UNITED STATES
DEPARTMENT OF AGRICULTURE

In the Matter of:)
)
DIETARY GUIDELINES ADVISORY)
COMMITTEE)
)

Pages: 250 through 360

Place: Washington, DC

HERITAGE REPORTING CORPORATION
Official Reporters
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Washington, D.C.
(202) 628-4888

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Tuesday,
September 29, 1998

Economic Research Service

1800 M Street, N.W.
Third Floor, Auditorium
Washington, D.C.

The meeting in the above-entitled matter was convened, pursuant to Notice, at 9:03 a.m.

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RAJEN ANAND

P R O C E E D I N G S

9:03 a.m.

DR. GARZA: Good morning. I was thanking Dr. Kumanyika earlier today for her clairvoyant presentation yesterday. She warned us about the controversy. And in today's paper is a discussion on salt. So we -- she was right on target. It gives us all a great degree of confidence on the ability of this Committee, not only to read science, but possibly the future.

(Laughter.)

And that being the case, this ought to be an easy task. We're going to continue with the presentation and discussion of issues that are in -- are in some way related to the Dietary Guidelines, but perhaps not discussed as explicitly as perhaps may -- may be warranted.

We talked about children's -- special dietary guidelines for children yesterday. The second issue that we're going to take up this morning is on dietary supplements. And Dr. Kumanyika, again, volunteered to take care of this one. And we expect her to be as scientifically correct and as clairvoyant on this one as she was yesterday. She set the bar and we will gladly make sure that it doesn't -- it isn't lowered I guess.

DR. KUMANYIKA: Good morning. I volunteered for -- in fact, I suggested this issue. I'm sure I wasn't the only one who suggested that we look at dietary supplements. But I suggested it particularly because I had a chance to become more educated about the issues during my service on the Commission on Dietary Supplement Labels that released a report -- wow, could it have been a year ago? -- a year ago. Time flies.

And I think probably all of you in this audience are familiar with the Commission on Dietary Supplement Labels and what our charge was and what we did. And I thought about the Dietary Guidelines and realized that perhaps in the 1995 round, we began to recognize that more guidance would be needed on supplements but didn't really do much with it. And so I hope to make the case that this is an issue that the Committee should really take on in a serious way and decide what kind of guidance is needed.

(Slide.)

So I went through the booklets from '85 to '95 to see what we had said about dietary supplements in the past and then have thought through and looked at some literature to see what has changed since 1995 that alters the need for guidance in this area. And I came up with these -- at least

these four bullets that are on the slide.

We have a change in the definition -- or actually, we have a definition of dietary supplements. We have a new regulatory climate for things that are labeled as dietary supplements. Because of that, we have a different set of marketing practices and consumer use of supplements has increased. I won't give you data on that, but I think it's common knowledge and we certainly can get data on the increase in use of supplements.

It's in the newspapers quite a bit. I have with me several articles. It's quite easy to pick up now in the Chicago Tribune or anyplace articles about dietary supplements and advice on them -- you hear it being -- you hear them being discussed in elevators and so forth.

Dietary reference intakes have come about and will change the context for guidance on supplements and there have been some changes in fortification. Next, please.

(Slide.)

So what -- what do we mean by dietary supplements? Currently -- the current definition is under the Act that we came to call DSHEA. Some people used to think that was a person because -- like, "Who is DSHEA?" Well, it's our acronym for the Dietary Supplement and Health Education Act.

And the definition any -- this is my definition. This is not a formal legal definition. I put it in what I could -- my sense of it from my head. And if it's not legally correct, I'm sure -- and that's here. Annette Dickinson, she'll correct me if I'm getting something wrong that's really critical.

But I'm thinking of now supplements or any substances that are ingested that are not conventional food, but for which the intended use is as a food rather than as a drug and where the intended use is determined from the marketing and labeling in a way that does not trigger regulation as a drug. And that's not double-speak. So let me explain what I think that means.

If something is -- is marketed as a supplement, meant to be used under the law that defines supplements as "types of food," as long as there is nothing on the label or in the advertising that triggers drug law that says it's a remedy or cure for a disease, it can be considered a food and dietary supplement and remain under the Dietary Supplement Act.

And the categories of things that are included under the supplement law are much broader than the last time that the Dietary Guidelines have considered making

recommendations about supplements.

The term can no longer be used to refer only to traditional vitamin and mineral supplements or to fiber supplements, but they also include herbals and anything else that is actually marketed as a supplement.

And this broad definition really complicates making policy because I think there are many dieticians or health professionals who would like to make recommendations about vitamin and mineral supplements about which we know quite a bit, and they have been in -- with us for a long time. And we know something about the uses and there is a lot of data that can be studied in the same way that traditional risk factors are studied.

The herbals and other things, shark cartilage and some of the other things which might be marketed as supplements cannot be as easily studied. And the benefits are in some cases in the transcendental realm which takes them out of the realm of science.

So I don't mean that as a joke. I mean, some of the benefits of supplements may indeed be things that cannot be studied by traditional scientific methods because they're what we would call placebo effects. They -- they are something that interacts with people's belief systems.

And a lot of the supplement-using behavior is spiritually motivated. I heard a talk about this recently from someone who is in the humanities and ethics field and was reminded that some of the original promotion of what's called health food and supplements was through religious organizations, Seventh Day Adventist, for example. And there have been some other elements and players entering the supplement field.

But why consumers use supplements and what kind of guidance consumers want is what the Commission on Dietary Supplement Labels had to deal with and that's what we're going to have to deal with. There's no longer any way for us to take a purist or old fashion view about what we think supplements should be because we're going to have to face the reality of how they're being marketed and used. Next.

(Slide.)

The supplement labels now may include statements of nutritional support which require notification of the Food and Drug Administration, but not prior approval by the Food and Drug Administration. So a supplement manufacturer can put a statement, "This supports normal" -- "Helps to build bones", "Supports normal liver function", or whatever, and can notify the FDA within 30 days of putting that on the

market with that label that this is what is -- the statement that's there.

And if the FDA does not -- they can continue to use that label on the supplement as long as the FDA doesn't say that it somehow is a drug claim and cannot be used without going through drug regulation.

Supplements also, like other foods, can have nutrition labeling-type health claims according to the same regulations as any other health claim. They have to go through the review and be shown to have significant scientific agreement, substantial evidence.

This is through randomized control trials or a large body of evidence supporting that health claim. And there is a fairly limited number of health claims that are authorized for food. And supplements may be able to participate in those same claims if they can meet the guidelines.

The -- many people consider that the nutritional support claims are unregulated. It's not that they are not regulated, but there's no prior approval. So I wanted to emphasize those statements. And the burden is on the FDA to go and find those statements -- or look at those statements and then to call them back.

The product standardization and safety are major concerns with respect to recommendation of some supplements because this category of products does not have the same systems for standardization. And they are presumed safe because they are classified as food as I understand the law.

And we had lots of help on the Commission from Food and Drug lawyers. And so I don't claim to get all the fine points right. But -- but foods -- so when something is classified as a food, it is presumed safe and there is a burden of proof then to show that it's unsafe.

The standardization of some of the products, especially herbals where the -- part of the plant used may differ or where the manufacturer is -- is not, say, a large company which would by its own procedures have standardization. And all these things may be on the market. so there is concern.

You may have seen the press recently from the New England Journal of Medicine about the safety issues, contamination of a supplement traced back to contamination of one of the ingredients that was sold from a bulk distributor in Germany. This came up a long time ago with tryptophan supplements.

So there are -- there -- even if it's

contamination or if it's from other aspects of use, safety is a concern. So this last point, although foods are presumed safe by definition, supplement safety issues include overdose -- consumers taking too much either of a traditional vitamin and mineral supplement or a -- some other type of product.

And for -- again, for vitamins and minerals, we have a lot of information on the toxic ranges and so forth. That's been well studied. And we usually know from the at least major manufacturers what the strength and consistency of that product is.

Contamination, which I mentioned. Drug interactions where a supplement, especially perhaps herbals or supplements that are not traditional nutrients, may interact with a drug someone is taking, but they won't realize that it's -- and it may be taken for the same thing.

If someone takes a product that's meant to help the heart that's an herbal and they are also taking a medication for their heart, something with Digitalis and they're taking Digitalis, then perhaps there is an interaction or there is some supplements that negate the effects of drugs.

There may not be that many of them, but it is a

concern because it's not easy to get the right information to consumers. And then the other concern that we talked about a lot on the Commission was inefficacy; that people needing treatment and possibly helped with, say, a pharmacologic treatment or some other kind of medical or surgical assistance might self-medicate with supplements beyond the point where that was actually safe for them if the supplement isn't actually doing the same thing that -- that the other treatment would have done. So that's just a way to think about some of the safety concerns.

(Slide.)

The advocacy for the DSHEA demonstrated the high consumer interest. And I think that anyone who thought that they could sweep supplements under the rug was really bowled over by the level of consumer interest in supplements. Just incredible large lobby, a lot of it coming from well-off consumers, people who are disillusioned -- if you look in the alternative medicine literature now, disillusioned with some of the traditional systems.

So there is a high and powerful consumer interest in supplements. And that's also confirmed by the popularity and the high availability that suggests that if we're going to mention -- that we need to mention supplements and that

what we don't say may be as compelling in terms of our credibility as producers of guidelines as what we do say.

Expanded definition: Requires clear guidance so that we can sort out now statements that refer to vitamins and minerals, fiber supplements. At least distinguish other categories of supplements if we're not going to give guidance. And then there are fortified foods.

And it's been pointed out that there are some inherent contradictions in current guidance because there are times when fortified foods are recommended, but where the sort of party line is that supplements are needed. And we're going to have to think through the consistency of what we're saying about the dose that's needed and how people get it.

(Slide.)

So I think that the existing guidance of supplements are not needed is inadequate or inappropriate. And I will review the guidance that we have published so far.

In '85 -- this is a statement. I may not have picked up all the statements, but I went through. And most of the statements were either under "Eat a Variety of Foods" or under the fruit and vegetable. "There are no known

advantages and some harm in consuming excessive amounts of any nutrient. Large dose supplements of any nutrient should be avoided."

And also in the "Variety" section, "you will rarely need to take a vitamin or mineral supplement if you eat a variety of foods." And there is a list of important exceptions which include women in childbearing years, pregnant or breast-feeding women, infants, some elderly people or people with -- taking certain medications that increase nutrient -- nutrient needs or that a physician may prescribe supplements. So that's '85.

And now 1990. Again, there's no separate guideline of course. A statement in "Variety", "These nutrients should come from a variety of food, not from a few highly fortified foods or supplements." And then a statement about possible harm; that some nutrients taken in -- taken regularly in large doses can be harmful. Below RDA levels, supplements are safe but rarely needed. And then the -- essentially the same list of exceptions. Next, please.

(Slide.)

And I found, let's see, separately -- for some reason, I don't see the one for '95. I don't see -- I might

have -- do you have -- do you have one for '95?

UNIDENTIFIED VOICE: No.

DR. KUMANYIKA: Because I can -- I can read it from here. Ninety-five is a little bit more -- I think there is a more generous statement or perhaps it is in the fiber supplement. So let's -- okay. Thanks. For fiber -- well, let me just go to the general -- yes, because I remember -- perhaps it's on the next to the --

UNIDENTIFIED VOICE: Page 11.

DR. KUMANYIKA: Yes, it's page -- it's page 11. And I have -- what I remember typing is under the heading of "Fiber Supplements". So we'll get to it. Let's look at the next one which mentions fiber supplements specifically. "Increase your fiber intake by eating more of these foods that contain fiber naturally; not by adding fiber to foods that did not contain it." And that's under, "Eat foods with adequate starch and fiber back in the 1985."

In 1990, "Some of the benefit of a higher fiber" -- I think I have them all. I just presented it differently and had not remembered. I think it's in the next one.

"Some of the benefit of a higher fiber diet may be from food that" -- "food that provide the fiber; not from fiber alone. For this reason, it's been to get fiber from

foods rather than from supplements. In addition, excessive use of fiber supplements is associated with greater risk for intestinal problems and lower absorption of some minerals."

That's from 1990 in the "Choose a diet with plenty of vegetables, fruits and grain products." So the emphasis here again is the possible harm from supplements and the fact that the evidence for fiber wasn't clearly for the fiber component. So perhaps it is safer to -- more conservative to eat the food. And then you will be getting whatever it was that was identified epidemiologically that was helpful.

(Slide.)

Okay. And the next one, and I think the statements from 1995 are all included here. There is a special -- a separate subhead, "Where do vitamin, mineral and fiber supplements fit in?" And the fiber supplements are included with vitamin and mineral supplements. And this could be seen as less negative.

But it clearly -- it talks about the fact that these supplements may help to meet needs. But it's also a "Yes, but". "However, supplements do not supply all the nutrients." And there was a real concern that people would be replacing food with supplements and would be missing some

essential nutrients because we don't really know all the things in food that are helpful to people.

And then the possible harm that supplements taken in large amounts regularly might be harmful and are not -- well, that they're considered safe if they are below the RDA, but they still are not needed.

And then finally, another statement about the fiber which is under the "Grain, Vegetables and Fruits". So this is the 1995 guidance. "For this reason, fiber is best obtained from foods rather than supplements."

So if I -- if I were a user or a proponent of any type of supplements, I would consider this guidance extremely negative for using supplements. It comes -- and I think the principle was mentioned many times in the 1995 Committee, that there is a principle that people should eat food.

And this is a very firmly held principle. And I'm not sure that we want to abandon that principle at all. I think people should eat food, but I'm also aware that if our guidance doesn't help to make the bridge to consumers about supplements, that they might ignore it completely.

And so it's really a practical concern that the way that we are promoting foods rather than supplements

might be so out of step with the way consumers are thinking as to be not heard. And to see if there is a way with the evidence that is available, we can make statements that are more informative. So that's all I wanted to say.

DR. GARZA: Are there any questions?

DR. STAMPFER: First, as a comment, and that is when we talk about what's new, I think there is now randomized trial data that would strongly support a blanket recommendation for folate supplementation for all women of childbearing age.

And the guidelines kind of skip around it and sort of say, "Well, you know, they should get folate and it's okay." But I think now the data are really strong enough to -- to make that a firm recommendation.

And then my question is what -- do you -- do you have sort of a proposal in mind, Shiriki, or how would you -- do you think it should be more positive in its -- the guidelines should be more positive in discussing supplements, more negative or --

DR. KUMANYIKA: I -- I couldn't -- I think that the guidelines should be more informative in discussing supplements which means that we will have to review the issue. We have not -- at least, I was only on the Committee

once before. We didn't actually review data on supplements.

Bert, do you think that's --

DR. GARZA: Yes, that's very true. There is some research, for example, and I don't know whether others have comparable findings. And David Pelletier, for example, and others at Cornell -- that's why I'm familiar with it -- I don't think they've published it yet -- suggesting for example that individuals that rely on supplements may not have as varied a diet or as -- as -- as healthful a diet in terms of following the Dietary Guidelines as those who do not which was a surprise because the expectation was that, indeed, people who would use supplements would somehow be more in tune to what their needs would be. And that was not what was found.

Now, I think it would be very useful in terms -- as we think about analysis if we would either ask those individuals or others on the staff to do similar types of analysis to get us to understand supplement use in relationship to the diet in ways that would help us analyze it.

I think that Shiriki is right, we don't really know -- at least I -- I should say I don't really know. And I don't think this Committee has formally ever reviewed the

issue from the context of a total diet and the role -- the percentage of specific nutrients that are contributed by supplements versus foods, the impact they have on the broader diet and what the health outcomes that we might be able to anticipate from patterns of use.

Obviously, I don't think that that research has been done. That's why I was careful to say, "might anticipate". Richard?

DR. DECKELBAUM: Well, two points in relation to what Meir just said. One, is the fortification now with the food supply with folate the necessary step or do we need -- is there a need for an additional supplement? Because a major step has already been taken in terms of fortification. And we don't have any data on how that's going to work out.

DR. GARZA: And FDA does. We may want FDA to come because they have looked at the impact of fortification in folate. Do you have other data, Meir?

DR. STAMPFER: The level of fortification was a compromise because it was a population intervention. But in terms of the amount of folate in the diet of women who may become pregnant, especially in the very, very first few days of pregnancy, it's not enough. The fortification -- the levels in fortification are not enough to achieve optimal

prevention of neural tube defects.

DR. DECKELBAUM: And I guess the second question also, Meir, is your studies have data I guess which would look at the diet of subjects who take supplements. And so that those are usually in the upper quintiles. And so do they have a less varied diet than other -- the other -- other quintiles in the Nurses Study and the Physicians Health Study?

DR. STAMPFER: We don't have -- our studies rely on food frequency questionnaires. So we don't -- it's harder to get a variability because it's averaged out over the year.

But in terms of what you would call healthful diet, actually, as part of the analysis that we're doing with Eileen Kennedy's support is to look at the Healthy -- the Healthy Food Index in our cohorts to look at not only patterns of diet, but also look at health outcomes for people who are scoring well on the -- on the Healthy Eating Index. But in terms of those -- we're doing those analyses now.

But in terms of the supplement users, actually, the surprising thing to me was even in these health-conscious cohorts, the diets of the supplement users were

not that much better. They were really pretty close to the non-supplement users. So we didn't see, contrary to expectation, a huge difference. Even, say, separate supplements like vitamin E -- separate vitamin E supplement users, their diets were a little better, but not that much better than the nonusers. So --

DR. GARZA: If I recall correctly, the population you're working with is much more homogeneous.

DR. STAMPFER: That's right. So that might be the reason.

DR. DWYER: I share your interest, Shiriki, in making the Dietary Guidelines more informative about this issue. It seems to me that we must also be more informative about perhaps fortification and those options as well as that.

But the big problem that we've encountered is that -- that there really isn't a very good database for supplement intakes. When it's vitamins and minerals, it's mediocre. But when it comes to some of the newer things that have become more popular within the past five years, it's -- it's very much more limited.

And even if one knows that someone is taking something, in some cases, it becomes difficult to know

whether the biologically active compound is at the level that -- what level you use. So that strikes me as a difficult issue for us to deal with.

DR. GARZA: Other -- Suzanne?

DR. MURPHY: I think it might be useful to look at the HANES III information on supplement intakes. That's a data set that's only become very recently available. And even though we only have 24-hour recall data to compare it to, at least it might answer some of the questions that are being raised.

DR. GARZA: Meir, and when you did the folate analysis, obviously your statement was fairly strong in terms of the adequacy of the American diet. Does that take into account the bioavailability differences between folic acid as it is added as a fortificant to the diet versus naturally occurring folate with a bioavailability that is very different?

DR. STAMPFER: Well, my comments weren't based on my research. But it's based on what the -- the distribution of folate is now that -- now that fortification is in place. And there's -- it does -- it's not sufficient to bring every woman of childbearing potential up to the level of -- I mean, basically, it's shifting the population so that many

more people are covered in terms of at least getting 400 micrograms per day. But it doesn't -- it doesn't shift everybody. And in particular, it doesn't shift all women of childbearing potential to that minimal level.

DR. GARZA: So do you think the strategy of recommending a supplement would be -- would be preferable to a strategy of nutrition education if it is achievable with dietary means? I mean, why would think that a supplement would be --

DR. STAMPFER: I don't think it's either --

DR. GARZA: -- would be greater compliance, I guess, with a supplement versus a non-supplement.

DR. STAMPFER: I don't think it's either/or. I think you do both. But here's a situation where we know we can benefit in terms of reducing burden of disease. And it's -- it's a widely held recommendation that we wouldn't be going out on a limb here.

DR. GARZA: It may be very useful then to invite Beth Yetley. I think Beth has some data.

DR. MEYERS: There's -- in follow-up to the Institute of Medicine's report on folate and other B vitamins, there is an internal group looking at and doing some preliminary analyses using the bioavailability

calculations of the -- of the -- in relation to the fortification. So I think it would be quite appropriate to invite a representative from there.

DR. DWYER: Also, I think Judy Brown did some work on that recently, didn't she? And it might be useful to see what they are doing in Minnesota again.

DR. MEYERS: And I think Irv Rosenberg, also -- I don't know if it's published yet -- may have some -- some data that pertains.

DR. GARZA: It would be very useful if any of you have any data in terms of how we -- although we didn't form -- how we formulate a strategy in terms of making recommendations because, Shiriki's right, this is going to be -- this is only one example.

I mean, calcium I think falls -- is another one in terms of strategies we would use whether it's -- it's food or supplements and if supplements then -- can we -- can we achieve a greater compliance or are the same people that are paying attention to diet going to pay attention to the supplements.

DR. DWYER: Well, is it that simple though. I'm concerned that it's not that simple yet again. And, you know, what do we do about the fortificants which seem to be

increasing a lot, too?

DR. GARZA: Rachel?

DR. JOHNSON: Yes. No, that was my thought. And I wondered, Shiriki, did you give any thought to functional foods and how some guidance in that area might fit in with guidance on supplementation, as well?

DR. KUMANYIKA: I think we would cover it. I mean, my -- my goal today was really to try to persuade the group that we need a subcommittee and we need to look at the issue. There are several types of things. I mean, a lot of the supplements that are -- that are taken are from the antioxidant -- are antioxidants for the benefits that people think are there while we're still trying to figure out if they are really there in food.

But guidance is needed, or at least not just a statement that, "Ignore supplements because we think we can get it from food." That's the part that worries me that we haven't been able to take it on and see what we can say about it, you know, whether or not we would get better compliance.

It's not whether that's how to achieve the Dietary Guidelines. It's that what do we tell people about something that's in the food supply that they're using.

DR. GARZA: Scott?

DR. GRUNDY: It seems to me there is a big difference between taking a supplement to reach a calcium RDA and take shark's cartilage because I don't think there is an RDA for shark cartilage.

DR. KUMANYIKA: Right. There is a huge difference.

(Laughter.)

DR. GRUNDY: I mean, you know, so it -- it's not -- you know, there -- it's a broad field.

DR. KUMANYIKA: I guess one question I have because I haven't been able to keep up as to what has happened to the recommendation that the -- some of the remedies be put in the realm of over-the-counter medications. I mean, it hasn't happened.

Do you know if any -- if this is not going anywhere because that was one of the things that was recommended that some of the things that are clearly intended as remedies should really be able to be regulated and sold as remedies and not sold with, you know, semantic issues in the label, to be sold as a food.

But we could decide, for example, that we would only deal with -- want to give guidance about supplements

that have some nutritional value or some evidence or some relationship to functional foods. But we have to decide something. And we have to sort out the topic and decide. It may look like some of the ones we've been fudging on would be the easy ones compared to some of the other ones.

DR. GARZA: Sodium.

DR. KUMANYIKA: No, I mean even for supplements. I mean, even sort of stepping lightly into folate and calcium may seem like a piece of cake compared to some of the other ones.

DR. GARZA: On that sort of note, I have a question for the government staff. There is new legislation that broadens statements that can be used as the basis of health claims. Are statements that this Committee might make in its report regarding either supplements or foods going to fall under that broadened net, I guess? Can we get -- can you explore that for us and let us know?

I mean, it's one thing to think that nobody will listen to what we say. It's quite another thing to realize that we might be taken quite seriously in what we say, not only in the guidelines, but in the report that we might issue. Are you aware --

DR. McMURRY: Are you referring to the

authoritative statements?

DR. GARZA: Authoritative statements. There is new legislation that I think enables health claims to be based on authoritative statements such as those made by, and there are -- the "by" are like -- the sense that I have are very comparable to groups like this. And that gives statements that we would make a legal meaning that would go far beyond that which scientists are familiar with.

DR. MEYERS: This is another one -- an area that we could offer a 15-minute presentation from the FDA staff who are quite articulate in explaining the -- their interpretation and the way the other public health service agencies are all a part of that implementation.

I think the bottom line at the moment, sort of laypersons interpretation of the law, is of course the Dietary Guidelines are an authoritative source. Everything you say in here may not be an authoritative statement because in some cases, you are referring to general literature or something like that. And that still needs to be sorted out on a case-by-case basis.

But there may be some implications for when you're being quite firm about something that from your deliberations you believe is an authoritative statement.

You may want to be very firm about the way you say it.

DR. GARZA: Richard?

DR. DECKELBAUM: I have a question. This is clearly a -- this is clearly a major question in the United States right now. And so the question is, if we look at the current list of guidelines, six out of seven applied to the entire population. The only one that leaves out a part of the population is the population that doesn't drink, number seven.

And if we consider what Scott brought up yesterday which is, you know, some kind of guideline relating to minerals, vitamins and maybe even supplements, certainly that's going to affect a big part of the population. Women to begin with is -- I'm not sure of the exact percent, but I would assume it's close to 50 percent, and quite a few men.

And is there an obligation when a major question like this affects the majority of the U.S. population for us to address it either in a guideline or a very guiding statement on it somewhere in this new document?

DR. GARZA: Anybody want to respond to that? I don't know whether there is an obligation, Richard. There certainly is -- we have that prerogative. I mean, there -- there has been, for example, a great concern that we don't

have water, a guideline on water. Well, that obviously influences everyone in the population, but yet the Committee has not felt that any guidance on water has been necessary.

We may decide to change our minds in the future if we -- if we were to highlight the role of physical activity because then the role of water is somewhat different under the context. But that's one example. So that it certainly is -- is up to us.

I mean, and if we feel that this is an important enough issue that involves the diet of the American public, then we may choose to either weave it in to the existing guidelines or any subset or larger set of guidelines, or have one set apart. All of those are within our prerogative as I understand them. Is that -- have I been accurate?

DR. LICHTENSTEIN: I think we're also going to have to consider somehow distinguishing supplements that one takes independent of food from supplements that come in from food whether it be passive like folate now in addition to the B vitamins and iron, or something like calcium in orange juice which comes to mind where it's a choice, but it's also coming in with a food associated with other nutrients.

And I think with the functional foods increasing in availability, we're going to see more of that. And

somehow that distinction needs to be made, also.

DR. GARZA: Johanna?

DR. DWYER: I think no matter what we do, we have to study it more. So we certainly at the very minimum need the supplement report from the President's commission and the other materials that the -- that would be useful in that respect.

DR. GARZA: Shiriki?

DR. KUMANYIKA: I -- I worry about -- I'll do this for the paper. I worry about issuing a guideline on vitamins and minerals for overlap with DRIs. I don't -- we have actually two from the National Academy of Sciences. There are two sets of recommendations already. One is from the Committee on Diet and Health which periodically has cited that it includes a sodium recommendation as someone reminded me.

I don't like the idea that the nutrient specific guidelines are coming from two different places in advisory groups. And so if there is some additional benefit over basic needs, additional benefit, I would rather see that incorporated into a DRI than coming separately from dietary guidelines.

DR. GARZA: If there are no other comments or

questions, let's move on then to the other easy issue, food safety. And Dr. Dwyer agreed to get the discussion going on that.

DR. DWYER: Thanks, Bert. This is not my area. So those of you who are experts in food safety, I hope you will be generous in your evaluation of my presentation. But I do think it's very important to consider this whole notion of foodborne disease and the possibility that we could say something useful.

DR. GARZA: Use the microphone, please.

DR. DWYER: Yes, of course.

(Overhead.)

I think we need to consider the notion of saying something useful about food safety and foodborne illness. If we look at the first question in the guidelines book, it says, what should Americans eat to stay healthy? And I guess what I will argue in the next few minutes is that food safety is as integral to good health as nutrition of the type that I'm usually concerned with which has to do with chronic degenerative diseases.

And if the Dietary Guidelines are about nutrition and your health, it seems to me that we -- perhaps people such as myself who are in a specific area of nutrition

haven't perhaps thought broadly enough. So I would like to argue that in terms of food and your health, this may be a very important thing for us to consider, something about food safety and its integral role in health and nutrition. Could I have the next overhead, please.

(Overhead.)

Well, where do we stand right now? There is no guideline at present. Reviewing the book as well as just the guidelines last night -- and please correct me if I'm wrong -- I don't think there is a mention of food safety in the book. There is nothing at all about foodborne disease in the book. It all concentrates on chronic degenerative disease and a little bit about health promotion. So that's the first thing that surprised me. I've read that booklet so many times and yet had never noticed that.

I think there is some interest in one. Shiriki pointed out that there is great consumer interest in the issue of dietary supplements. I think with regard to food safety, there really isn't interest, at least when it comes to foodborne disease. It's sort of a topic everybody tunes out on.

But certainly in terms of recent reports to the National Academy of Sciences and to the Institute of

Medicine -- within the past month, I think two reports have been issued. So people are concerned about it, perhaps more from the production end than from other ends. But there is certainly concern. And the President has taken an active role himself in trying to bring more attention to this issue.

There's also I think more awareness than ever before of the need for considering the whole food chain and not just a specific part of the food chain when we're thinking about food safety.

Some of the reasons I thought of when I put these slides together for this, thinking about a guideline in this respect, were the notion of harmonizing guidelines with other guidance -- labels, the pyramid and so forth. I realize that isn't the ultimate goal, but -- but it would be helpful to do that.

The other and much more compelling reason is the notion that this is -- this is a source of preventable morbidity that depends on many things; but that those of us who are eaters have some role in determining. So it's an actionable sort of thing. And the question is, what are the actions? Does it make sense for us to go forward? Next slide, please.

(Overhead.)

So what I would like to do is organize the presentation around the rational of pros and cons, next steps and some preliminary ideas that I have. Next slide, please.

(Overhead.)

Well, the rationale, as I saw it, was that there is a relatively high prevalence of preventable -- I'm sorry, that shouldn't say "mortality". It should say "morbidity". And it really does help to have people all the way from the farm to the fork thinking about these issues.

Now, we do have some federal legislation with respect to -- to looking at this food chain sort of problem for producers and handlers. But when it comes to consumers, we're sort of at the eating end, the fork end. There are some things we can do in our homes. There are some ways we can be wise about our choices of take-out food and -- and street food that may help. But it seems to me that it's down here that we need to think about a guideline. Next slide, please.

(Overhead.)

I took this from some of the materials I reviewed for this just to emphasize that there are many different

types of foodborne illness. And death is rare. Obviously, it occurs and we see that in the newspaper when that happens. But morbidity is considerable.

And what's happened that's new, again, compared to ten or five years ago is that we're beginning to learn to count better. We're beginning to be able to -- to count foodborne illnesses a little better than we used to. It's always been there just as some of the -- the substances in food that are now able to be analyzed for -- have always been there. But basically we can count it better.

The interesting thing is that for many of these hazards, particularly bacterial, there are some things we can do about it. We can do other kinds of things for the chemical and viral and parasitic. But there are things we can do. Next slide.

(Overhead.)

Looking for prevalence estimates of foodborne illness, I had a lot of trouble. And so I decided what I would do is just make a statement that the prevalence is unknown. It's known to be high. And much of it is known to be preventable.

Certainly, some of it is caused by handlers and producers. But other preventable morbidity is caused by

people in the home, not only by cooks, but by people who eat food that has stayed out too long. Next slide, please.

(Overhead.)

So I would argue that everybody has a role to play in this type of food safety. And producers and -- and food handlers we're coping with fairly successfully by -- by -- by various regulatory measures. And these certainly can't be left off the hook. I'm not suggesting that this is a consumer issue and not a producer issue.

But I am suggesting that those of us who are eaters, cooks and food handlers also have a role to play. And that's why I think it might be useful to consider a guideline. So the key is across the whole food chain. Next slide, please.

(Overhead.)

Just thinking about bacterial foodborne illness alone, as you know, there are many different types, some of them listed on your left. And the necessary conditions vary considerably. So it isn't a simple process and I'm not suggesting that the guideline is all that's necessary. I'm simply suggesting that it's good to call people's attention to this. Next slide, please.

(Overhead.)

Well, Bert's second question was, what issues require evaluation and what potential changes might we consider? It seems to me that there are several issues that need to be considered about a guideline such as this. First of all, is it -- can we think of something that would be actionable to say? Certainly, we know that there are some groups that are specifically vulnerable.

We also know that -- that there are other things out there. I guess there's even a food safety pyramid someplace. That also needs to be considered. And, again, this harmonization thing seems to be very important. And the notion that one can deal with this preventable cause of morbidity is also I think important.

The cons as I thought of the issues are that -- that if you look back at the pyramid or if you look at any guidelines, that it really applies to specific food groups or specific guidelines within the Dietary Guidelines rather than across all. I realize that food safety applies to all the guidelines. But if you look at the -- the ones that involve -- on the pyramid, the groups that are -- I'll show you in a minute, there are a couple of groups that I think deserve more attention.

One could also argue that -- that doing this would

detract from a chronic degenerative disease focus which was after all what led the Senate Select Committee and later, the Department of Health and Human Services and the Department of Agriculture to focus on these issues and produce the first Dietary Guidelines.

One could also say that, "Well, these issues are perhaps sickness issues; they're not very serious; they're not necessarily chronic and degenerative and, therefore, they don't deserve attention because they are only acute for the most part." And the other argument would be that this is an inappropriate message. It dilutes the thrust of these guidelines. Next slide, please.

(Overhead.)

Well, what -- what could we say -- what kind of changes might be suggested. Well, one of the ones that have been used by a number of campaigns so far would be just something that concentrated on food handling practices like cleaning and separating and cooking and chilling and avoiding contaminated food or food that's sat out for a long time. Next slide, please.

(Overhead.)

The Chinese have an easy guideline, if you've seen the Chinese dietary guidelines from the mainland. They just

say don't eat any food that's been left out overnight. But hopefully that isn't one that we need anymore.

There are also some guidelines that have been popularized by the "Fight Bac" campaign. You've probably seen this, keeping food safe from bacteria. But I'm not sure that's exactly what we're after. It just seems to me that that's a little too narrow. Next slide, please.

(Overhead.)

We want a more generic statement if we go in that direction. What I tried to do here was just take the different sorts of food groups that people are using in guidance like the pyramid -- food guide pyramid, and then just tried to sketch out the precautions that might be appropriate by food group.

And, again, I'm no expert on this. But it seems to me that some of the groups have more -- need more attention than, say, others. So there is an inequality, if you will, in terms of applications. But this alone might be news to some people. Next slide, please.

(Overhead.)

So the question I came up with in reviewing this is, does it fit best under variety in the text where food groups are discussed or is it better as a separate

guideline? And a week ago, I decided it was really better as under the text. Next slide, please.

(Overhead.)

And I think in the last couple of days, I've decided that it might be better to consider a guideline. So I -- I leave it up to you. But we do have an obligation, it seems to me, downstream, to make sure that these things are all harmonized. I realize the focus of this Committee is on the top. Next slide, please.

(Overhead.)

This is my -- my feverish work at 1:00 this morning. If you think about it, there is a wonderful word that is in a lot of USDA legislation if you've ever had a chance to read it. It talks about wholesome food. And when I was on the President's Reorganization Project in the Carter administration, briefly, I always went up to the agricultural economics people and said, "What does this wholesome food mean? What do you mean by that?"

It seems to me that what we mean by that is really something that involves not only the nutrients and not only making sure that the other things that are in the food are healthful, but also this whole notion of handling foods with safety in mind.

And so it seems to me that the materials that have stemmed from the Dietary Guidelines so far, things like the food guide pyramid, are very useful. But it may also be useful to consider something about food safety in some manner. Certainly, we shouldn't let another edition of our guidelines come out without the words "food safety" being mentioned. Next slide. I'm almost done.

(Overhead.)

So I think the next steps, Dr. Garza, would be to consider if, in fact, this is useful at all to consider going farther with; what to include; how to include; how to write it up. Next slide, please.

(Overhead.)

And to -- to decide how it should be handled. The options include a separate guideline, changing the text under "variety". Certainly, if we do this, we must always remember that joint responsibility for producers and consumers must always be recognized. But we need to think about steps eaters and consumers can take at home or by themselves or by the cook in eating out or eating elsewhere and then I think also reporting problems. Next slide, please.

(Overhead.)

So we certainly do need to keep in mind the producer as well as the middlemen and the eaters that -- but it seems to me those are dealt with better by other means, regulatory means. I think we need to think -- I think regulations also need to find better ways to give eaters ways to report interactions and maybe we need to mention other hazards. Next slide.

(Overhead.)

So there are many other things that must be done and that we can't do in Dietary Guidelines in terms of producers and handlers and also government, the kinds of things government needs to do. But it seems to me a guideline might bring some of these things to the consumer-eater attention. Next slide, please.

(Overhead.)

UNSPECIFIED VOICE: So, you're going on to supplements?

DR. DWYER: Oh, yes. Let me just finish up with this. There are a lot of other ways that one could characterize the idea of food safety, and certainly environmental contaminants, unintentional additives, intentional additives. Those are also perhaps of interest. But I think what I'm specifically talking about in terms of

food safety is foodborne disease, things that people can do themselves.

I think I'll skip the other ones unless there is discussion. Thank you.

DR. GARZA: Thank you. Any comments or questions of Johanna? Shiriki?

DR. KUMANYIKA: It's interesting to think about food safety and the Dietary Guidelines. The last slide that you thought was not relevant was actually the one that -- that I thought was relevant to the guidelines because this is -- my view is that our role is to think about issues that need some deliberation and a decision that are not clear-cut and advise on that, and then how that's packaged and promoted to the consumer is up to the agencies.

So I could -- where I could see that we could say including guidance on other nutrition or food safety issues as you package either a pyramid or Dietary Guidelines is helpful. The one that I think consumers are very interested in for which we might consider which might relate to chronic disease are things like additives and contaminants. I mean, that's a big issue.

But if people are worried about carcinogens in the food supply, they say things like, "But don't fruits and

vegetables have pesticides?", and they want to know is that really a good recommendation because maybe it will increase my risk of cancer while it's doing something else. So the food safety information about washing or whatever if you think there is residue on there could fit into that kind of a chronic disease.

The other seems to me more of a decision of the agencies about what the booklet is for than something we would deliberate on. That's just my view of it.

DR. DWYER: Well, that's why I changed my thinking in terms of -- I think -- I think a general statement might in fact be very useful on -- on the whole issue of what consumers can do about handling. And then perhaps the way to handle those other issues would be in guidance.

My concern is that if we always wait until something is something consumers are demanding, guidance about that some very important things will -- will not ever get in the guidelines. For example, physical activity in the obesity guidelines. I don't think there was a groundswell of urgency for people wanting to be told about physical activity.

DR. JOHNSON: Johanna, maybe I'm misunderstanding you because my read of some of the literature is that when

consumers think about food or when they go the store, that their top concern is food safety and that nutrition or, you know, avoiding chronic disease or whatever is -- is secondary to food safety and that it really is a very, very considerable concern among American consumers.

DR. DWYER: You may well be right. I guess the stuff I've read has usually said taste and, you know, preference is the first thing and then these others fall out. It depends on the survey.

DR. JOHNSON: Yes. I know I read something recently.

DR. DWYER: There's -- the problem is how to operationalize it. You know, how so you operationalize, make that concern something that people can do something about in a positive way that will be helpful to them healthwise?

DR. GARZA: Alice?

DR. LICHTENSTEIN: I seem to remember seeing a lot of pamphlets through the years sort of come across my desk dealing with food safety that came from some agency within the government. It would probably be useful if we could get some of that information because I think it's relatively extensive. And also if we could clarify the issue of -- of

consumers' perception of it as far as what's foremost in their mind.

DR. DWYER: Yes, I think we need to take it out of the category of whoever makes the potato salad for the -- for the church picnic is the person who needs to be worried about that and read those little pamphlets. What we need to do is to get this into the "It's everybody's business", and the question is how to operationalize that.

DR. GARZA: How many of you feel though -- I mean, I don't want to take a vote. But it would be very useful to have a discussion of whether or not this is appropriate to include in the Dietary Guidelines because Johanna is right. Certainly, I don't recall it ever being mentioned, either in the sense that Shiriki raised in terms of contaminants and risks that relate to additives or pesticides, or to steps that the consumer can take to minimize risks of microbiological contamination, growth, et cetera.

DR. JOHNSON: Well, I think what I'm struggling with is the very point Shiriki made which is people are more concerned about the things that they have no control over. So they may be more concerned about E. coli in the apple juice, the unpasteurized juices, that they have no awareness of than the actual food handling issues that they have

control of. So they are very different issues about what is in the food supply versus what are controllable food safety precautions.

DR. GARZA: Scott?

DR. GRUNDY: How big is the problem of the latter, the consumers' inappropriate use of food leading to disease? Is that a major national problem? I mean, I understand the problem of contaminated food and things that people don't have control over and we want to do all we can to avoid that. But what about practical advice? Are we dealing with a major problem?

DR. DWYER: I think we need more data on that from CDC and from the other relevant agencies. But it's my impression that there is a considerable amount of preventable illness that consumers themselves can prevent that is over and above the Jack-In-the-Box accidents and all of those other things. So that I do think there is a considerable amount.

The other thing, Dr. Grundy, is that as time goes on and as we measure these incidents better, the prevalence is going to go up no matter what else happens just because we measure things better. So it seems to me that in a sense, this is an anticipatory guidance measure that could

be -- could be quite important.

DR. GRUNDY: I mean, I think you made a persuasive case for having something in the guidelines about this. But I think it would be important to know where the problems -- the major problems are so we could target those.

DR. DWYER: I agree. It was the best I could do in two weeks, was the little chart showing that clearly it's in some areas more than in others. But the question is what could be done about it is a question I can't answer. I'm sure somebody can.

DR. GARZA: It's my understanding, Scott -- I don't know how good the data are -- that in fact most of the food safety issues, at least in terms of microbiological contamination, occur in the home and that, in fact, the majority are not at the producer or food handler.

Now, whether that's true or not I don't know because I don't know how strong the data base are. But certainly as you hear this problem discussed, the major -- at least from a prevalence standpoint problem, appears to be at the home. Now, I don't know whether that's consistent with what the rest of you have read.

DR. STAMPFER: On the slide -- one of the slides you showed the different causes of problems. And it looked

like unknown was the -- I don't know what the scale was, but unknown was the -- was the most common or --

DR. DWYER: That's just because they didn't -- these were reportable incidents. And they were -- where they didn't do any -- they didn't have any fecal samples or anything else, so they couldn't tell anything.

DR. GARZA: People called in and said, "I'm sick", so you couldn't attribute it to any of them.

DR. DWYER: The others, they at least had a diagnosis. So it's --

DR. MURPHY: I think Bert's right, that a substantial proportion of foodborne illness can be prevented in the home. "Caused" is a more loaded word. But certainly if there is salmonella in the chicken, you would prefer it not be there to begin with. But if it is, you can certainly handle it by cooking the chicken well.

So I think there is a case to be made for it being appropriate in the Dietary Guidelines booklet. I guess I would like some reassurance that we can cover it adequately in a short, bulleted sort of message because I don't think we want to take several pages of our booklet to talk about food safety.

So maybe someone from the "Fight Bac" campaign or

one of those could talk about ways to make the points concisely and if that is possible.

DR. GARZA: Alice?

DR. LICHTENSTEIN: I would also be interested in getting some information on how effective the previous campaigns or attempts have been as far as educating the public as far as foodborne illness because there is some history with this, and get some assessment. I mean, clearly it's an issue. Probably as far as prevalence goes, it's more likely to be under-reporting than over-reporting.

But I would be very interested in getting some kind of assessment of how effective a major effort, let's say, in the Dietary Guidelines would be versus in another realm.

DR. GARZA: Shanthy, in the work that the Department has done, has there ever been a consumer group that has been asked whether or not they would consider food safety as an appropriate part of Dietary Guidelines or were we to include it, would we just confuse consumers for the reasons -- some of the con reasons that -- that Johanna went over; that, indeed, it would take focus away from chronic disease and other sorts of issues of that type? Do you know if that's ever happened in any of their focus groups or --

MS. BOWMAN: On the part of the national guidelines, no.

DR. GARZA: Or in any other --

DR. McMURRY: I think the recent --

MS. BOWMAN: Go ahead.

DR. McMURRY: I'm sorry -- the recent focus groups that LC ran, they included that as a probing question. But I'm not sure where they came out on.

DR. DWYER: Can we get access to that material?

DR. McMURRY: I'm sure they're planning to share that information when it's ready.

DR. DWYER: I don't think the guidance or the -- the focus groups that you did for -- that we were given ahead of the meeting didn't have anything on it.

DR. McMURRY: No. I don't think so.

DR. MEYERS: We can provide -- we can provide some background from the President's Food Safety Initiative which is a government-wide, huge -- I wish Congress would show more interest in it -- initiative that -- that in one of its earlier iterations actually discussed food safety guidelines similar to the Dietary Guidelines.

And I don't know whether that is in the final version and whether any work is being done on that. So

that's something we can also check out for you.

And I know there are people in the room today who are involved in the -- the "Fight Bac" campaign which is a large public-private partnership and may have some information on effectiveness and efficacy that they could provide. So we will provide some more information to you so you can -- at least the best we have, so you can make an informed judgement.

DR. DECKELBAUM: I think we really need more of the science base here because if you look -- so there is sort of a science base on the producer's side because that goes through the CDC and it gets reported both to the CDC and the newspapers.

But in the home, you know, if we look at the things that can be transmitted in the home, salmonella -- the major way that salmonella appears or even gets reported where it's a reportable illness in certain states is it comes from fecal-oral transmission, from kids, day care centers, that kind of environment.

And we need to be able to get a handle on the direct food component to this sort of basket of diarrheal diseases and other diseases that can be brought in directly from improper handling of food. And it must be -- I'm not

sure where the data is available, but I think that's going back to where we were yesterday. We really need the science base in considering how strong or how much space we should provide this in -- in the Dietary Guidelines.

DR. GARZA: Perhaps, Linda, we could also ask -- I know Sandy Schlicker is in the audience -- that we could go back to the Academy and see if any of this information was collected as part of the Academy's recent review on food safety in terms of -- of at least the extent to which food safety issues occur in the home because they may have obtained that information as part of their review.

DR. DWYER: I don't know if it is appropriate to suggest this as well because I don't know the grants that well in that institute, but the Infectious Disease Institute at NIH -- I know Jerry Kirsh, for example, has worked very actively in this. And he has just come down to that institute. And also, perhaps CDC would have a number of things on day care centers and the whole business of these things.

It seems to me there is a lot of research, as Richard pointed out, that -- background material that we would need to consider.

DR. GARZA: Okay. Is there -- is there any other

comments or questions of Johanna -- are there any other? Okay. Well, that brings us to a -- close to the break. But before we take the break, it may be very useful to have a general discussion on the principal decision we have to take today. And perhaps we could do that before the break.

And that is hearing from each of you as to whether or not you think there is sufficient reason to undertake a much more detailed review of the Dietary Guidelines or if, in fact, the various presentations you've heard have convinced you that, in fact, we would serve the American people and ourselves better if we just declared them adequate to the task and we could all go home and that would be it.

We could probably set a precedent if that were the case. Who would like to start that discussion? Suzanne?

DR. MURPHY: Well, I -- I'm not sure I want to volunteer to start the discussion. But I would like to start with a question if I may. I have not heard too many really compelling reasons to change the wording of the guidelines themselves. But I've heard a lot of reasons to change the text that supports some of them.

When we take this vote, which of those -- how do I distinguish those or should I distinguish those?

DR. GARZA: Well, it could involve either one. I mean, we may -- we may want to change the text or consider the inclusion of other guidelines or exclusion of existing guidelines or change the wording of the guideline itself, so that any of those, as I understand it, would fall under, "No, there is substantial reason to continue the review."

Adopting the present format pretty much says that you're buying both into the test, the specific guideline and the inclusiveness of all the issues that you feel need to be considered. And, you know, whether we go to ten or five.

DR. WEINSIER: If we're just taking a vote, I would have to vote for, yes, we need to review because I feel there are areas that need revision. And I guess if we go so far as to say one word needs to be changed, then I have to vote for, yes, to revise.

But if I can add an editorial, you know, to that, I -- if I had to go in one direction or the other, I have the feeling we're moving toward being more encyclopedic and all-encompassing in the guidelines versus being less encyclopedic and more, you know, focused and directed on some -- some key issues. As a scientist, I think at least my tendency and probably others around the table is to be encyclopedic.

So it just -- in the back of my mind, I'm thinking if I had to make a choice between being encyclopedic and extensive in the report to bring in the food safety issues, perhaps even drug-nutrient interactions which we haven't discussed, more detailed information about supplements, calcium, folate, et cetera, then we could take the risk that we are increasing the size of this booklet from the 23 pages, 1985, to 41 pages in 1995. At the rate of increase which is a 20 percent increase in the first five years and a 50 percent in the second five years, we can project that the next booklet will be over a hundred pages.

(Laughter.)

And so we really do have to choose between if we had a choice of having in the back of a grocery store a text that would be available for purchase by a small proportion of the population who would be willing to purchase it, but they would be well informed, versus a sign hanging when you enter the grocery store that says here are three pointed guidelines that will direct you to the fresh fruit and vegetable section, and we would therefore reach a large proportion of the population who would only be somewhat better informed. You know, I think that would be a tough choice that we're going to have to make.

But in saying -- voting, yes, to revise it, I think we have to be going back constantly to Alice's first statement: How many guidelines? How much information? How encyclopedic can we be?

DR. GARZA: I feel we should have a disclosure statement at this point. You will have a very resistant Chair into getting this more encyclopedic. You will have a very enthusiastic Chair to going back to 23 pages. I don't know if I will be enthusiastic about one placard. That might be a little bit too distilled. But -- but certainly, I would agree with Roland. I mean, we cannot afford to get to the hundred page.

So that any way you think of this, please try as we -- if we decide to go through this process to really distill out the most important issues and -- and provide advice to the departments that would get those issues before the public in an effective way. But going -- going to a hundred pages certainly is within our purview. But I would be highly resistant. If I could have a strong ally --

DR. WEINSIER: Well, because every topic we've brought up, I feel, you know, that we could strongly make the argument the public needs to be informed about all these issues we've discussed. But can we get it down to a single

bullet or do we dilute so much that now we're giving with the single bullet just enough information to confuse and mislead?

DR. GARZA: Well, that's why, remember, that I said that one of the Cs -- the five Cs was going to be complexity --

DR. WEINSIER: Right.

DR. GARZA: -- because of that distillation. That is the hardest job this Committee has of all because I don't know -- I think it was Woodrow Wilson who once said that if somebody invited him to speak and wanted him to speak for an hour, he could do it in about ten minutes notice. If they wanted him to speak for ten minutes, he would need three months to prepare. And it's just -- it's distilling the message in a way that neither confuses or distorts, but fully informs that is difficult. Or -- or --

DR. JOHNSON: No, I -- I've been -- I think that what I've heard about total fat, sodium and some of the issues about moving to whole or refined grains is enough to make me think that, yes, we need to go forward.

DR. STAMPFER: I think the text for each of these guidelines needs revision. I don't think there is any guideline that should remain unrevised in the text. For the

sound bite, I think there are several of the guidelines that need some major surgery.

DR. KUMANYIKA: Well, I think we need to revise them. I won't go into detail.

DR. GARZA: Just revise. Okay. Richard?

DR. DECKELBAUM: And I also vote for more meetings.

(Laughter.)

But I think following what Meir just said, I think -- and trying to balance encyclopedias versus the -- going back to 23 pages, I think that there are areas in the existing guidelines that could be surgerized or condensed. And that's something we actually haven't spent very much time on at this meeting. We've really been spending most of our discussion on what -- either what do we change or what do we add. But I think there are areas that could be condensed or quite a bit -- maybe even removed from the current guidelines.

DR. GARZA: Johanna?

DR. DWYER: I think that we should go ahead and not get fixated on the number of pages in the booklet. Think of the major things that people need to know. If it's nine, we're still one less than ten. And in Washington,

perhaps ten is a good number of commandments to be obeyed.

(Laughter.)

So there's plenty of room --

DR. GARZA: That was Dwyer, D-W-Y-E-R.

(Laughter.)

Do you want to give your social security number?

(Laughter.)

Add anything? All right. Scott, can you top that one?

DR. GRUNDY: I think that the -- these guidelines sort of -- as they exist now are -- represent the end of the last era of nutrition thinking. I think in the last five years, there has been a tremendous change in the way people think about nutrition. So I don't think we have any choice.

DR. GARZA: Okay. You've got to ask a question.

DR. LICHTENSTEIN: Can I --

DR. GARZA: Oh, I'm sorry, Alice. I went right through you. I apologize.

DR. LICHTENSTEIN: That's okay. I sort of did it at the beginning of the deliberations. Obviously, I agree with the rest of the group. I think we actually have an obligation to revise them and to take a hard look at everything, especially because there are so many different

choices of foods that are actually on the market. And I think consumers are challenged more than they ever have been before.

And I think what I've gotten out of these discussions is that it's not real clear where some of these things fall out. But I think that we should probably give the best guidance we can at this point. And I suspect five years from when we, you know, finish, there will be, you know, further refinements. But I think we have to do it.

DR. GARZA: Suzanne?

DR. MURPHY: So it's now time to vote here. Yes.

DR. GARZA: Well, I mean, whether -- you said you had a question, but you were not prepared to make a recommendation. So I'm just coming back to you now.

DR. MURPHY: Right. Well, your -- your answer to my question was in effect -- stated my view which is there are certainly changes in the text that need to be made. And if that is a necessary condition for us to have additional meetings, then we certainly need to have them.

DR. GARZA: For somebody that lives in Hawaii -- or will soon be in Hawaii, that's a strong vote of revisions.

DR. WEINSIER: And your position?

DR. GARZA: I, too, feel that in fact they ought to be revised. I'm not quite sure the extent to which I would revise the bullet messages. I think that requires still a lot more discussion. But I certainly heard issues that relate to carbohydrates, issues that relate to sodium, issues that relate to the way we present the alcohol recommendation, to salt, to the need to explore whether we need other guidelines or incorporate other text that relate to food safety, to supplements.

I think Scott's -- Scott's point is -- is right; that, in fact, the issue of the role of nutrition generally in science and health is changing very dramatically and that the guidelines are going to have to start reflecting that change.

I feel very strongly that indeed we are missing an opportunity in the U.S. as the health system undergoes the changes that it is to really create a health system that minimizes the need to treat. And this is a major vehicle for minimizing that need by contributing, as the Surgeon General has said, to building a healthier population and that the guidelines could help do that.

The other piece, though, that I would ask you to think about is as we go through these recommendations, to

think about what could make them more actionable. And a greater part of -- of just having them out there.

But I'm -- but if we're going through an exercise and less than one percent of the population or whatever the number may be doesn't even know they exist, then we need to start thinking about, not because we'll be responsible for it, but just to make sure that the advice we provide is given in such a way that it's going to be actionable both within and outside of government.

Otherwise, it's -- it's us coming together and it can be quite enjoyable and useful scientifically. But it doesn't serve the public -- the public good.

DR. LICHTENSTEIN: It would be very helpful for me to have a discussion about what we all feel is sort of appropriate for Dietary Guidelines because that's going to really impact tremendously on the length and the number and whether issues like drug-nutrient interaction are appropriate for this document of food safety or is appropriate for this document and perhaps some others.

But right now, I -- it seems to be an open field. And I don't have a real good feeling for where that is. And then when that decision is made, how that is going to impact on how actionable the specific guidelines that come out are.

DR. GARZA: Does anyone have any comment to that discussion? Johanna?

DR. DWYER: Yes. I -- just thinking about Scott's very cogent remark about what -- what's coming and what was, it seems to me that there are some paradigm shifts that have been suggested today or yesterday. One is the whole issue of chronic degenerative disease versus broader issues. A second thing that seems to be there is the issue of food-based dietary guidelines versus something else that is a combination of a whole bunch of things.

Another is healthy lifestyles and the emphasis on physical activity versus food alone. And a third theme that could be a paradigm shift is age, sex, condition-specific guidelines. And all of them have been dealt with by one speaker or another. So it seems to me that we are faced with several very serious philosophical views. I don't think anybody that I've heard has talked about not having chronic degenerative disease as a focus. Nobody said that that I've heard.

So the issue isn't that which is a paradigm shift of 1977 that was so painful for many people in this room and who probably some of us still have the stab wounds from that one. But these others are very important, too, and maybe

will lead us into a broader view of nutrition for the twenty-first century.

DR. GARZA: Any other comments before we break? Alice -- the only other guidelines -- I'm sorry, Shiriki?

DR. KUMANYIKA: Well, I just happened to think looking at the booklet is that the other thing that's changed a lot since '95 is the worldwide web and somehow with the amount of information that's on the web, the key -- the attempt to give consumers information about good sources of this, that and the other, a sub-effort for putting this together might include some cross-referencing or use of information, good sites on the web to bolster up the advise.

DR. GARZA: That's very good. Whatever guidelines we come up with obviously have to apply to healthy people. This is not included to be a therapeutic document. It should be of interest to the country as a whole to all age groups over the age of two.

And obviously, the prevalence and the severity of opportunities, problems, have to be significant enough to include in a document that isn't encyclopedic. And so that leaves a lot of room for judgement. And we're going to obviously rely on each of you for that. All right. Let's -- let's break for lunch -- for lunch, for a break.

(Laughter.)

And we'll -- we will come back and begin planning out the rest of your lives.

(Whereupon, a brief recess was taken.)

DR. GARZA: All right. Let's -- given the fact that the -- the group has decided that there is substantial reason for wanting to review the information in the guidelines, not necessarily that they may have to be revised, but certainly to review, there are several items of business we have to take care of.

The first is I would find it very useful to have a Vice Chair that complements at least my scientific background. And I have asked Suzanne Murphy if she would be willing to play that role because of her role in epidemiology and nutrition education and with that, et cetera, in terms of uses, that she would compliment at least the experience that I have.

And we would also get some geographic balance as well, although some of my friends in New York feel that we're out in the provinces or out west because it's west of the Hudson or something. At any rate --

DR. DWYER: I so move.

DR. GARZA: Thank you. There is a motion that

Suzanne be appointed Vice Chair and a second. Are there any objections or discussion? If not, then all those in favor, please say, "Aye".

ALL: Aye.

DR. GARZA: All opposed? Thank you, Suzanne.

DR. MURPHY: I vote against it.

DR. GARZA: We -- she has some black and blue marks, but they're mild. The second that may cause more -- more angst in the group is a preliminary division of labor. And I want to make -- before I give you the -- at least the initial division of labor -- two points very clear.

One is that we're going to divide people out according to the present guidelines and some of the issues we discussed. That should not be taken by either the public or either of you as a buy-in to the fact that we're going to end up necessarily with the same guidelines.

It's just the most straightforward, organizational way that we can approach the task. But as I announce these groups, if any of you have any concerns as to the group that you've been asked to lead or to work with and you want to be reassigned, then please call me and we can work it out.

The second is that if -- if groups as they are put together feel that it is really important to have

communication with another group because we either have to bring together guidelines or take portions of the text that have been associated with one guideline to another, then all of that can occur.

After we go through those work assignments, then I will make some suggestions for the time frame that we're going to be trying to accomplish certain tasks. And then we can discuss both the assignments, the organization and the time frame.

So on the variety guideline, I'm going to ask Suzanne to take the lead on that. That's not a surprise based on the presentation. Roland, if you will -- if you will join her on -- on that one. And we will ask Dr. Tinker -- she won't be available until April. But we will find a mechanism to keep her involved with e-mails and things of that sort so that she -- it's clear that -- that she then not come into the process totally uninformed.

On physical activity and weight, if Dr. Weinsier will take lead on -- on that guideline. And Dr. Kumanyika and Johnson, if you will join Roland with that one.

On diet, grain, vegetables and fruits, Dr. Deckelbaum, if you will continue taking the lead on that with Dr. Tinker and Lichtenstein. If you will join him on

that one.

On fat, saturated fats and cholesterol, Dr. Grundy, if you will take the lead on that with Dr. Deckelbaum and Lichtenstein, again, joining that group. I'm afraid we're going to make up for the fact that Alice didn't present. So you'll see what I mean in just a big --

Alice, nothing comes for free in this organization you'll soon learn. But in the end, it all works out I hope.

On the diet moderate in sugar, Rachel, if you will continue -- you did such a great job with that -- leading that group with Dr. Deckelbaum and Lichtenstein joining her. We're not through yet, Alice.

DR. LICHTENSTEIN: I was wondering why I wasn't presenting.

DR. GARZA: That's right. There -- on salt and sodium, Dr. Kumanyika is going to do this alone. We will offer her a face change with a Committee protection plan. We've worked it out with the CIA and --

(Laughter.)

DR. KUMANYIKA: I love it.

DR. GARZA: So you will -- I think your husband may not necessarily like the new role, but I don't even know. Johanna and Dr. Stampfer, if you will join Shiriki on

that.

The moderation in alcoholic beverages, Meir, Dr. Grundy and Dr. Dwyer. And then we have two other issues that we feel we need groups, not necessarily to develop a guideline -- I want to make that very clear -- but to help flesh out the area in helping us decide whether the appropriate role for this would be in fact a guideline or whether it ought to be embedded in the text or whether we ought to just leave them as they are in terms of treatment because after we do our review, we decide it's not necessary.

On supplements, Dr. Lichtenstein, we're going to ask you to lead that group. And Dr. Murphy and Grundy, if you will join Alice in helping us think through that one. And then I'm sure that Dr. Kumanyika will help. But we didn't want to give you two of the more controversial issues at least. If we believe The Post, you have one already.

And then on food safety, if, Johanna, you will take the lead on food safety. And, Dr. Johnson, if you will help her think through that with Dr. Tinker. And we will ask her to join you in that.

Now, are there other issues that either didn't come up or that you feel need focused attention by a

subgroup?

DR. JOHNSON: Have we put the issue of dietary guidelines in children to rest?

DR. GARZA: I think so. I think you were quite persuasive and that there is a -- we could decide if we wanted to look at the under twos -- I know that was a matter of great discussion at the last -- the last time the Committee met, the rationale being as I recall that because so much of the Department's efforts are directed at young infants, it was perhaps a bit incongruent that we wouldn't have guidelines for that very important group.

But no one raised it in the discussion. And so I felt that --

DR. JOHNSON: I suppose at the very least we could have a statement about breast-feeding somewhere.

DR. GARZA: Well, actually, there --

DR. JOHNSON: Or is there --

DR. GARZA: There is -- there is something included in there, but it's sort of anomalous because we say that it -- it applies only to the under -- I mean to the over twos. And then these current recommendations go up to two years. So there is a statement there, but I think it's a bit anomalous.

We could look at that, but perhaps we could postpone that decision of group because we really didn't have a chance to review it. My sense from the discussion though was that people felt fairly comfortable that the current guidelines apply at least to children over the age of two. And that while the tools we might want to use for communicating that information to either caretakers or children would differ from the booklet, that the substance, both the report and the booklet itself, was generic enough to apply to all that age range.

Now, we might change the text, but then we didn't need a separate dietary guidelines. So that seven or ten differing items would be directed exclusively at children from zero to 18 or two to 18. Did I read the Committee's sense correctly or is that not -- is that not accurate on my part? Richard?

DR. DECKELBAUM: I think it's accurate. But coming from the pediatric side, I would urge that each committee when -- if -- especially if there is going to be changes, that they consider special groups. And we might even have a checklist of special groups that need to be considered, peri-conceptional women, children, the elderly. You know, are there -- should there be some special sentence

or comment relating to special groups in different groups that we have to deal with?

DR. GARZA: And that's a very important point. And the -- the other is --

DR. DECKELBAUM: We might decide what those groups are.

DR. GARZA: Yes. Well, why don't we try to do that right now. I mean, we have a little bit of time. Yes, Alice?

DR. LICHTENSTEIN: Well, I would strongly argue for the elderly. I think we need to consider whether there needs to be some modification or not.

DR. GARZA: Yes. I think -- I think the -- the groups that you mentioned certainly would all be included. The other group that is there are those that are on -- are dieting because so much of our population diets at one point or another during any given 12-month period. And so the dieting brings in some added concerns.

Are there other groups that haven't been mentioned? Johanna?

DR. DWYER: Yes. I would think somehow to deal with teenagers, particularly pubescent teens.

DR. GARZA: Yes, adolescents.

DR. DWYER: I'm trying to think of Healthy People 2010. Do you break it out -- what are your break-outs there? It's children, infants, teenagers?

DR. MEYERS: It's a range.

DR. DWYER: Okay. It's just easier if you harmonize across the --

DR. GARZA: This is a -- this doesn't mean that we can't come back and revise those groups. The other important point that I -- I failed to make and I need to make it now is that even though there have been subsets of us that have been assigned to different groups, this doesn't mean that you don't have responsibility in the discussions for all of the guidelines.

And that's certainly to the degree that you feel that a group is either being overly encyclopedic or -- or leaving out an important issue. Then the expectation is that none of -- none of us will be shy and hold those observations back.

This is truly just a way to help the discussion get going and -- and giving responsibility for specific tasks to groups as a way of organizing the work. But the guideline -- the advice to the Department are not issued by subgroups. They are issued by the entire Committee so that

all the discussions of all the work groups will always come back here to the -- to the plenary session. Johanna?

DR. DWYER: Bert, I'm not entirely clear what the group's TS is.

DR. GARZA: Well, I'm about to get to that.

DR. WEINSIER: Define for me -- you mentioned as the special group, dieters. How do you define "dieters"?

DR. GARZA: Anyone who is trying to control their caloric intake below their -- their physical activity needs. And that has been brought up in the past because of nutrient density issues and whether or not nutrient density issues for individuals that are trying to actively restrict their intake should in any way influence the advise that we give in the dietary guidelines. We may decide that dieting is not -- is not relevant. It's included in the present -- in the present text.

DR. LICHTENSTEIN: I'm still a little unclear where things like the functional foods would fit in.

DR. GARZA: Why don't we ask the supplement group to think about that one. No, and I don't mean that because you raised it. I mean, I just think that that's -- I mean, it's sort of tied in with that whole issue.

And I think it's very difficult because given the

definition that Shiriki correctly pointed out, supplements are no longer just vitamin and mineral supplements. They are somewhat broader. And so that group needs to consider that broadened definition. And certainly that -- the report -- the Commission report from a year ago I think will be very helpful to that group.

As to -- as to charge and task of the various work groups, Carol Suitor, who some of you met last night and has joined the group for the last day and a half, will be helping the group put together much of the material in terms of pros and outlines along with the staff, both at DHHS and USDA.

It's my understanding that the staff will be assigning a specific task member to each of these groups as a contact person. Is that correct?

DR. MEYERS: If you would like us to do that, we will do it.

DR. GARZA: I think that would work best so that you don't have to -- you know, you will have a contact person within the staff so there is -- are references, analyses. Then that individual can play the traffic cop to direct you to the right person. But you will have a primary contact who will be familiar with the work of each of the

subgroups.

And then internally, we can figure out who is going to do what for whom. But if there is a primary contact, then it certainly helps, I think, the work groups identify help quickly.

The -- originally we had thought we were going to try to bring everybody back in January. That may still be what we want to try to do. But what option that we think -- that we've thought about is that if each of the groups between now and December 1st -- that in essence gives you about two months to outline a rationale that would be included in the report booklet, analogous to this -- an analogous booklet to this one -- that provides a rational for either any deletions, additions in text or guidelines.

Not worry too much within that time period of the specific changes that you would -- I mean, the wording, the semantics to change, but developing a scientific rationale for the change. If within that two-month period one can develop an outline for the types of changes you would like to see within the booklet, I don't see any difficulty with that.

But if we could get those to Carol and the staff here by the first of December. And what they would try to

do is to flesh those out in a way that is uniformly consistent in terms of the level of -- of the science. And by that, I mean the level of detail that are -- that are provided, get those back to you in time for you to revise them, s that we could come back by, say, late February or early March at the latest with very, very preliminary first drafts of both rationale and change.

By that time, we would have a -- an oral comment period and you could begin to have that template in mind in terms of the strength of the data, the directions of change you would like to see, and modify that based on the added input that we would get, both at that point and written comments throughout that period.

We would then enter a second phase of revision and at that point decide whether we could accomplish those revisions by mid-summer or late summer, then bring the group together again at that point, go through that information and the added analyses that might have been completed at that period, go through a -- the last revision, I hope, so that by October, we would bring the group back together again for a last -- the final meeting where we would be adopting both the text and the -- well, the advice that we would be forwarding to the -- to the Secretaries.

Now, none of that is in cement, not even in jello. So we can -- we can modify either the initial time line, the assignment for the next two months I suppose. But certainly, we are going to be free to modify the -- the schedule as the work progresses. That gives us sort of a time frame and a set of tasks that we would have to accomplish.

With that in mind, before we leave today, also it would be very useful if we had a discussion of the types of analyses, not in detail, but the types of analyses you would like the staff to start thinking about so that if in reviewing that catalogue of tasks others come to mind, then you can go back and within a week or two provide some more detailed descriptions of the analyses that we would all be able to look at over e-mail and then -- and then the staff would have sufficient guidance for the information you're after in those analyses.

So first of all, let's take care of the time frame. Does that -- would you like to meet before then? Is the two month period too short? Is the discussion of the issues we've had to date insufficient so that we really should try to get together once again before you get to the level of specificity that I'm suggesting, or is -- are the

issues sufficiently laid out that the individual groups I identified are some subset of that group that we have to reorganize it in some way, feel that, gee, no, that the issues and the discussion are enough that -- that we can get to the outline stage knowing full well that they would be discussed and revised, is in the final? Shiriki and then Suzanne.

DR. KUMANYIKA: A question about the process. We have literature searches which may need to be enhanced if specific things didn't show up on this literature search. And then the process of getting articles and getting them to Committee members hasn't been discussed. So part of whether December 1st is too soon depends on how much support we'll be able to get for the logistic.

DR. GARZA: I am assuming that the -- that gathering that type of information will start and continue past January so that the staff person that each of the groups will be assigned, if you can communicate with them. Let them know the -- the ways that you want the searches expanded. Then they will be able to get that information back to you.

Now, what we've done now is that we're trying to make sure that you get the most salient publications so that

you may be sent some very extensive searches. But asking you to go through those outlines and select out those rather than having the staff automatically send you copies of everything that shows up because that hasn't worked out very well in the past.

DR. KUMANYIKA: Right.

DR. GARZA: You get inundated. We've already had some -- some of you have been warned by previous committee members to empty out your offices because you will be inundated in paper. We're trying to control that for you in a way that puts you in the driver's seat, but doesn't necessarily overburden you either. I mean, you -- you'll -- you'll control the faucet.

DR. KUMANYIKA: Okay.

DR. GARZA: They will send you as many of those pieces of literature as you request. But we will begin with the searches. As the process continues, you're going to find that perhaps you need other searches. So I don't want to say that, gee, we're going to do the search and be done by December. Rachel? I'm sorry, and then Suzanne. Go ahead.

DR. JOHNSON: Can I go? Could you clarify for us what type or if any assistance might be available to us at

our own institution for expenses, time?

DR. GARZA: If someone, for example, wants to hire a graduate student for X number of hours to help with either a summary or a review, is that type of support available?

MR. BOWMAN: I have to find out. I would think so. I'll find out. I'm not sure.

DR. MEYERS: For those of you who are wondering about the quizzical looks, the Department of Agriculture operates under some fairly strict regulations on their advisory committees and the source of funding for their advisory committees, which means that they don't have the flexibility to spend their own program funds to support you all.

And so that's what some of the looks are, because the amount of funding for this effort is -- is restricted. And what I think is still being sorted out is how much, you know, we can contribute to other parts of it that aren't -- you know, does a grad student count as part of your advisory committee activities or not? And so some of those things we have to sort out. But that explains the looks.

DR. DECKELBAUM: If we did have an interest in a student, could we put a student on some question or -- and that student would interact with staff in getting some of

the material together, I mean, without any stipend or anything for the -- without any cost added for that student to work on this?

DR. GARZA: You mean that you can -- yes. I mean, that person can act as your -- under your instructions. I mean, they can't be independent of you.

DR. DECKELBAUM: No, no, but --

DR. GARZA: We'll be very careful here. The government likes free. We -- free with acknowledgement is fine. I would really encourage both departments though to see if in fact resources can be put -- can be made available so that each of you can get the type of help that you need. Not -- generally that type of help is relatively inexpensive and high quality. And so it's not a -- I don't think it will be a very huge expense.

If any of you need that, why don't you communicate with the individual that your work group will be assigned and let them explore what your needs are and how they can best be met.

DR. JOHNSON: Who did you -- I'm sorry.

DR. GARZA: We're going to -- I don't know who those people are going to be. They're going to be -- we're going to be assigning a staff person to each of the work

groups. You will -- you will be notified who that person will be. And they probably will be the best contact.

I mean, I would like to the extent possible give you as much one-stop shopping as possible rather than having you go to person A for this and person B for this and C for the other. You don't have the time, I understand that. You are busy people and we can provide -- and staff doesn't have time.

So that rather than them be bombarded by eight people and you being -- I mean, search out eight people. It's much better if we get this down as clearly as possible. Suzanne and then Roland.

DR. MURPHY: Me next. Me next. I'm a little concerned about starting to write before we've had feedback on some of the issues that have been raised. We've talked about, first of all, bringing in people from one agency or another to talk about some specific topics. We've also talked about an oral comment period.

I don't want to get too far down the line before those things occur. Do I understand though that your original proposal is that we don't meet again until next summer?

DR. GARZA: No, no. Around February, early March

--

DR. MURPHY: Okay.

DR. GARZA: -- would be the latest. And what I am asking is, is it in fact -- if you -- if in drawing your outlines it's clear that this type of feedback is going to be required, then just leave that part of the outline out and we'll fill it in after you get the appropriate input. What I'm concerned though is that if we wait for the presentations, then a lot of issues are postponed. And then we hurry towards the end to try to deal with a lot of substance in a very short period.

I am hoping -- now, please reassure me that we're dealing with an objective group of individuals who will always reserve the right to be smarter tomorrow than we are today. And so that as these presentations come up, that you have to judge them against the templates that you're developing or the outlines and modify them. The report is not due until October. But I would like for you to start thinking about the outlines of rationales.

And at least in my experience, if you have that in mind, again, not in cement, but in mind, and then these presentations are made, the questions are more pointed, the requests to staff are more focused, and we get a much more

comprehensive review.

It doesn't work if by doing this you're going to reach conclusions because I think that Suzanne is right. We're not at that stage. And I -- if -- I don't want anyone to interpret that my suggestion of this time frame is to get you to that conclusion stage by early March.

There was a question here and then -- Roland --

DR. WEINSIER: Yes, just a quick question.

DR. GARZA: -- and then Johanna.

DR. WEINSIER: Should we plan in preparing each of these document drafts just having for ourselves our own reference list or are these references that are submitted as part of the drafts or are there separate white papers that support the final conclusions which do not include references? In other words, at what point or do we at all develop a reference list?

DR. GARZA: I would ask you to start developing that reference list from the first time your pen touches paper so that in fact we don't have to reconstruct where in fact specific points came from that need to be documented. So that if -- there has to be some mechanism within each group to make sure that in fact those lists are being compiled in a way that are going to be most useful to you.

DR. WEINSIER: So in other words, changes are documented with references. That would make sense to me --

DR. GARZA: Right.

DR. WEINSIER: -- versus develop references for every statement that's in there which was presumably done back in --

DR. GARZA: No, no. I'm sorry. There is no -- we have to document any change and a rationale for it. We don't have -- we're not responsible for going back and documenting every sentence. The assumption is that obviously if you don't change it, then you feel that it's well documented which you don't have to document it anew. Johanna and then Meir.

DR. STAMPFER: So in terms of the format, we should just follow the format that's in that -- in the previous report?

DR. GARZA: Yes. I mean, but that -- that -- you know, if in doing that we decide that there are ways that could be improved, then let's -- let's work on that.

DR. STAMPFER: But then --

DR. GARZA: This is just -- I mean, as a first -- first cut, that's what we should do. In terms of both the level of detail and its encyclopedic extent, I mean, I would

hope that we would come out with something that would be comparable to this because we do rely much more than other committees may on consensus-type documents rather than exhaustive reviews.

DR. STAMPFER: And then -- so at -- we're going to shoot for December 1. And would then everybody's subcommittees' report be shared with all -- shared with the group --

DR. GARZA: That's right.

DR. STAMPFER: -- even though we're not meeting as a group.

DR. GARZA: Well, we would meet at the end of that -- of that period. I mean, so that I would hope that if we can get things in by December 1st, that a two-month period -- maybe, you know, ten-week period would be enough to try to get these into some format with some exchanges and questions.

I mean, the staff are not going to be doing this in isolation of you. So that staff will be coming back to you for questions, for clarification. And so that period of interchange will continue. And then once we have things in a fairly uniform format -- which may just be outlines at that point -- then all of that material will be sent to you

in I would hope at least two or three weeks before the meeting date so that you would have an opportunity to review it, formulate your own questions, and then we could format the agenda based on those initial discussions.

And we would very likely have an oral comment period before our formal discussion so that you would be informed both by the outlines you get and the comments that would be made.

DR. WEINSIER: Can I just -- one more question on that line. I think it makes good sense to allocate subcommittees according to the current guidelines. But at what point in the -- in this current process do you foresee that the set of guidelines that are on the cover, maybe not the exact wording, but at least roughly will be set, because, obviously, the text follows from that?

DR. GARZA: I would -- I would think that if, for example, as the groups get together to develop their outlines, it is clear that in fact we need to change the number by either merging or deleting. That might -- that suggestion could come before the group by our January or rather February meeting so that in fact we don't spend a lot of time developing a rationale for something we're not going to then obviously follow.

DR. DECKELBAUM: We've talked during the last couple of days of bringing in expert witnesses.

DR. GARZA: That's right.

DR. DECKELBAUM: When will that happen? And perhaps we might summarize exactly what witnesses we're going to have for which fields and -- because if not everything is covered, I guess the subgroups might want to bring in one person from one of their meetings, as well. Is that possible?

DR. GARZA: I think that's possible. I mean, you could -- you could invite someone. If you decided to get together physically, then you could invite an individual as a consultant, I suppose, or an advisor. If you could -- if you wanted to get together by phone, you could invite that individual. Or what I would hope is by the time the outlines are in in December, we would clearly identify those individuals or those fields in which we would want additional review. We would then have two or three months to line those people up and invite them to that meeting.

And so that both -- both -- we have the flexibility to involve them as you develop your outlines. Or if we think that, gee, this is the type of thing that we all need to hear -- for example, sodium -- then we may want

to invite them to that -- to our next meeting.

But having you go through the outlines I think really will help identify where those needs are the most pressing. Johanna?

DR. DWYER: Yes. I'm just trying to think through a process. And I really don't have an answer. But what I'm concerned about is what always happens on committees. And that is when you make assignments and people take them seriously and they work hard on things. And then you end up with a whole bunch of text and well thought-out ideas. But they may be diametrically opposed to the other 12 people on the committee. The three people on the working group or the six may be, you know, speaking to each other, but not really reflecting the Committee's views.

And I guess I'm concerned that -- I think I heard Meir sort of suggesting it, too -- that the outlines it seems to me deserve some discussion within the Committee before they are put out for public comment. In other words, I don't know -- I don't know a lot about salt. I don't know a lot about a lot of things. But I at least want to know the thrust -- the thrust of where people are going. And I want to be able to have a vote on that early on.

DR. GARZA: Now, I'm sorry --

DR. DWYER: I don't -- I'm not sure I see how the process is going to do that. But perhaps you've thought it through from the last time around.

DR. GARZA: No.

DR. DWYER: What I don't want is for people to get so invested -- and I've had some experience with this as you have, too, Dr. Garza -- where people get so invested in a position that -- that it becomes them instead of an issue that's basically just --

DR. GARZA: Okay. Now, I'm sorry. Was it -- I don't think that there is a requirement for us to publicly share those outlines. So that in fact those outlines are being prepared for precisely the reason that you -- that you identified, is so that in fact the whole group at that early stage can begin to review the extent of the issue and the considerations that each of the subgroups are considering.

So it's not because, gee, you know, once the outlines are prepared then they're out for public comment and we as a committee then feel that we're wedded when in fact we haven't had a chance to discuss them as a group.

Secondly, the reason why Carol and the rest of the staff are being brought in early is to try to make sure that as you prepare those outlines, that in fact we start

distancing all of us from the pros and specific positions so that each of us can view these as a Committee function. So that in sending those outlines, Carol and I and others possibly -- Shanthy, perhaps Carole Davis as well -- will try to be in as many of the calls or physical meetings as possible.

So that if we see one group really being -- going off in a direction that is diametrically opposed from another in the way they are approaching, we can either bring these groups together but have some sort of cohesive approach to the issue.

So there is two things we hope we will be achieving. One is as you are developing these outlines, there will be someone -- there will be some overlap between either Carol and -- you notice, I didn't assign myself to any specific group.

DR. MURPHY: Yes, we noticed that.

DR. GARZA: Because I will try to be on each of your -- on each of your calls. Or when I can't make it, then making sure that Carol and I talk afterwards. But a continuing presence at least to be aware of where -- which direction the various groups are going.

Secondly is when we bring those outlines back,

then everyone will be able to see them, as well. If there are issues as these come up where you feel that, gee, it would be very good to talk to Group B, then we would expect that that would happen. If that doesn't happen, then we would probably be encouraging it.

So does that -- so does that process answer some of the issues that --

DR. DWYER: No. I still don't see where an outline on December 1st goes between then and February. Also, please speak to this business of physical meetings.

DR. STAMPFER: Can't we have the December 1 proposed outlines disseminated to the whole Committee?

DR. GARZA: Certainly. I think that would be a -- no, that's no problem. You had -- by physical meetings, Johanna, I mean that if subgroup A, you know, wants to get together and come to a meeting in Washington and Boston, I understand that's possible. You can do that.

DR. DWYER: Coach or first class?

(Laughter.)

DR. GARZA: I think we'll probably sign you up for a marathon. Shiriki and then Suzanne.

DR. KUMANYIKA: I think there is another task for the subcommittee chairs that's partly implied by what

Johanna said which is to describe the process that we're using for looking at evidence because -- I mean, part of my job I would think would be to get you so that you feel that you know enough -- you know what the key articles are.

You know what's come out since the last guidelines and that there is some buy-in on the set of information we're using because we will be sent information, at least if my past experience is true, we will be sent potentially boxes of information by people who want to make sure we see certain things.

And you can't -- there may be a lot of information around. And I would like to know for each subcommittee, what information you're choosing to look at and why so that when we have to sign off on all these words, we will have become educated equally.

DR. GARZA: We're going to be asking individuals who may want to send individual Committee members information that they please send all that information to Shanthy rather than directly to your offices because some of the assignments may change.

And then we will try to direct that information to all the appropriate individuals so that you don't -- you don't get inundated by information that either you don't

want or can't deal with because you're not being assigned to that group. So we're going to try to help with some of that in that way.

DR. GRUNDY: Shiriki raised a question that I wanted to ask. You know, a lot of the -- there have been other groups that have done sort of evidenced-based review of this. And we have access to previous deliberations. Do we -- are we expected or -- to start from scratch on this business of evidence-based approaches?

DR. GARZA: No, I don't think we -- the extent of the material we would have to review is -- just doesn't lend itself easily to very rigid evidence. And I wish I could give you more specific guidance in terms of which extreme, I mean, where you fall in the middle of the extremes I described yesterday, between a very strict evidence base or one documents quite literally why you deleted -- why you didn't' ask for a certain reference, to the other extreme of saying, "Gee, you know, we got together and we really like this. So we did it."

I think Shiriki's suggestion is a very good one. We may want to get the leads of each of these subgroups -- that may mean everyone, obviously, perhaps at our next meeting to describe the process that each of you used so we

could bring greater coherence to it as we go through the entire review because it will fall somewhere in the middle.

And one of the issues that we hope by getting the outlines in in early December to Carol is that in her getting back to you to say, "Well, you know, this was more detailed than Group B or, you know, can you cut back a little bit or, gee, you know, this awfully sketchy, can you provide more?", is to get us to that happy medium together.

DR. MURPHY: Continuing a little bit with Johanna's concern, which I think she stated rather well, the same concern I have. And that is that we not, any of us, become wedded to a specific addition or deletion at this point. Is it fair to say that we should each be thinking of alternatives, not a single method? And as we think about our particular guideline and our group thinks about it, alternate ways, not just a specific way. Do you see what I mean?

DR. GARZA: Yes, that's very good -- that's very good advice. The other one that I would pass on, based on experience both Johanna and I have had, is that none of this is intended to be personally satisfying.

(Laughter.)

This is not going to be something that Bert Garza

is going to write or Scott Grundy or Johanna Dwyer or Suzanne Murphy. This is a committee document and therefore has to go through a committee process. And as scientists, it is a very different behavior that we are asking you to adopt than what you do within your own laboratories where, in fact, you know, if you don't agree, it doesn't go out. There is an element of compromise here. And where that element comes up is very difficult.

On some cases, it may be so clear that in fact, you know, 95 percent of the group is wrong and I'm right, that there may be some persuasion that is necessary of the other 95 percent. But we hope that that will always be science-based. But in the end, the product has to be acceptable to the Committee, not necessarily the product of one individual mind. And that's probably the hardest part of something that is this broad and -- and important.

So I would take the caution of the alternatives and don't -- don't become too wedded to a specific approach because then it gets very difficult as a committee process towards -- as you get to greater and greater specificity. Alice?

DR. LICHTENSTEIN: As I think more and more about supplement, I'm wondering if I can have some more guidance

on exactly -- I mean, I can -- I can see evidence-based approaches to -- to dealing with it. But then by the time December 1st rolls around, what do you envision as far as that? Is it more an idea of we should continue or we shouldn't continue or this is what we should do and here are the alternatives?

DR. GARZA: Well, I think that the decision of continuing or not continuing would not be the work groups. That in fact you would try to bring together as much of the evidence or a rationale for various alternatives, as Suzanne has said. To say, "Well, you know, for this" -- you know, this is the science base that says, "Gee, we need to consider these in greater detail."

That would include not only the role that they play in health, but also the role they play in the diet in terms of practice. And then define alternatives for how we could best meet the demands of that science within the constraints of the Dietary Guidelines.

And that, you know, very simply could be, "Gee, you know, let's stop considering them; there isn't enough there; no, we need a guideline that is specifically targeted to this; or, no, we think we could embed it in the text, for example", and you may just give one example. But there

could then be embedded in other texts. There may be other alternatives. I mean, those are just three.

DR. LICHTENSTEIN: Thank you.

DR. GARZA: Yes. Are there any --

DR. MEYERS: Going back to Cutberto's comment about comments, it -- if there are any of you who would like all of the comments sent to you, there was no -- no intention that you be denied that. But -- so that we need to let -- we need to let Shanthy know. Otherwise, we will try to -- she will try -- she will try to direct them to the relevant work groups. Is that -- is that a fair way to say it?

And the other thing I wanted to mention briefly is the role of your ad hoc subcommittees to provide an opportunity for you to do some information exchange and information gathering. And under the Federal Advisory Committee regulations which you operate, what you would do then is bring your -- the -- the conclusions or the findings of your subgroups back to the -- to the final meetings which is the way -- to the full Committee meetings which is the way it is structured.

So that gives an opportunity for you to do your information exchange and then come back and report back what

you -- what you found out.

Alice, your comment about the supplements, just a reminder, that you can start with 1995 as kind of a guidepost of what you what to change and don't want to change. In that regard, I think one of the struggles that the '95 Committee had was that they didn't have a series of benchmark documents from which to draw. There are now a few more.

Their task was a lot harder than, say, the 1990 Committee who had the benefit of the Surgeon General's report on nutrition and the NRC report on diet and health and did in fact draw heavily on consensus documents. So there is some precedent for doing that.

DR. GARZA: Okay. so then is -- we might actually be finishing on time or a bit early. Is there any -- are there any other -- at least -- this is very valuable time. I want to make sure that you all have a clear picture of what we have to produce by the end of December -- or I'm sorry, by the end of November, early December -- December 1st.

DR. JOHNSON: Just to clarify, so we should work with our assigned staff person to our subcommittee regarding setting up conference calls, if we want face-to-face

meetings, funding if any -- I'm assuming that there is funding for those types of things --

DR. GARZA: Yes.

DR. JOHNSON: -- conference calls, potential meetings.

DR. GARZA: I mean, it's limited. I don't think we could -- we could get you together on a weekly basis, for example. I don't think we could get you to Hawaii. We may have to rely on Suzanne coming at times to the mainland.

But -- but -- and then we have to be able to -- we would have to be able to rationalize and you know, why the group has to come together and why it couldn't be done by e-mail or couldn't be done by conference call.

I would -- I would encourage you to -- because I know budgets are going to be limited, to postpone the coming together when the discussions get more focused. Right now, it would probably be best not to shoot our budgets, whatever that may be, in developing these very preliminary outlines for the reasons we've given.

But we do want to get the buy-in by the whole group. And -- and you want to have the benefit of a wider discussion. And that -- that could then inform when best to get together to start getting down to the nitty-gritty

details. Shanthy?

MS. BOWMAN: I do not think we can pay for subgroup meetings, only for the overall meetings.

DR. GARZA: Okay. We need clarity on it because I thought -- I was -- I understood that we -- that that might be possible. I will let you know. But this is -- this is one thing that in fact that staff person, they would have explored all of this and gotten back to you, Rachel, and say it can't be done or, yes, we can do it. Johanna?

DR. DWYER: Well, we -- I think we could probably assume there is a way to do conference calls. Maybe the government has to call. But can we assume that we will know, the group leaders will know by the end of the week who the government individual is and then by next week, we can set up conference calls if we wish to?

DR. GARZA: Yes.

DR. DWYER: Is that a reasonable time frame? Great.

DR. GARZA: No, that's very reasonable.

DR. DWYER: Thank you.

DR. GARZA: Now, the other thing is that I don't how -- how -- I know that Carol and I will try to be on all of your lists -- many listservs so that if there are e-mail

exchanges, it's not because that I'm looking yet for more e-mail.

But it is a very effective way of keeping track of where the discussion is going and -- and if any of you would like to be included in any of the other exchanges with -- with the other groups, let us know because the intent is not to keep information from you. It's just to let you be in charge of the faucet so to speak or the spigot.

DR. GRUNDY: Yes, since I was assigned to the supplement subcommittee, I do see what Linda said, that there is a small section in here worth a page. Could you just kind of give us your position or your view on where we stand with this -- how this is going to be positioned? And I know that we had a talk on it today, new emphasis. And I think it might just be helpful.

DR. GARZA: Well, I would say I don't have a position yet. I think that this is -- I certainly will be waiting for the guidance that the group and an oral comment and a written comment.

The issue that has come up repeatedly is that with especially the DRI process broadening the criteria to include health promotion and disease prevention much more explicitly than had been done in the past, that there needs

to be some guidance as to what are the appropriate roles that consumers should depend upon or supplements versus more conventional food in -- in meeting those needs whether it's the same sort of -- of approach that has been adopted here. Then that's fine.

I think based on the review of the data, then we may decide that this is totally appropriate. If in fact for the reasons that Shiriki went over we need to -- to start thinking about, well, there needs to be more research and we need to make sure that in our report, the reason we couldn't go past this is clearly outlined and we ought to be able to say that.

Or if in fact there is enough information and we want to modify this substantially and recommend research, we can do that, as well. I get the strong sense though as I speak to different people that there is needed guidance or what -- how do I fit a shrinking energy need against a growing nutrient need if I have to get it all from food. And I mean, it's a legitimate question. Shiriki?

DR. KUMANYIKA: I was trying to think if there is some background work that could be relevant to all of the subcommittees. What I was thinking about was just a packet that has the relevant guidance from other agencies and

organizations. I don't think we've been sent that yet in the materials.

DR. GARZA: Like the American Heart and --

DR. KUMANYIKA: Yes, just to know what other recommendations are sort of on the street, if there are any key international ones from other countries like the U.S. It would just be nice to have that as a set of information and including the DRIs just so that we know what we're dealing with and what we might be contradicting or tying into by -- by chance.

And the other is some summary nutrition monitoring data -- I was thinking about life stage and ethnicity -- on the key nutrients and foods that we're talking about. And I'm sure those data have been put together by the two agencies in various forms. And there may be -- short of sending out again the third nutrition monitoring report, but really the most current tabulations so that if a group is trying to see, well, where -- where is the population on this, they would have it handy. I think we will all need something like that.

DR. GARZA: Yes. That's very good. There's -- there's also in your packet a list of other documents that are available. And so you may want to go through that and

let -- let the staff know what it is -- which of those reports you want. If some are missing, then, you know, let the staff know which are and we'll try to get them to you.

I know that Alice and Meir have to leave at 12:00. And I wanted to make sure that we got to the types of analysis. Are there any analysis that you would like the staff to start thinking about so that, in fact, if there are others around the room that want to weigh in on -- on those suggestions, they can have an opportunity to do that.

Now, the sorts of analyses I had in mind are with data sets, that the government -- we usually think of the government keeping rather than reviews of the literature that would be integrated. So that's our role. But if you want, for example, to look at issues of variety, the type that Suzanne outlined, then we need -- this would be a good time to --

DR. LICHTENSTEIN: I would be very interested on an analysis of the impact of supplements on diet. So what the nutrient profile is of the diets with and without the supplements and if there is any type of breakdowns that can be done within that. I think that would be very helpful.

DR. GARZA: Now, if -- if -- if -- when you go home over the next week, if you can bring some greater

specificity to that. Or what are the questions you want -- you want them to -- to address? Then we'll try to circulate that among the group, make sure that -- that there are not related issues. They want other -- others on the Committee would like answered. So when the staff begins to perform these analyses, they'll have as complete a set of questions as possible.

But I think there would be a consensus on getting that type of information. Meir, are there others that -- we talked yesterday, for example, about the elderly and some of the issues that -- on alcohol or -- I think it was alcohol.

DR. STAMPFER: Yes, that would be great. I don't know if there are any sources that the issues where -- somebody suggested that the elderly may -- may be more prone to alcohol abuse and may be more sensitive to the -- physiologically sensitive to the effects of alcohol. But --

DR. GARZA: Is there any accident data or -- that's tied in to dietary intake data that would help us review that?

DR. STAMPFER: The other -- alcohol, I don't know if this is appropriate. But the current guidelines say that among those who shouldn't drink are -- is anyone who is taking prescription or over-the-counter medications. And

that's pretty broad. Is there a way to get a comprehensive list of medications that are reasonably known to have an interaction with alcohol? It's not all of them, obviously.

DR. GARZA: I don't know whether FDA would have that compiled in some way. That would be very useful.

DR. DWYER: Well, certainly the National Institute of Alcohol and Drug Abuse might have some monographs on some of those topics.

DR. GARZA: Yes.

DR. MEYERS: I'm sorry. And also the Substance Abuse and Mental Health Services Administration. Between the two of them, we'll see what -- what we can get for you.

DR. GARZA: Alice?

DR. LICHTENSTEIN: The report of the committee that Shiriki served on and talked about as far as supplements, that would be very helpful.

DR. GARZA: Okay. And are there other analyses that -- Rachel?

DR. JOHNSON: Some of this may have been done and I'm just not aware of it. But I would be interested in this idea of the fat-sugar seesaw and whether in either CSFII or NHANES we're seeing any kind of inverse relationship between fat, carbohydrate and sugars. And I'm also interested in

this idea of whether or not total fat intake -- and obviously, it will reflect the carbohydrates as we deal with it with sugars -- is related to obesity.

And probably -- it would have to be probably -- well, NHANES or CSFII. But I'm particularly concerned if anything has been done that looks at under-reporting and if they pulled out the under-reporters and then seen if this relationship changes. Because I think that this idea that fat isn't obesogenic is very, very confounded by the problem of under-reporting. I think we need to look really closely at that.

DR. GARZA: Great. Johanna?

DR. DWYER: Just a broader thing that may be helpful is the whole issue of -- of the proportion of the American public that eats out, that is using consumer convenience foods, take-out foods, all of those things by -- probably by age and sex or something similar because it will get at a lot of things like the fat, the sugar, salt. All of those things will be probably different in the foods at home versus foods away from home.

And I've got a whole list on food safety-related things. But I won't go over it with the group.

DR. GARZA: Okay. But if you could put --

DR. DWYER: They're here.

DR. GARZA: -- summarize them and then we'll try to get them to the rest of the Committee so they can also take a look at those. Scott?

DR. GRUNDY: Yes. The point that Rachel raised I think is very -- it interests me a great deal. And it raises a question in my mind about whether at this stage there can be interaction between the subcommittees because the question about the sugar-fat relationship might need to be addressed pretty early on. Is that --

DR. GARZA: That is encouraged. I mean, that's --

DR. GRUNDY: Yes.

DR. GARZA: -- that's why I think we may end up with very different subgroups because if in the process it's clear we want to organize the guidelines in some other way, then that would -- the way that would come about would be through those interactions.

DR. JOHNSON: On two, look at the way the sugar and the fat group -- the -- both Dr. Deckelbaum and Lichtenstein are on each committee and you and I are chairing. So I think it's a really good structure there I think for those two.

DR. GRUNDY: Yes. So we can start interacting

early on.

DR. JOHNSON: Right.

DR. GRUNDY: Yes, good.

DR. GARZA: We try to -- we try to build that -- build some of that in now. But if it doesn't work, let us know.

DR. GRUNDY: Okay.

DR. GARZA: Richard?

DR. DECKELBAUM: I was going to say what Rachel just said.

DR. GARZA: You went over a list of analyses. I don't know whether the group has any -- anything to add to those in her presentation or we'll just circulate those again when it goes to be written out --

DR. MURPHY: On variety.

DR. GARZA: Yes, on variety.

DR. MURPHY: Right. Right. I'll write that up.

DR. GARZA: All right. Well, I think we've come to a --

DR. JOHNSON: Can I just say one -- I mean, this is very procedural. But -- and two people have left. Does everyone prefer e-mail? Because I know there are people who don't check their e-mail regularly and so, "You have to fax

me or I won't look at it". I mean, do we have anybody who is not a regular, sort of routine checker of e-mail?

DR. WEINSIER: You don't check e-mails regularly?

DR. JOHNSON: I do it all the time.

DR. GARZA: Well, I describe e-mail as the worst and best of worlds.

DR. JOHNSON: Okay.

DR. GRUNDY: You never answered mine, Bert. So I always fax you a letter.

(Laughter.)

DR. GARZA: My sins are being uncovered.

DR. KUMANYIKA: I will mention that for me, there is somebody else who needs to be included in my address who covers me, especially for scheduling of calls and stuff like that. So I check e-mail regularly for content. But the ones that have to do with, "Are you available on these three days", so I will give the name. And I just would ask that people include it.

DR. GARZA: When the -- when the staff person contacts you, we will try to put together a -- a list of e-mails and fax numbers that might be updated. Then -- I don't know whether staff has any other comments.

If not, I want to thank you again, each of you.

DR. DAVIS: I just want to --

DR. GARZA: Carole?

DR. DAVIS: I just want to stay and talk about the committees.

DR. GARZA: Okay. I wanted to thank each of you for the time and effort. I would like to thank the audience for their patience. There will be opportunities at the next meeting for oral comment. We hope you have found this as informative as -- as I have. We really got much further today than I think either the staff or I had originally planned. And that's -- that's a credit to how seriously and well organized you guys are. So thank you for that.

And we will be in contact in terms of setting up a time for the next meeting with Dr. Satcher's appointment -- or rather schedule also in mind. We would like for him to come. Dr. Anand?

DR. ANAND: Well, I just want to thank the Committee members for actually coming and agreeing to be part of this one. I think you have a very important mission to accomplish. And if these two days is any evidence, you have the scientific expertise, you have the wisdom to use that science. And I'm sure you have the dedication to make sure the job is completed.

As always for these committees, be prepared to receive some bricks and some bouquets, hopefully more bouquets than bricks. But I think this is an important job. And on behalf of the USDA, we really thank you very much for accepting and doing this job. I hope to see you soon. Thank you.

DR. GARZA: Thank you. We will take the bouquets and we will miss the bricks.

DR. WEINSIER: Can I express appreciation to Shanthy for the -- what I think is outstanding organization in keeping us well informed and the preparation of the materials. I appreciate it greatly.

DR. GARZA: Thank you very much, Shanthy.

(Applause.)

DR. JOHNSON: Could I urge that we set this next meeting as soon as possible because --

DR. GARZA: Oh, yes.

DR. JOHNSON: -- I know our calendars are filling up.

DR. GARZA: No, we'll try to do this. What we needed to make sure and settle was that the time frame that we discussed was going to be acceptable. Then we could go to Dr. Satcher's calendar and see what it looks like. And

then we'll send out a list of dates and -- with late February, early March in mind.

DR. DECKELBAUM: Just one plea for those of us who have children, that late February is the -- the last two weeks of February, most schools and colleges in the United States are on vacation, one of those last two weeks.

DR. GARZA: Well, we will send calendars out and make sure that it's -- no, we won't set the -- the date. We will send you all calendars so you can let us know when. Okay. Thank you.

(Whereupon, at 11:58 a.m. on Tuesday, September 29, 1998, the conference was adjourned.)

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Docket No.

Washington, DC
Place of Hearing

September 29, 1998
Date of Hearing

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