles for evaluating data to be used as part of health claims and health claims authorization.

We were asked to provide comments on the utility and the approach that one might have for developing software to guide preparation of health claim petitions. What we hope to produce is a document and maybe in the long-term some workable software, both of which will contain format guidelines for submittal of health claims.

The basic idea that we were given is that the petition and the approval process should both be as straightforward as possible and that concepts and guidelines should be easily accessible and fully transparent to anybody, I guess, that had an interest.

We have had a couple of meetings. Let me back up. I have been asked to just sort of summarize my impression on where we are, rather than read to you the minutes of our most successful meeting, which was our recent one.

We have had a couple of meetings in association with our full committee meetings, and then we had in February of this year a dedicated day's worth of meeting, which I think was extremely successful, during which time we set out to, at least, just come to an understanding of the job that we had to do and then to try to get an outline for a framework of the first draft of the document we wanted to get and then to prioritize things that we thought should be done first.

We were assisted, in addition to the individuals listed in your minutes, by Dr. Yetley and Dr. Steve Woolf who gave some presentations and remained to participate in the discussions.

I will not repeat for you all the things in the "Keystone" document which we dealt with and which we are doing our best to codify into this framework. But some of the other things that we talked about that might be of interest to you are we discussed how can you actually attract petitions that have good science and make sure the petitioner knows what is expected before they begin to submit things that are doomed to fail; of course, what are the guidelines to determine what that would be; again, assuming this is going to be an open process and remain flexible and remain transparent but still try to find a way to standardize things to help people who want to make a petition.

We had some pretty good discussions about surrogate markers, biomarkers and how some exist for some diseases, but for things like cancer, where we could really use this, we don't have any approved biomarkers. We talked about ways to maybe help people get into this business with research, as though people are not already doing that, more biomarkers that we could then take advantage of.

We discussed how to make it easier for the FDA to make a timely response, and it turns out that this is a non-trivial exercise for a lot of reasons, one of them of course being resources, but another one being that no matter how rapidly the FDA comes to a conclusion frequently other agencies are involved and their approval is needed as well and so sometimes, at least as I

understood the discussion, the FDA is sometimes at the mercy of other government agencies.

We had a really outstanding discussion of causal pathways as they relate to the disease process and discussions of whether we could find intervening steps that we could access with this process. We also discussed things to do with external peer review and triage.

We came, I think, to the conclusion that we were all strongly in favor of a cadre of experts who could be mobilized very quickly to help the FDA on a specific petition rather than having a group like this that takes a little while to mobilize, maybe mobilize two or three people to help on an ad hoc basis.

Within the framework of that, and all of the other discussions, we like most other people came to the conclusion that if this is to be done properly the FDA will have to have additional resources in the way of money and personnel in order to do this in an extremely timely manner. We finished by designing a framework for the first document.

Among the things that we thought that would be important was to begin with the charge to the FDA so that a petitioner would understand why the FDA was making certain requests and what those requests were going to be in very clear terms. Then we decided that, also to be included, would be an example of a well designed study so that a petitioner would know what the hurdles were done properly.

Then there was to be a list of very accessible, very transparent steps so that the petitioner can read step one, complete that, move to step two, so it would be as easy as possible and as straightforward as possible for the petitioner to complete the process.

As a result of the discussion and subsequent heroic type work from a number of people, Chris Lewis and Steve Woolf mostly, we have generated two documents: one is an initial predraft which is currently under revision so that it can become a draft, and the other is a treatise from Steve Woolf on the key points that one should consider when dealing with data from the perspective of the petitioner.

I thought we might have this available for the Food Advisory Committee if anyone wants to look it over, but we will not have that available yet.

We are going to try to meet this afternoon as soon as this meeting is over. I would like to invite all of the members of this working group to remain. I think it will only take us an hour or so to give our own comments on this document and then we will try to move forward from there.

Thank you.

CHAIRMAN BRANDT: Thank you. Are there any burning questions?

Hearing none, we will move on to Economic Incentives, chaired by Ms. Richardson.

DR. RICHARDSON: Donna Richardson. It is sort of ironic that the shortest chapter in the "Keystone Report" has proved to be the most challenging.

The charge was for our group to identify and prioritize options for implementing the recommendation that research be increased with regard to the relationship among foods and diet and disease and that more private and public sector funding be available for that purpose, as well as also exploring the various economic incentives to stimulate private investment and research.

Our group met informally, and I also then had one formal meeting. We have sought to identify the barriers to research, and we totally agree with what we did see in the "Keystone Report", that the barriers are economic, design, legal, ethical concerns, and also disincentives.

The question is whether we can poll the industry to find out what they would see as an adequate incentive for them so that they would be able to increase research as well as finding out what is considered inadequate. That is especially in light of the inability of the industry to agree

on what was in the "Keystone Report."

I think everyone recognizes the fact that federal dollars are decreasing and that all the industry has been spending more, that when we talk about incentives for basic research, and there is not a final product at the end of the tunnel, that the incentives just are not there.

We still see that the challenge is for us to identify how we are going to talk about incentives when the issue of nutrients does not lend itself in promoting incentives because of the issue of market exclusivity.

The possibility of the tax incentives certainly raise many questions, one of which is, well, what does FDA do about tax incentives other than saying that, yes, that sounds good? But also the questions came up as to who the credits would go to, what would the tax credits -- what activities they would be for, how much of a tax credit, and who would fund it. That then brought up the issue of how do you get FDA and consumers to support the tax credit issue.

I think we are going to have to look at how we can resolve the issue of market exclusivity as well as exploring further some changes in statutory requirements which the industry views as barriers and certainly to look at how the OTC model could be adapted for food research.

I think the other question is, how do we demonstrate outcomes from the research dollars. I think that is a big issue, and certainly we may need to look at getting information from other agencies like AHCPR. We will be meeting tomorrow to go over these questions in depth and I believe that the reports that are in the packet will help alleviate some of the questions that we had earlier.

CHAIRMAN BRANDT: Good. Any questions anybody? Yes, go right ahead.

DR. CLANCY: I am confused. I am sorry I wasn't here when you started. What is the process for the rest of the afternoon?

CHAIRMAN BRANDT: We are going through these working group reports and then we are going to adjourn, and at least the SSA Working Group is going to meet this afternoon.

DR. CLANCY: On each working group report, is there time for the whole group to have discussion about that report or --

CHAIRMAN BRANDT: That is what I am asking for right now.

DR. CLANCY: Okay. Thank you.

CHAIRMAN BRANDT: That was what I was just asking about. Okay. Seeing no one rise to the occasion, we will now move to ES. I have forgotten what that stands for.

THE COMMITTEE: Emerging Science.

CHAIRMAN BRANDT: Emerging Science. That is with Dr. Harlander.

DR. HARLANDER: I don't think I agree with Donna that she got the most challenging chapter out of "Keystone." I am chairing the Emerging Science Working Group. The charge to our group was to consider what criteria should be used to determine when, if ever, Emerging Science could be used in the regulated media, that is, on the food label or in labeling and what criteria should guide the agency in disseminating emerging science in the non-regulated arena, primarily the news media. Currently, emerging science cannot be used for a health claim on food labels because, by definition, it lacks significant scientific agreement.

We did have a meeting on February 11 of the entire committee. I viewed that as a place for us to get some grounding in this issue, and also we had several representatives that participated in the Keystone dialogue that could give us their perspective on this emerging science issue.

One thing we began to focus on very early is the ultimate beneficiary of all of this

nutrition information is consumers, and we need to understand how consumers are viewing nutrition information and how it is delivered to them.

So, we had a number of studies, and one was from the International Food Information Council, as well as from FDA's Division of Market Studies that have begun doing consumer research to ask them about how they receive nutrition information.

That was very interesting and revealing, to me at least, because one thing that became real clear is that consumers don't differentiate between health claims and nutrient content claims, and so we have a big debate about how we deliver that information when, in fact, consumers don't always differentiate that.

The other thing that was interesting is that consumers think that FDA regulates the back panel, but that food companies can do whatever they want on the front panel, and so we have got a long ways to go just for consumers understanding the current system let alone overlaying it with emerging kinds of issues.

That kind of information is extremely critical for our group, I think, and how consumers will perceive emerging science information as it is communicated to them because right now they are fairly confused about nutrition information.

When one study comes out that indicates something positive about the diet and a few months later another one comes out that refutes the first one, it becomes a real issue for how much are we going to confuse consumers by allowing the use of emerging science information on the label. We already know the confusion that is created in the nonregulated media. That was kind of the morning was kind of consumed with that.

It is also fairly important that we understand the dietary supplements and how they are managed differently than food. Ken Fisher, who you heard today, came and talked with our group. It was before the report of the whole commission was actually out, but he at least walked us through some of the differences in how dietary supplements and foods are managed with regard to labeling and information that can be provided at the site of purchase of those kinds of materials.

In the afternoon, we had a discussion for those people that were on the Keystone Dialogue, and I was not a member myself, so it was important to understand what the different perspectives were. I think there are a whole range of perspectives about emerging science and how that information should be managed.

The output of that was that we have some good grounding but now we really need to get down to the tasks at hand, and the output that we have been asked for is a specific and usable definition for emerging science. I guess I personally view it as a continuum.

Steve Benedict and I are sitting on each other's committees, so the Significant Scientific Agreement Group and the Emerging Science Group will at least have a continuum or consistency there. A big question for us, I think, is going to be, how much is enough? Is one well designed study enough, or how much does it really take? Really, we need to be very tied to the output of the other groups.

Then we are going to have to come up with some criteria for when, if ever, could emerging science be used on the label. We have also be asked to consider what the consumer impact will be, what is the perception of label credibility if we have a situation where we allow something on a label and there is some information that refutes that.

Then, I think one that is going to be a little difficult for us is, how should emerging science be addressed by the agencies, especially in the non-regulated arena. We are kind of

struggling to get some experts to help us with that.

In listening today about the national food safety campaign and their initiatives to try to reach consumers on food safety, it could be that we could piggyback on that with nutrition information as well. I would really like to explore that further. I hadn't really considered that kind of thing, but FDA may have a broader mandate in education where we really should consider several of these different things that we are trying to communicate to consumers and see if there isn't some way to leverage that.

We will be trying to come up with a definition for "emerging science." We will have to investigate FDA's statutory authority in dealing with the nonregulated and regulated media.

We have had several models that have come forward. I think it is probably premature to discuss those right now, but we will be meeting tomorrow afternoon. Lynn Larsen, who is working with our group has suggested a number of tasks. I think the way we will proceed is to break up into smaller groups to go off, because we don't actually have anything drafted at this point that we can share, other than the minutes of our meeting.

DR. LARSEN: Tomorrow morning?

DR. HARLANDER: Tomorrow morning, yes, not tomorrow afternoon. What did I say? I guess tomorrow morning, if any of you are here. Most of my committee is not.

CHAIRMAN BRANDT: Okay. Are there questions, discussions, anything about Dr. Harlander's Emerging Science report?

Okay. We will then turn to the Meta Analysis Group and Dr. Blackburn.

DR. BLACKBURN: I disagree, I think ours is the most difficult problem.

Some of us don't even know what it is and many people don't want anything to do with it.

CHAIRMAN BRANDT: They just misuse it.

DR. BLACKBURN: Yes.

Our charge was to identify the criteria that could be required to incorporate meta analysis into evaluations of health claims by the FDA and then to outline a plan for getting there and prepare a series of recommendations for the use of such treatment of multiple study results in dealing with health claims.

We met on March 19 with a very interesting committee of people who had a great deal of experience doing meta analysis and a few of us users and one cynical but very interesting consultant, Sandra Greenland, if any of you know Sandra.

We decided what they were, and we decided what their main uses were, and I am sure you know these: to increase statistical power when individual studies don't have adequate power themselves to resolve uncertainty when the reports disagree; to improve estimates of the magnitude of the effect; to answer new questions; and to improve the original science.

We set out our assignments and a subgroup has come up with a very fine body of information on how best to carry these out, and we will be summarizing and digesting these and preparing them for a report.

Lynn and I are responsible for the introduction and the summary and the synthesis of that approach. Our discussion was wide ranging on subjects that I am sure would interest you, and I will just touch on a couple of them.

It was agreed that such meta analysis should be submitted to the same scientific standards as evaluation of any individual studies as well as the groups. There was discussion whether we should consider results at all of a meta analysis performed by petitioners and whether we should consider results of their studies which were unpublished, by definition, of petitioners and hadn't

gone through peer review. We are arriving at ideas of how we might deal with these if they conform to the criteria that we set out for their validity.

There were a lot of technical considerations, probably of less interest to you, one being whether there would be prior criteria before doing meta analysis or whether you could develop the criteria as you went along, whether they should be exploratory or only analytic.

Then there was a vast pessimism on the part of a few people that measurement methods in nutrition and diet were so unreliable and invalid that we had no business in pooling data from such things. Because the measurement methods for one aspect, serum carotinoids, for example, has no relationship to the frequency of which one eats a food item and its reliability, and if you pool these, aren't you going to distort your results.

As you can see, we are having a good time. We haven't met since March, and I don't know when we are authorized to meet. We are working on that. We will hope we will meet certainly by the time of our November deliberations and will have more to report to you.

CHAIRMAN BRANDT: Questions, discussion, comments?

Okay. I don't think that we will have a vote on which of these working groups is the most difficult, but we will just let you all argue about it back and forth.

We now turn to Dr. Askew and the health claims issue, and he has slides. He is more than 50 miles from home, so he qualifies as an expert.

DR. ASKEW: I will move this up so you can see the bottom when we get to it. I just wanted to introduce the members of our working group. Our group was charged with evaluating the Keystone recommendations of the health claims wording.

Our group consisted of: Bruce Chassy from the University of Illinois; Mary Wang from California Public Health; John Guzewich, who at the time was in New York in Public Health and now with FDA; Donna Porter who is our outside expert; and some industry representatives, Alta Engstrom from General Mills; Guy Johnson from Pillsbury; Nancy Ernst from National Institute of Health; Peter Greenwald from the National Cancer Institute; Tawana Dwyer from Tufts. Then representatives from the FDA to help us on various issues: Chris Lewis, Alan Levy, Ed Scarbrough, Lynn Larsen, and Ken Durham. So, this is the group.

We met upon two occasions, once right shortly after we were given our charge while it was still fresh in our minds, which was fortunate. We were able to concentrate on it when we knew exactly what we were supposed to do and then we kind of forgot between the next meeting and that one exactly what we were supposed to do. The final meeting we kind of finalized things. It started to gel and we feel we're ready to give our final report. We met in August 1996 and in February 1996.

If you recall, the Keystone Report Dialogue Group concluded that the appropriate standard for evaluating health claims is that they be compelling and nonmisleading. This then to have satisfied both the manufacturers' interest in making their products more appealing and the nutrition educators' interests in making the information that was put out truthful and nonmisleading, especially that it be nonmisleading.

Presumably, health claims that are compelling but not misleading would then help the consumer achieve a healthy diet. That is kind of the context or framework in which we began considering these things.

Specific recommendations of the Keystone Report, the Dialogue Group, was that the FDA improve the flexibility of wording, perhaps evaluate whether or not any of the required elements should be optional, and evaluate whether the abbreviated health claims may be used on

the principal display panel. There is this issue of whether or not they need to be on the front, in the back, whether they can be split, and so forth like that.

We talked about all of those things, and I will tell you a little bit about our summary. Then the charge, specific charge, that was given to our group was to identify and prioritize options for implementing the Keystone Dialogue recommendation.

Well, this is just a little bit, shall we say, nebulous and so Lynn Larsen helped us a little bit by giving us some more focused charges for our working group, which are shown here, and which I would like to go over for you just a little bit to show you the specific things that we were talking about.

We were to examine the required elements to determine which of these required elements for the health claims, there are currently eight health claims and there are a number of required elements but they vary a little bit between each claim, which ones that really should be essential and which ones should be optional, and whether there could be additional flexibility to the wording of these claims, and for that matter whether or not abbreviated claims could be accepted.

Then we needed to identify what more is needed. If we thought there wasn't enough information to make a health claim, what more would be needed, and primarily along these lines it would be research to improve the validity and credibility of the health claim wording.

Then we were asked to identify some likely sources of research and ways that the FDA can promote such research or at least ways to gain access to the type of research it needs to determine whether a health claim is a valid and nonmisleading claim.

Now, these were the issues then that were examined by our group, and we started out by considering some of the statutory authority. We had Ed Scarbrough come in. Ed, at that time, had been working for a number of years in labeling. As you just heard, he moved to the CODEX responsibility now, but he gave us a background of the history of labeling with regard to the FDA.

We talked about the Interest of Labeling Act, and we also looked at some statutory regulation and also the rulemaking announcement that the FDA put forward in the "Federal Register," 60 FR 206, you see there which covers food labeling, nutrition content claims and health claims. It is kind of a background before we entered into our discussion of our group.

After we had all this, we kind of felt we were trying to go ahead and talk about some of these things, flexibility of the FDA, health claims wording and FDA safe haven. The FDA has made some proposed wording that if manufacturers were saying, that is the wording I want for my product, and could establish that in fact it did fit the product, this was the wording that could be used, that was the term "safe haven."

There was a question as to exactly how flexible FDA could be with regard to health claims wording. The "Keystone Report," I believe, had encouraged FDA to be more flexible, and basically what we heard in our conversations was that the FDA is not only willing to be more flexible, but they are being more flexible at the current time.

We reviewed the literature on how consumers understand and interpret health claims. This we thought was very important. When we got ready to review the literature, there wasn't hardly any literature there really to review.

Fortunately, the Consumer and Marketing Studies Branch of the Center for Food Safety and Applied Nutrition had just completed a relatively large and comprehensive study, not necessarily giving us all the information we needed, but at least giving us a starting point on how consumers interpret health claims. This was presented to us by Dr. Alan Levy. We used that

information in coming up with some of our conclusions and recommendations.

This is kind of a summary of the work that was done by the Consumers Branch. This was work done by Alan Levy, Brenda Derby, Brian Rowe, and I presume others from the Consumers Study Branch. I am just trying to summarize. I am not gaining everything that they said, and maybe I am not fairly summarizing some of the things that they said.

Alan, if I am misstating you, be sure and let me know if you are here.

Is Alan here yet? Okay, don't let me misstate you. Anyway, I would just like to review for you some of the things that came out of this study. Now, we thought this was important because when we were trying to make decisions, we like to have some data to make decisions from. We like to know, well, if you say this on a package, how is a consumer going to interpret this.

And, is their interpretation going to be in keeping with the intent of this health claim from both the manufacturer's standpoint and from the regulatory standpoint and from the nutrition educator's standpoint?

These are some of the things that came out of the discussion we had with Dr. Levy: One, that food labels do not seem to be a significant source of nutrition education to the consumer. This was a little bit of a surprise to us. We kind of hoped that this would be a way of getting education to them, but they seemed to take this business with a grain of salt.

The level of knowledge of the original eight health claims is already high before they appeared on the package with most consumers, and so they already knew about that apparently. Nutrient claims have about as much buying influence or causing the consumer to pick the package up and stick it in the grocery cart as do health claims.

What came out of their study was that what the consumer is really looking for is turning the package over and looking at the nutrient content on the back. That is really one of the primary buying decision things that are influenced, much more than if a statement is made on the front of the package. Consumers use labels for product information such as nutrient comparison. That is one of the primary things that the consumer is using these things for.

Basically -- and I've got a few more points I want to put up from Dr. Levy's study, but before I go to that panel I just wanted to summarize a little bit. The information that was provided from this study seemed to find that consumers don't necessarily assume that health claims on product labels fulfill a public health information function.

Health claims appear to have only a limited ability to communicate information of educational value about the health benefits of the product. What this is leading to is that the claim itself, it's impact is relatively diminished by the way that the consumer is using the information or at least receiving or interpreting the information.

This is a further summary. Consumers are rather skeptical of what they read on the packages. They have a health skepticism. They don't necessarily accept hook, line and sinker what appears in that health claim on the package.

They pay attention mainly to new claims; and if they have already heard about or know something about it, it is kind of old business to them and it doesn't make much of an impression on what is on the package. There is not a lot of difference between long and short messages. They seem to prefer short messages.

Prior knowledge, if they have a prior knowledge, if they know something about it from other publicity -- newspapers, magazines, radio, television, and this and that -- it kind of potentiates the health claim message. If they know about it and then they see it on the package,

there seems to be some synergism there. Now, "potentiates" is not Dr. Levy's word, that is my word, and maybe it is not a good one but that was kind of the way I interpreted that.

I teach from the other side, back at the University of Utah, and that's why I'm in trouble here.

Recommendations of the Health Claims Working Group; these are some of the recommendations that we came up with. With regard to research, we feel that more research is needed into this area to determine the exact impact health claims make and the way that consumers interpret them.

This research should be done similar to studies that have already been done by the Consumer Marketing Group by the FDA, but FDA shouldn't be alone in doing this research. We think that industry should support this type of research, either sponsor it at a university level or do some of their own direct research, and this would be manufacture studies then in terms of support of shortened health claims. If they want to make a short health claim to make sure it is not misleading, it would be good to have more research done to show that these short claims can convey a message without misleading the consumer.

Now, there was this issue of the FDA approved logo. If you will recall, we had discussions about, well, maybe you don't need to put a lot of writing or words on a package if you convey the message primarily with a logo.

The suggestion was made if there is a logo that would represent the FDA has looked at this health claim and agreed that it is a nonmisleading, scientifically valid and accurate claim and then put their logo on the package, then this would anchor it and would be a way of getting a message across similar to the "Heart Healthy" logo of the American Heart Association which a lot of consumers are aware of. There is good evidence a lot of consumers do select for this particular logo for a particular type of diet that they are trying to choose.

The problem that surfaced from the study that was presented to us is that there is really a lack of prior knowledge regarding the meaning of this logo. If this logo is to be effective, there is going to have to be a public education effort to tell them exactly what it means. This is kind of understandable.

Using the logo in Dr. Levy's study didn't seem to have much of an effect on the consumer primarily probably because they didn't know exactly what the logo stood for or represented or meant to them. More research is needed on that. We did not dismiss it as a bad idea, just one that needed more work.

Further recommendations with regard to the Keystone Dialogue, our Health Claims Working Group basically endorsed the Keystone Dialogue recommendations. We thought that they were reasonable recommendations. With regard to the required elements, if you will recall for the health claims and the different required elements, that differed for several different health claims and were numerous in some and not so numerous in the others.

Our group, after a long discussion in considering these claims, kind of decided that there were two principal required elements that should be retained for certain. Those were the food/disease relationships. This food is related to this disease or health problem and a qualifier saying, "maybe" or "might" with a degree of certainty that the information is known or at least a current understanding of degree of certainty.

All of the other elements could be optional as long as the resulting message conveyed that information was scientifically accurate and is not misleading. The last sounds simple enough, but is very difficult to do. That was our kind of summary of our discussion with regard to the

required elements. I think our goal was to try and give a message that simpler might be better, but we weren't exactly sure how to simplify and to still make it coherent.

More recommendations, this will be my last chart, is that health claims are already well understood by the general public and the consumer can be shortened without being misleading, just a few key words with regard to a claim that they already know such as, I'll use an example here, "fiber and cancer," something like that.

It can be pretty short and they got the message. Just bring back a whole amount of information that they have had previously and communication message pretty well. A short health claim is okay in certain instances.

However, we thought with newer claims, probably, you would have to have more information, and the information might be so extensive that you wouldn't be able to get it all on the front panel.

This gets to whether or not you could split a health claim message, which apparently was a contentious issue in the discussion with regard to the Keystone Group is whether or not you split information it be abused in an attempt to try to hide it.

Put a little bit on the front and a whole bunch on the back, and people just think we are trying to hide it. No one is ever going to read the back, this and that. We didn't think that was such a terribly big deal. We thought it was okay to split the information between the front and rear panels. There really needs to be a two tier system where short claims could be used for well established, diet/disease relationships, once that we and the public generally understand well; and then longer split claims for new claims, things that are more complex, that are new to the general public.

This is kind of a summary. You have in your notes there our full written report which contains this in greater detail. As I said, this is hard to come up with something that is specific, one, two, three, exactly do it this way or do it that way. We don't know if our group is more difficult than the others or not, but we had a little bit of trouble of jumping on top. We would slip and slide and fall off and get right back on, and kept trying. This was our end result.

Now, quite a few members of our committee are present here today, and I asked them to be sure and comment and amplify some of the things I said. Likewise, if the committee has questions that they would like us to respond to, why we would be happy to do that.

At this point in time, I am ready for discussion, Dr. Brandt.

CHAIRMAN BRANDT: This report is under Tab 5 in your book, the "Report of the Health Claims Working Group" that has been submitted for our consideration and potential endorsement. Ready for discussion.

MS. COHEN: I have a question for Dr. Levy.

DR. LARSEN: Would you come to the microphone?

CHAIRMAN BRANDT: Come to the microphone, because you have to be recorded.

MS. COHEN: Thank you.

CHAIRMAN BRANDT: You knew that.

MS. COHEN: Yes.

DR. LARSEN: Your name?

MS. COHEN: This is Marcia Cohen. Dr. Levy, I just had a question about the findings of your research, because you said food labels don't provide nutrition education, but the level of knowledge for the original claims is high. I just wondered if you speculated at all whether if what you were dealing with were totally new claims that had not been around for a long time,

whether the label would be acting as nutrition education in that circumstance when you were dealing. I assume, in the context, where you were working with claims that had been around for a long time.

DR. LEVY: One of the claims we dealt with was a folic acid birth defect claim which has significantly lower awareness levels in the population. Well, the argument that the health claims have a limited ability to educate has to do with their ability to communicate information about who the risk groups are, special population risk groups, some of the other things that are part of the required elements in the original regulations.

It is those kinds of details, even in the new messages, which are not really well -- the health claim, even a longer health claim which has more information about those kinds of areas, don't seem to really have much impact. People don't learn what the appropriate risk groups are when you put them on the message. That was even true in the folic acid situation. But it is particularly true when it is a more familiar health claim where they don't even seem to bother to read most of the information that is available.

CHAIRMAN BRANDT: Dr. Chassy?

DR. CHASSY: Wayne, I just wanted to show out one other point that I thought we made, and it is the last point in our report, which was the notion that maybe manufacturers could have the option of doing consumer research which substantiated the truthfulness and the scientific validity that a claim was not misleading and use whatever claim that they could demonstrate to fulfill those requirements.

As we said there, use alternative wording. Make it short or whatever, but as long as they had the consumer data that demonstrated that the claim had that desired effect that would be an alternative. I think that is an alternative that is available now, but we just wanted to reemphasize it.

CHAIRMAN BRANDT: Dr. Benedict?

DR. BENEDICT: I think I probably asked Dr. Levy this question once before, but I am sort of impelled to ask it in public. As a former member of a fairly low socioeconomic strata, I am curious to know how well the studies address the questions that some of my relatives might have.

I think when you say "consumer" I think you pretty well take care of people who are aggressive about what they eat and want to know and they are preinformed, and I understand all that. What about the person who really doesn't know very much and walks into a supermarket and wants to learn from the label? Is this addressed in the studies?

DR. CHASSY: I have to say that there is no real attempt in the study to examine the information needs of basically less informed groups in the population. We just took a fairly wide, broad selection of general consumers. We do have significant representation of older people and lower SES, less educated consumers, but we did not really find much important differences between the way they reacted to the health claims from the others.

But it certainly could be that there are significantly different, qualitatively different kinds of communication issues associated with people who are really less informed. Perhaps, the label might have some role in that respect.

The thing that is probably most germane to that is that most people, and I think this true of all education strata, all SES strata, are getting their news about nutrition and health issues from the general news. I mean, it is an area that has been extensively covered over the past year. They get it as news on news programs. Oprah actually in some of our research was seen as a

very reliable, very popular source of this kind of information. They are getting it from mass media type channels currently, the kind that virtually everyone has reasonably good access to.

CHAIRMAN BRANDT: Maybe she will start endorsing food labels like books, food label of the week or whatever.

DR. ASKEW: Mr. Chairman, I kind of would like to ask one of our representatives from industry, Guy Johnson, to comment if he would.

MR. JOHNSON: Yes, thank you. Guy Johnson. Obviously, the research shows that there is some skepticism about what appears on food labels. I think that is understandable, given the status of the way nutrition information evolves. But I think it is important to recognize that the information on food labels is reinforced by advertising and other things.

In all of the discussions that have occurred about health claims, there is kind of an underlying assumption that somewhere there is a big win here in getting information out that would really be helpful and telling people about nutrition and diet/disease relationships.

I would like to just recall that the 1984 health claim that Kellogg's made with All-Bran put fiber on the map. The FTC did a very detailed analysis of the effect of that health claim, and it was coupled with advertising, but it also precipitated a lot of other positive changes.

The conclusion of that report was that more people found out about fiber from that health claim than from all of the educational efforts, all of the nutrition education materials that existed up until that point.

To your point, Dr. Benedict, the groups that benefited the most from that information were lower socioeconomic groups who might not have access to more traditional forms of nutrition education. The key is to be able to provide this information in a compelling, truthful, nonmisleading way so that we can get the message out.

I can tell you, as a nutrition guy in the food industry interacting with the marketing people, that they are not exactly clamoring to put this information on the label right now. It competes with extremely precious label space, particularly on labels that are smaller than a cereal box, simply things like a picture of the product that conveys how great it looks and how great it is going to taste, or what you can add to the product, it can be recipe information or it can be premium offers.

In order for manufacturers to really take advantage of providing this information, they have to feel like -- manufacturers have to feel like, they can craft the claim in a way that really responds and sizzles with consumers in compelling language. I really continue to believe that it is a big win there if we can figure out how to do it.

CHAIRMAN BRANDT: I think you have to follow up and point out that Kellogg may have put bran on the market, but the FDA stopped them from using the health claim for various reasons.

I was assistant secretary then. Dr. Clancy?

DR. CLANCY: Yes.

Since the report is more complete and finished than the others, I wonder if you could just fill in a few more things. In my move, I lost my "Keystone Report." Could you just fill me in on what are some of the required elements that would now be made optional? You said what you want to keep, but I am trying to think of what are those required elements that were there before that are now optional. Also, can you give just a couple of examples of an abbreviated health claim?

DR. ASKEW: An abbreviated health claim would be, well, for example, the oatmeal

claim. Oatmeal contains fiber and increased fiber is related to decreased incidence of colon cancer. That would be a pretty abbreviated claim if it were put on the front of the package.

Now, with regard to the required elements, Lynn, do you -- where did Lynn go?

DR. LARSEN: I am looking to see if I've got them.

DR. ASKEW: Yes. Lynn is looking to see if he has got it. In the "Keystone Report," it lists the eight health claims and the required elements that are there for each claim. I cannot remember right off hand what all the required elements were to give you an example.

DR. CLANCY: Maybe I can --

DR. ASKEW: Yes. Why don't you just open that up, and let me look at that.

DR. LEWIS: I think to help you just a little bit, Wayne, one of the more contentious issues was the idea that it had to be set in the entire context of it being a multifactorial disease. This report and certainly the proposal that came out from FDA was the elimination of cancer as a disease of many causes, heart diseases. That was considered by many to be cumbersome wording. That would be a major change, yes.

CHAIRMAN BRANDT: Are you okay, or do you want more?

DR. ASKEW: Lynn made a chart for us here, and it is a very great chart. He has got an "x" where the requirements were dropped. Is that just a small "x" on that? Is that what that is? I had a little trouble interpreting this when I saw it in the first place. Is that an "x" right there, for example?

DR. LARSEN: No.

DR. ASKEW: No. Where is the "x"?

DR. LARSEN: I debated about putting a copy of this chart before the committee. When I first faxed it to Wayne, he says, this is very complex. It is a very complex chart. In the process of getting all the other stuff together for the committee, I did not, unfortunately, get it copied so that we even had copies available to you now.

What I did is I took the Keystone chart and I took our proposal and the existing regs in the CFR and I tried to go through step by step and take every element that I could find and match them up. The "R" with the little "x" that means, like, a drug prescription type thing.

I used that symbol to indicate where the Keystone recommended either optional entirely, "RXO" means optional entirely or "RX" that means optional on the front panel but they want it on the back. So when you read that chart, Wayne, that is what those little ones mean.

DR. ASKEW: To answer your question, Dr. Clancy, an example of a claim that would have only the two elements and the rest be optional would be the claim that saturated fat and cholesterol and coronary heart disease are related.

The required components would be identify the food substance and the disease, and then specify whether it may or might reduce the risk. Optional then would be to place it in a dietary context and to talk about multifactorial ideology. The multifactorial ideology makes some sense, but it gets very complicated to discuss that in a health claim.

Now, there is one here that has a whole bunch of requireds on it. Well, I think probably the folic acid and neural tube defects would be one that would have more of the required elements attached to it than something such as this. Basically, we looked at this and it looked to be an extremely difficult job to have a set of different requireds for each individual thing. We said that the most important thing was the two items. If it meets those two, then you could make some decision with regard to what else might be required or might be necessary for clarity, but that is the big hurdle. Once you got through that, you would have 90 percent of the problem

licked.

Yes, Chris?

DR. LEWIS: This is Chris Lewis again. I think there needed to be, from what I remember of the discussion, a certain amount of flexibility. The example I can think of has to do with the approval of the soluble fiber claim. In this case, soluble fiber from oats.

The scientific evidence suggested that soluble fiber worked only in combination with a diet low in saturated fat and cholesterol. You would want a claim, therefore, to be able to incorporate that caveat, that is: it couldn't be considered extraneous information. You can think of some examples where that type of information might be unnecessary. In the case of soluble fiber, it was considered essential. You would get a longer claim in that case because of the scientific evidence.

CHAIRMAN BRANDT: Dr. Chassy?

DR. CHASSY: Yes. I just wanted to respond to a point that Dr. Johnson brought up. I think he made a very good point with regard to the Kellogg example, but I think one of the things he talked about was whether if you had a smaller package than a cereal box you could do the kind of educating that Kellogg did to sell bran.

They, of course, had quite an educational advertising campaign. I think they did a terrific job in spite of the FDA's reaction to it, but I think are a very limited number of products you could do that with without really putting a lot of advertising into the media to do the educating. I think that is what Dr. Levy's study basically shows is that the health claim becomes much stronger when people recognize it, understand the underlying science a little bit.

DR. LEVY: That was my term, "potentiate."

CHAIRMAN BRANDT: Dr. Johnson?

DR. JOHNSON: I would just like to emphasize that with a real live example. I think when the NLEA regulations were finalized, we used a health claim for vegetables and cancer on some of our Green Giant products. We spent a considerable amount of time word smithing the model statement to try and get it to the shortest possible version.

Some of the elements that you have to include in that claim are the fact that vegetables are good sources of either vitamin A, fiber or vitamin C. You have to actually work that into the claim two times, if you read the regulations literally. You have to talk about a low-fat diet. There were a number of other elements.

It ended up as a pretty long claim that was very polysyllabic and the reading level was way into the college age range. Obviously, even though frozen vegetable packages are fairly large, it was way too bit to put on the front of the package, so we put it on the back.

The impact of that claim, even though we were really proud of it, was minimal. Of all of the people that call our 800 line, we have not had a single person ask a question about it. We have very little evidence to suggest it was noticed at all.

Now, if we had an option of putting a four word claim on the front, like, wow, did you know that vegetables can help reduce the risk of cancel, see back panel for more information, it might have been a very different story. That is the kind of thing, the kind of flexibility, that the industry needs in order to get this message out. Like I said, the trick is to do it in a truthful, nonmisleading way.

CHAIRMAN BRANDT: Ms. Cohen?

MS. COHEN: Well, Dr. Johnson, also with the fiber, since FDA reacted negatively you had this huge controversy that produced a lot of press. You cannot discount that as having been

one of the reasons why it landed up in educating people. Maybe what you need is a government agency that is in the business of just causing trouble so that the press covers it. That was not my issue.

CHAIRMAN BRANDT: We have one, and it is called EPA.

MS. COHEN: The last sort of throw away paragraph here, the manufacturer's responsibility option, where the committee said, you know, we don't know what to do with this, I wondered if something would be done with it? It seemed to me to be a crucial point that reflects on another working group's territory, Dr. Richardson's.

It is a similar issue to the one of incentives, because one of the incentives that was talked at Keystone at great length was proprietary rights and the way this health claim approval system works does not give the proponent a proprietary right.

This was sort of making the suggestion that one's wording would be a service mark or a trade mark or God know's whatever the lawyers say it would be. I wondered if you wanted to leave that in here or toss this ball to the other committee?

DR. ASKEW: Oh, we would be happy to toss the ball to the other committee. As you say, we could come to no conclusion on that really because we had no expertise or we couldn't revisit that.

I guess it would be sort of a legal sort of issue, but certainly something that is important to a company if they invest a lot of time and effort in research and polls and things like that, and establish something and then have somebody walk in and say "me too" probably isn't going to be acceptable.

What group do you think should consider that?

MS. COHEN: It is the incentives, that is where it belongs.

DR. ASKEW: Okay.

CHAIRMAN BRANDT: Yes. I would say if you will take that on, too, in addition to this one.

DR. RICHARDSON: It's good. Marsha is on that committee.

CHAIRMAN BRANDT: Aha, a conflict of interest there.

MS. COHEN: I'm giving myself work.

CHAIRMAN BRANDT: Yes. Dr. Chassy -- oh, I'm sorry. Dr. Harlander? Excuse me.

DR. HARLANDER: Sue Harlander. I am just wondering, and maybe it gets to Kate's question too. In an elaboration of this report, if you actually took a few health claims, and maybe that is what the chart does, it actually walks us through what they would sound like or look like. If you are going to have a very simplified claim, a split claim, take the current language and then break it out all the way to a logo kind of thing.

One thing Steve Benedict, I think, brought up is, Could you ever imagine a consumer report kind of analysis where if you had a full dot it was significant scientific agreement and FDA gave its total endorsement; a half filled circle was you're not quite there yet; and an open circle is like you're on your own, it is emerging science and take a risk.

I mean, you could imagine something like that would be very simple, if you could educate consumers about what the meaning of it was versus wordage. I wondered if your group did that, if you actually took the eight health claims with all of the required language right now and then went through what versions would look like? I think it would be really valuable for me and I think maybe others to see.

DR. ASKEW: We did discuss each of the eight health claims. We did not word smith a

shortened message for each of them and so forth like that. I assumed that shortened message -- I'm just pulling something off the top of my head right now -- if you had a product which had some anticancer activity, if the short message on the front was "fights cancer", and then you would want something more on the back than that.

DR. BENEDICT: "May help."

DR. ASKEW: Yes, "May help," or something like that. We talked about those kinds of things. We did not go through an example.

Donna, do you want to give us an example of what she is talking about?

DR. PORTER: Well, I wasn't going to give you an example. I was going to make two points, and one is I think some of that was done in the "Keystone Report" in the appendix, so there is some work. We didn't actually go back and look at the specific things. I would like to go on record right now and say I would prefer not to be on the dot committee.

CHAIRMAN BRANDT: Okay. Any further discussion?

DR. PORTER: Actually, it could be sunshine and moon, you know? It conjures up all kinds of possibilities.

DR. ASKEW: We didn't get into that.

CHAIRMAN BRANDT: Dr. Chassy?

DR. CHASSY: There was one point that came up that I thought was sort of interesting. It might be germane to why people don't respond to health claims on vegetables, and that was consumers seem to have an idea already of what are the healthy and good for you products which are the bad junk foods. I mean, that is just the way people think.

The health claims put on an ice cream product or a snack just don't have credibility, and it may be the reverse for everybody knows vegetables are good for you and you are just not telling them anything. They are used to not eating the vegetables they should be eating every day.

CHAIRMAN BRANDT: DR. Wang?

DR. WANG: Dr. Levy, did give us some examples because of his studies. He showed us some packages, okay. That is one clarification. The second one I also want to clarify with our group is there was a question asked as to, How would dietary supplements fit into this scheme? In our discussion, we have stuck with conventional foods, okay.

CHAIRMAN BRANDT: Okay.

DR. ASKEW: I didn't see our committee's deliberations as being at odds with the Commission on Dietary Supplement, the report that has come out of here. What Dr. Wang said was true. Dr. Levy had various wordings and we looked at those. I think, as a matter of fact, we presented that to the main group, showed some of those. Some of them were staggeringly long and detailed, and others were very short and to the point. He did look at that.

I want to ask Dr. Levy if I quoted him correctly in some of my summaries, or do you want to qualify any of that?

DR. LEVY: No, no, I think that is fair. This study is actually a very rich study. It is a tremendous amount of information, but I think you have called it quite appropriately.

CHAIRMAN BRANDT: Yes, ma'am?

DR. PORTER: Donna Porter. I would like to make two points. While one can see the conceptual appeal of using a dot or a sunshine or that kind of thing, I have two concerns: One is a product that says "FDA approved" or "authorized" claim or whatever gives one the notion that other foods are not approved by FDA.

The other point is that you have to understand that some of the people in the supplement

industry consider it a badge of honor if FDA has not approved or looked at their statements or products. I mean, that is a real selling point among them and their consumers. So, one has to be careful how one might use this kind of a logo thing.

DR. HARLANDER: I am not endorsing it, Donna, believe me I'm not.

DR. PORTER: I thought you would chair that committee, Susan?

DR. HARLANDER: No.

CHAIRMAN BRANDT: Okay. Yes, Dr. Benedict?

DR. BENEDICT: Well, I do semi endorse it, just for the sake of having it be discussed. What we have heard, it seems to me, is that it really doesn't matter what you put on the label. It matters what you can get, and I don't mean this in a facetious way, Oprah to talk about.

The only reason that I support this in a fairly strong way is that what you need to do is convey to the consumer that there is something important associated with this product.

If the industry would be comfortable -- call it a dot, call it a number, call it whatever you want -- if the consumer sees that number, then they know that perhaps somewhere in the vicinity of this product there is something they would like to know about, and they perhaps knew it when they came into the room.

It seems to me that is an easy way to not take up all the label space to allow pictures of the product and Michael Jordan and whoever they need to sell it, I think, if we could just examine it. I am pressing the Emerging Science Group from the rear to actually talk about that, but I didn't want Susan to be out there by herself having said something that I have been yelling about on the record.

CHAIRMAN BRANDT: Okay. Yes, ma'am?

DR. PORTER: Donna Porter. The only other point I would make about that is that it seems to me that it in some ways is already there, and it is called the Nutrition Information Panel.

We have a ways to go in terms of communicating to consumers that they need to do what Bruce Silverglade at one point said, which was we needed a claim on the front of the package that said to people, turn this package around, stupid, to get people to the point where they do look
at what is on the package. I mean, there are various ways to approach this that certainly need exploration beyond what our committees were able to do.

CHAIRMAN BRANDT: The chair will entertain a motion about this report. Do we want to adopt this report with its recommendations or not?

Nobody is going to say anything?

DR. LARSEN: I so move.

CHAIRMAN BRANDT: Thank you. Do you want to second it?

DR. ASKEW: I second it.

CHAIRMAN BRANDT: Thank you, I appreciate it. Any further discussion?

I think we have about discussed it out. You too?

DR. LARSEN: I was just handed some editorial comments on the report. I guess you can accept it as it is, but we do have some additional editorials, so you can decide if you would not rather --

CHAIRMAN BRANDT: Who wrote those?

DR. LARSEN: These were by Donna or Marsha.

MS. COHEN: I have some grammatical, truly grammatical.

DR. LARSEN: Okay. We have some grammatical corrections and some other language

corrections. I don't see that it has anything on the substance.

CHAIRMAN BRANDT: Okay.

DR. LARSEN: This is as a draft report, and it can stay as a draft for now, the committee draft, and we can circulate it through the mail.

CHAIRMAN BRANDT: There is no reason that we can't adopt the report subject to grammatical changes.

DR. LARSEN: Okay.

CHAIRMAN BRANDT: I mean, gee whiz, we are not rigid. Yes, Dr. Clancy?

DR. CLANCY: The only reason that I would hesitate to do anything is whether there is, and maybe there isn't, anything in this report that would change when we heard all the other final reports from all the other four groups.

I would feel a lot more comfortable approving all of these five at the same time. They are really all out of the same report, they are all related to each other. That would be my reason for saying, why do we have to vote now?

CHAIRMAN BRANDT: Well, we don't have to vote now, but my view was that we can always amend them. That is not a big deal.

Yes, Dr. Porter?

DR. PORTER: Donna Porter. I only have a question for my groupmates, and that is with some of the questions and concerns and issues that have been raised in the discussion here whether there are things that we would like to append to the report, you know, maybe examples of shortened claims and/or this table that talks about the consolidation of -- excuse me, the shorter claims and that kind of thing, if there are examples that are instructive in terms of what the report actually currently contains? That is my only point.

DR. ASKEW: If any of our members would like to draw up some examples to illustrate and respond to some of the questions, I would certainly be willing to attach them to the report after everybody has reviewed them. My enthusiasm for doing that personally is relatively low. Does any other member of the committee wish to volunteer and do that?

DR. CHASSY: Bruce Chassy. I am not volunteering.

I would volunteer to attach certain health claims and the table Lynn Larsen has provided. I mean, that was the first draft we were looking at, and none of the other committee members bothered to offer any grammatical changes or any of that. I do think it needs some word smithing. In fact, there has been a suggestion to make a couple of changes in it which won't change the content. I think we ought to maybe incorporate some of that stuff.

If there are some compelling points that people want to submit to me, because I think I will be the one to do those changes, I don't mind trying to put those in. I don't think we need a big rewrite. I agree that maybe we ought to wait and see what the other four reports do, but maybe we could amend the motion in some way to indicate that the report is accepted.

MR. ASKEW: Mr. Chairman, I think that basically what we are saying here is that we could fine tune it just a little bit without changing the substance, and we would be happy to wait until all of the other reports had been presented for approval, if that is your pleasure.

CHAIRMAN BRANDT: Okay. Do you want to say something?

DR. WANG: This is Mary Wang in support of what Bruce has said, that even though our committee felt that this report in the draft form consists of the major substance that we want to discuss, but we are willing to attach whatever suggestions the other members have made or make it read better or whatever. I will be happy to work with Bruce on that.

CHAIRMAN BRANDT: Okay. All right. We have a motion on the floor, it has been duly seconded, to approve this report and adopt it.

All in favor, since there seems to be some disagreement, please raise your hand? This is to adopt it.

DR. WANG: Clarification. I thought the motion --

CHAIRMAN BRANDT: Yes. With nonsubstantive changes, sure. Okay. All opposed to the motion, please raise your hands?

Those not voting?

DR. WANG: I didn't vote because I am not quite clear what we are voting for, sorry.

CHAIRMAN BRANDT: Okay. One abstention. All right. Are there any other comments or questions about any other working group report that you have heard today?

Yes, sir, Dr. Clancy?

DR. CLANCY: Kate Clancy, going on what Marsha said about this report and the piece that we just put back into the incentives report, it seems to me there are a couple of pieces in meta analysis that are the same problem. I see the issue of proprietary data -- it came up under the meta analysis. My question is, should it be dealt with anywhere that it comes up, or is it better to put all of that into one committee?

CHAIRMAN BRANDT: At this stage of the game, I would say that we ought to deal with it wherever it comes up, and then we can worry about combining them all later.

Any other comments, discussion, anything?

DR. ASKEW: I would just like to ask the members of the Health Claims Working Group if they could remain afterwards for just a few minutes to discuss the spiffing up of our report for the final -- help Bruce spiff up our final report.

Thanks.

CHAIRMAN BRANDT: Okay. Oh, yes, is there anyone here in the audience that wishes to make a comment or address this committee?

DR. LARSEN: I might point out that there was no response to our "Federal Register" notice inviting members to comment in the open public session, or I should say the members of the public to comment in the open public hearing. There were not requests formally submitted.

CHAIRMAN BRANDT: Boy, we need to record that. That is a rare, if not unheard of, thing for this committee. I have to then do one thing. I have been chastised by Professor Coleman for not being accurate earlier today, and BST was actually not taken up by the entire food advisory committee. It was a group of people and the veterinary medicine committee met together. I chaired it, so I just assumed everybody was there, but certainly you were there to talk. That was a wild day.

If there are no other comments, we are recessed until 8:30 in the morning. Now, two committees, health claims, and SSA, "Significant Scientific Agreement," are going to meet in just a minute.

Well, we are estimating that we will be through in the morning by, roughly, 10:00 a.m., that is, but it could be delayed if we get the Senate bill.

DR. LARSEN: We will be done with the committee meeting itself, but we have got the two working groups that would meet the rest of the morning or until mid-afternoon if they want to, until they decide they are done.

CHAIRMAN BRANDT: Have a wonderful evening.

(Whereupon, at 2:30 p.m., the FOOD ADVISORY COMMITTEE MEETING was

adjourned.)

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