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DEPARTMENT OF AGRICULTURE

U.S. DEPARTMENT OF AGRICULTURE

DIETARY GUIDELINES ADVISORY
COMMITTEE MEETING

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Waugh Auditorium
1800 M Street, N.W.
Washington, D.C.

Wednesday,
September 9, 1999

The parties met at 8:50 a.m.

BEFORE: Cutberto Garza, M.D., Ph.D.
Chair

APPEARANCES:

Shanthy Bowman
Carole Davis
Richard Deckelbaum
Johanna Dwyer
Alyson Escobar
Sandy Facinoli
Scott Grundy
Rachel Johnson
Eileen Kennedy
Shiriki Kumanyika
Alice Lichtenstein
Joan Lyon
Kathryn McMurry
Holly McPeak

Suzanne Murphy
Meir Stampfer
Carol Suitor
Lesley Tinker
Roland Weinsier

PROCEEDINGS

(8:50 a.m.)

DR. GARZA: The schedule this morning is that we're going to finish up with the research recommendations on the physical activity guideline. After that, we will take up the food safety guideline because of some scheduling conflicts with some of the individuals we've asked to attend. And then, we will do salt. And, then proceed as the agenda was originally planned.

I want to welcome all the committee members. Everyone looks — I think the operative word was "perky". Some of the committee members are perkier than others. They were so perky, they were out here before seven making sure 30 minutes — 45 minutes, okay. Oh, we all know what your goal was.

Okay. Leslie, why don't you get started?

DR. TINKER: For the physical activity the future research that I've considered based on comments — future research recommendations that I think I've heard comments about through yesterday's discussion: One would be a data-driven activity pyramid. And, potentially then considering incorporating physical activity into the food guide pyramid if we're going to use the pyramid. It is a little concerning to me that we'd have, you know, multiple pyramids. Have an activity pyramid and a food guide pyramid. But some way to incorporate physical activity, either into a pyramid or within the food guide pyramid.

That's one. A second recommendation is to continually strive for better measurements of physical activity, not just the actual going out for structured exercise programs. But, how to capture routine activity during the day, lifestyle activities because that seems to be one of the areas that in the exercise field is still being developed and is quite hampered by not having reliable measures.

Another area is nutrient physical activity interaction. Talked about those a little yesterday and felt that some of the evidence was not so strong to command a lot of discussion about those, particularly with the interactions.

Another idea is the impact of convenience items on physical activity. So, whatever you want to call it, the western lifestyle or the technology-driven less active lifestyle, but some way maybe an ecologic study if there was some way to do that, to capture what's going on in this country with access to remote controls and phones everywhere. And so, we're not moving around as much, and see if we can't connect that to the more need for physical activity.

And then, the last thing that I have on the list is a question about what motivates people to engage in physical activity. Think what Scott and Shiriki commented on yesterday with some of the recent conferences they've attended on physical activity and weight management, and the data being not very encouraging as far as the role of physical activity on weight maintenance.

I began to get curious as to what was motivating people for physical activity. And, if weight maintenance wasn't one of the motivators, then maybe it's — in general, it's logical that we wouldn't see much of an effect on weight management with physical activity.

Those were the ideas that I have.

DR. GARZA: Are there any other comments or questions for Leslie? Shiriki?

DR. KUMANYIKA: I don't think this was covered in what you said. I think that we could recommend more research on attitudes towards routine and work-related physical activity. There's so much done about various attitudes and leisure time and so forth, but how people — whether doing something that requires physical activity is really considered a low social status activity. That should not be taken up by people who've achieved a certain level.

Those kind of attitudes are underlying this whole societal shift, and we don't really access those in trying to change peoples minds about whether, you know, if only poor people walk and you're rich, will you take up walking as a mode of transportation, or only for leisure time? That sort of thing.

DR. GARZA: Lesley, the other — go ahead, Johanna.

DR. DWYER: I think that's a great plus, Lesley. Could we emphasize even more the role of physical activity programs in primary and secondary schools because they are eroded --I guess because of pressures on budgets. And, I think there are two — at least two well tested curriculum. One is DASH. Another one is developed dy Dr. Salis — out in California. And, I'm sure there many others that you could have used — the technology is there —

DR. GARZA: Roland?

DR. WEINSIER: Yes. Lesley, I don't remember if you mentioned this, the growing recognition that there may be distinct and potentially complimentary benefits of aerobic versus strength training exercises. Aerobic endurance versus strength resistance-type activities — not

necessarily exercise, but activities as well as exercise on certainly, weight control. Also, other health aspects.

DR. GARZA: Alice?

DR. LICHTENSTEIN: I'm wondering whether you think there is adequate evidence to indicate that the more, let's say, important is physical fitness versus weight loss. That there has to be an emphasis in one place or the other. I know we heard a fair amount of that from Steve Blair. But whether that requires additional work?

DR. GARZA: The only other area, Lesley, that I would suggest we add is that given the importance of physical activity in health promotion and disease prevent, by not having a tool by which we can easily assess and measure physical activity is going to make it difficult to have people implement recommendations because it's awfully subjective. And, at least in medicine, unless we can measure it, it's very difficult to get the attention of a physician and other health professionals.

There are a variety of bi-axial, tri-axial accelerometers that give you at least some measure of physical activity. Or, perhaps we can do strength-testing. But something that would provide us — and, you know, this would probably take — it's not something develop easily, but both norms and ways to measure easily whether or not someone is engaged in physical activity to a point that is going to be helpful them. And, not being able to measure it will present a barrier to the implementation and the assessment.

Richard?

DR. DECKELBAUM: I raise this as a question to the Chair, and I wonder if the Green Book would be the appropriate place to say that the Committee is concerned about the lack of facilities for physical activity that are available to children in certain neighborhoods, in certain kinds of settings. And, that if for successful implementation of these guidelines, we must insure that the facilities and the environment is available to allow this to happen, especially in the pediatric age group.

DR. GARZA: We can probably bring that in the form of a question that there are ways that needed to be able to assess community access.

DR. DECKELBAUM: Right.

DR. GARZA: And, have suitable ways of implementing your changes.

DR. STAMPFER: And, not just for children, but for adults, too. Bike paths and walking paths.

DR. DECKELBAUM: Well, Meir, you know my prejudice. You can take care of yourself.

DR. GARZA: Okay. Any other additions or suggestions? I don't think we'll bite on that one.

Okay. We'll move on then to food safety.

Johanna?

(Pause.)

DR. DWYER: Let me introduce the colleagues who are here to help explain somethings. Sandi Facinoli. She's over at USDA/FSIS. And, Holly McPeak. Holly, who we've talked with on the phone.

(Pause.)

DR. DWYER: Let me start with two overheads, and then I'll go to the slides.

I'm sorry. I don't know how to turn this on.

Our Committee has worked diligently over the summer. And, the first thing that we need to do is to tell you that we did listen to the focus groups and found — if you read your Blue Book — which is the focus group, results. Handle food safely was not a good guideline according to the consumer results.

And so, thanks to Lesley Tinker and others, I think Rachel, we talked about changing it to keep food safe to eat. And, that's what we propose today.

The reason for getting rid of handling food safely was that at least some consumers — as we understand the research — thought that meant somehow balancing the groceries as you took them home from the supermarket or farmer's market. And, this is short, sweet and to the point. And, we think it's probably better. So, that's the first point that we want to make that's changed rather dramatically.

The second set of concerns had to do with responding to the public comments. And, I'll try to do that without the benefit of a Committee meeting. Since we last talked, I think it was August 24.

So, I've gone through the various public comment and tried to look at them and see if we needed to change the guideline farther. Then, I'll talk about our expert consultations with colleagues at FSIS and elsewhere on some technical points that are important and need to be changed, as well.

Let me just go through the food safety public comment. Colleagues from California made a very thoughtful — gave a letter. And, they talked about for food safety, do a Q&A, rather than a guideline. And, then they went on to say — talk about adding emphasis on illegal use of pesticides. While important for people working with chemicals, maintenance workers and so forth, that this hasn't been associated with any chronic disease, including cancers or any birth defects.

I think we deal indirectly with the pesticide issue, but not in as much depth as that as that would suggest.

A second thoughtful and well prepared set of public comments came from Center for Science in the Public Interest. And, as I read that, there were three points.

The first was safe food handling practices should be used when preparing foods at home. I think guideline as we're drafting it, addresses most of the things that are listed there.

The second thing is the issue of special populations that are vulnerable to food-borne disease. And, I'll try to point out that I think, again, that we have addressed that.

And then, there were suggestions to add some specific things. And, I think most of them are included. So, I think we've done that.

A couple of other public comments that I remember, and please, tell me if I haven't mentioned them all. There was a very thoughtful one from a person who's done a great deal of work in Government. Very thoughtful economist, who does not feel it's a good idea to have a separate guideline. I guess I would disagree with that, but respect that person's opinion.

If I can just — yes, I'm going to come back to that at the end.

Okay, now?

MS. LYON: Are you ready for this?

DR. DWYER: Yes, I'm ready for that. I'd just like to walk through the guideline. And, if it says, "handle food safely" on anything, you'll have to forgive me. I made a mistake when I was doing the slides. It should say, "keep foods safe to eat." That's what we're proposing now as the guideline.

Let me start out by saying a little bit about the CDC's definition of food-borne disease which is: two or more people (they put as necessary to trigger an investigation).

Since we last met, a very good article has appeared in Journal of Food Protection. The first author is Bean. And, it describes the CDC's work from 1988 to — I think, it's '92, isn't it? Or, is it through '96?

Anyway, it takes a look at a question that we've been wrestling with over the past seven months. And that's, what kind of problems are there?

And, from 1988 to 1996, if we look at the outbreaks of food-borne illness, the types of outbreaks, 79 percent were bacterial pathogens, of which 90 — that would be 90 percent of all the cases, especially staphenterodidus — from eating undercooking or infected eggs. Fourteen percent were chemical and non-bacterial food-borne illness, which constituted two percent of all cases. Two percent were parasites accounting for one percent of all cases. And, four percent were viruses accounting for six percent of all cases.

Over the course of those years, there was a rise in e-coli 0157H7 on contaminated produce. In a couple of the years, it went way up.

Now, the other thing about 1988 to 1992, if you look at percent of outbreaks in terms of place, and that's important from the standpoint of this issue. This issue about back in the food chain, other issues — other problems being involved. If you read USA Today yesterday, you read about this tragic incident in my home state, New York, in Albany, where run-off in a farm ended up contaminating the water supply in a — it was a fair. I don't think it was the State Fair because the State Fair is in Syracuse. But, it was a local sort of — an Albany fair. And, one child died, and several others became ill.

So, that's an example of something that really — consumers had no control over whatsoever. It was contaminated water back in the food chain.

In terms of looking at those '88 to '92 cases that CDC investigated, the percent of all outbreaks, 40 percent of those outbreaks were in restaurants and commercial food services. Forty percent. Another 18 percent were home.

Now, the problem with these statistics is that when you look at the home, you don't know if they brought it in from take-out, or whether they prepared it right there in the home. But, the basic point is that either prepared or take-out, where the site of the episode was at home is 18 percent of cases.

There's still a lot of cases where we don't — they don't know what was the pathogen or they don't know what — where the site was. Some of that is simply because if things are reported, like seven days later and there's no fecal sample and there's no food, you can't really tell anything about what was going on. So, we need to think about ways of helping to improve that situation.

So, let me just bring up one other thing. It came across my desk a few days ago. And, this is a report of a 1997 home food safety survey of 106 households in 81 cities by a group called Audit International. It's a bunch of registered dieticians who involved — observed meal preparation service, left over handling and clean-up sorts of things.

And, what they did was to use the same standards of food safety and sanitation that restaurants usually use for evaluating how safe they are from the Food & Drug Administration's model, FoodCo. And, they marked down critical violations, an issue that by itself, can cause food-borne illness or injury.

What they found was that 96 percent of households that they surveyed — it was out of 106, so the sample size wasn't terribly large — had at least one of the — one critical violation. Now, this is just processed. We're not talking about people getting sick. What we're talking about is behaviors that might lead to people getting sick.

The largest problem was cross contamination, which was in 73 percent, not washing hands. Obviously, these are not mutually exclusive. Fifty-seven percent improper storage and so forth was lower. And, not cooking to proper temperature was 24 percent. Improper leftover handling, 29 percent. And, refrigerator temperatures being too high, about nine percent. So, in terms of the process, there is some information there.

Now, they've also done another study, I think in April of 1999. I just told you about the September of '97. In April of 1999 — in September of '97, they found four percent had acceptable ratings. And, many of the other people had other things wrong. And, by April of '99, there was a greater proportion of acceptable, up around 26, with --- 26 percent. Things like cross contamination, leftover handling, neglected hand-washing. I'm sorry. Going down considerably.

So, people do seem to be able to change if given some advice.

There are just a couple of others. Let me just run through these very quickly.

The basic point of talking about those sources of problems is that we have to think of the whole food chain. And, consumers are just at the end of the food chain. We have to have strong regulations and enforce them farther back. But, consumers aren't batting 1,000 either as both two pieces of data show.

Now, you know that we targeted bacterial food-borne illness. It's the major cause of food-borne microbiological illness that is identified now. It may well be that others are under-reported. For instance, viruses, for example. But, as of today, I don't think the data would justify not showing it bacterial.

And, we talk a little bit in the draft text that we're reviewing today about the various essentials for food borne illness of this type to occur. The bacterial cells, the food's vehicle, conditions, and then the person eating enough to fall ill.

We talk a little bit about who the targets are, getting at some of the concerns that CSCI raised. Everybody's at-risk, but certainly older people, the very young, those who are immuno-suppressed because of various immuno-suppressive medications or cancers or people who are pregnant have specific risks. And, within those categories, there are specific illnesses that are of concern. So, we have to think of everybody.

We also talk about special-care foods that need special attention, the perishable foods. And, maybe we want to emphasize more on the raw foods because raw foods are risky.

And, please just disregard the topic. I made a mistake on this slide. It should say, "Keep foods safe to eat. Keep foods safe to eat."

We then go through these criteria or actionable measures. Cleaning, separating, cooking. And,

they should say, "keep foods safe to eat." Refrigerating, following the label, serving. And, if in doubt, throw it out. Pretty straightforward.

So, the details that we talked about are things like washing hands and surfaces often. And, we've tried to take wording that is in accord with the Government agency materials that already exist. And, we tried to use our experts to get us this. The issue of separating various kinds of foods while storing and preparing and keeping things at the bottom of the refrigerator so they don't drip all over everything else.

We talk about thawing, some of the things about convenience foods that we didn't originally think about that public comment and other experts have suggested we include. We talked about cooking foods to a safe temperature. And, in your draft — I don't have a slide of it — but, there's a nice colored thermometer that has temperatures for various heating to various levels.

I want to come back to the T sticks. I know that that's a cause of some consternation on the part of some and I'll conclude with that.

We talked about reheating leftovers. Talked about raw or partly cooked eggs and unpasteurized milk and raw mild cheeses.

We tried to soften the word about raw seafood. But, our experts tell us that there is risk associated with raw seafood no matter how you slice it. There is.

And refrigeration again. Lots on refrigeration, including temperatures.

A little on following the label to try to key into some of our other tools for consumers. We talk about fine perishables last. Taking food home and putting it right into the freezer, following label instructions and so forth.

We talk about serving the perishables right before eating and serving safely, chilling them right away when you're finished. Not leaving perishables out for more than a couple of hours. Keeping hot foods hot and cold foods cold and out of that danger zone of 40 to 140 where life begins or flourishes for the bacteria.

And then, the last, if in doubt, throw it out. And, I've got some wording changes here, too, that the experts suggested. So, that's it.

Now, in terms of resources, there are a number of things that are coming along. And, I just wanted to show you, too, and we can pass them out.

People are — one is a food safety information resource that you may want to take a look at. These are not cited in the text. The only resources we cite in the text are Government resources. But, several private and volunteers have come up with things.

One is this thing, which goes through all of the different pathogens. And the other is home food safety. It's in your hands, that the ADA and the Con-Agri Foundation are doing. That pretty much limits what we're doing.

Let me now just go through some specifics in terms of the experts, and then ask them if I've made a mistake on anything or the slides are wrong.

The first thing is a minor thing. It's that we need to think about viruses as well as — on page 15 of the text. We need to think about viruses, and they were not included when we talked about food-borne illness. And, that's a mistake. And, it needs to be.

The second thing that probably the Committee needs to think about adding is on page 16. Some of the expert advisors suggested that we consider at least adding something to this effect: "All uncooked foods are potentially unsafe. Proper cooking makes most unsafe foods safe. However, certain toxins and contaminants cannot be neutralized by normal cooking temperatures and procedures. So, other steps to keep foods safe are also needed." In other words, cooking or freezing isn't enough in itself. You have to think of these other things as well.

The other changes that I picked up from the comments from the reviewers that might be suggested are on page 19 of the text where we talk about, if in doubt, throw it out. We say if you're not sure that food has been prepared or stored safely, throw it out.

A revision of the next sentence would be as follows in line of the advisors recommendation. Instead of saying, "you cannot make foods safe," say, "you may not be able to make foods safe if it's been handled in an unsafe manner." Some cases you can, some cases you can't.

So, the comments from the reviewers, first of all, that suggesting that not all food toxins are bacterial, we think we have to change. We have put in the virus issue.

This whole issue of the source of most food-borne illness being unknown is not that there — I

don't think — what was meant by that comment was that there was some mysterious thing out there that we didn't know about. We know what they are. The problem is we don't know in individual cases what caused these things.

One change that might want to be — might — you might want to consider would be to add to the part of the guideline where we talk about people — what you should do if you think you have become sick from eating a food, instead of just saying write down where you ate, when you ate, and when you signs and symptoms came. Maybe, save a sample of food. Put a skull and crossbones on it or something so that nobody else eats it. But, save the sample. Don't know if that would help. So, that is one comment.

The other comment is, I think, cope with — if we add the sentence I just read about all uncooked foods are potentially unsafe. Proper cooking makes most unsafe foods safe. But, certain contaminants and toxins can't be neutralized by normal cooking temperatures and procedures. So, that gets at those two things.

And then, the final thing is a little show and tell about some of the thermometers. And, at this point, I think I'll ask somebody who knows more about the T sticks, which I have not used myself, to talk about. I thought it might be fun since some of us probably have never seen the T sticks, to at least take a look at them, and at some of the other thermometers that are available today.

So, if you ladies will come up and show us. Sandy, would you mind coming up? Is that okay? Good.

Where are the T sticks?

MS. FACINOLI: I'm not sure why we're only talking about T sticks.

DR. DWYER: Oh, no. Talk about them all. It's just that nobody knew what they were.

MS. FACINOLI: Okay. I'll pass it around. The reason for talking about T sticks is, many people on the committee were not aware of what they were, what they looked like or why they were necessary. So one issue we need to resolve today is whether to mention them, mention the whole business about thermometers, or whether it's not important and we just shouldn't do it.

DR. DWYER: Well, we definitely want you to mention thermometers. And, we do have a great

deal of baseline data that hopefully will help you understand the information and the interest in thermometers. And frankly, that the audits international survey you just showed — from '97 to '99, a four percent inappropriate activity to 26 percent — four percent appropriate to 26 percent appropriate — we would like to credit to the Fight Fat campaign, by the way, that kicked off in October of '97. But, we do know that with the right advice and right education, people can make changes. We know that a great deal.

But, let me just talk about thermometers and T-sticks. I'll pass these around. I'm sorry. I probably could have brought a few extra packages. But, how many have you seen these in the stores? None? You have seen them, okay.

Well, I have to say I bought these in our stores in the Washington area. TransWorld Services is the company that makes these. It's a disposable thermometer. This particular one is thematically prepared so that if you put this little cardboard piece — if you want to open the package, that'd be fine to see what that's like — ou put it into the food after it's prepared and you think it's at the right temperature. And, that little dot at the end turns black when it reaches 160. It may take a few seconds or a minute or so for that to happen, but it will happen. There are others of them that are prepared for other temperatures. But, this one is the 160 for hamburgers.

I do know that there have been a million sold this last year. The company estimates — of course, they always do this, but they told us they estimate five million sold next year. This company has shared thousands and thousands, in fact, hundreds of thousands of them with educators for extension and other kinds of activities.

So, there's an 800 number on there, I happen to know. And, I guess if it's not in your market area, we need to be letting managers and grocery stores know that it's not available. But, T-sticks are just one of a variety of thermometers.

There are some other disposable thermometers that are on the market. And, I'm not an expert on these. If you'd like to know more about that, we'll be glad to get you the technical specs. We'll be glad to connect you with the companies.

Because as a result of the USDA's survey information study last year with ARS And FSIS about the undercooked hamburgers turning color inappropriately, the results we shared with the thermometer companies last November, and they have now created a company — an organization, an association, The National Thermometer Indicator Association. And, they are

working very closely with each other and with educators and with us to get those thermometers out there.

And, we've made suggestions to them about the appropriate information that should be on the containers and things like that. So, I'm hoping that there'll be some changes.

There absolutely was a response that we need to get these thermometers in the grocery stores. Wegmans in the Northeast has sold thousands and thousands and thousands of them. Giant here in the Washington Mid-Atlantic area has had a campaign in January and in May. And, they sold many, many, about 40,000. And, basically, these other — these grocery stores were not selling many thermometers. Cobbs out in Wisconsin, a number of other stores. Big Y up in Massachusetts, Connecticut. They've had a huge campaign. They've sold thousands and thousands of them.

So, we know from our focus group-testing and from surveys and from these grocery stores that getting the information out there, getting the product out there, people are buying it, and we hope are going to be using thermometers.

A couple other thermometers to show you. The digital thermometer is available. A couple different companies make them. It has a little battery in it. You get it, it's ready to go. There's an extra battery that you have to — after, you know, a certain amount of hour usage, you change the battery.

Have any of you used the digital thermometer or seen it in the grocery store? At these grocery stores — no. You're not looking for thermometers, though.

(laughter)

Is that — yes, you have the big one, right? With the big dial that you use for years with turkeys and chickens and roasts. Well, that beats nothing all to pieces, right?

Well, we'd like you to add another tool to your toolbox. And, that's the digital thermometer, or the "instant read" thermometer that an awful lot of people in food service have used.

The digital thermometer — let me give that to you. You turn it on and off. And, the good thing about the digital thermometer is that you only have to get the very tip. Your little dimple right on the end into a small food, like a hamburger or chicken breast or a piece of fish. Or frankly, if

it's a larger piece of meat or poultry, you just have to get that little bit into the thickest part. And then, in a few seconds, five seconds, that digital temperature will read out for you.

They cost, you know, between $9.95 and $19.95. These grocery stores that are doing major campaigns are selling them for $9.95. I don't know what the loss-leader is there or whatever, but they are trying to make them affordable for folks to get home and add to their toolbox.

The instant read thermometer has a dial. And, it has to, however — you have to get this little — there's a little dimple right here about two inches up, two and a half inches up. All of that area has to be in the thickest part of the food because the temperature's read as an average of that space, of the temperature along that whole space. And, it takes a little bit longer, maybe as much as 15, 20 seconds to get that temperature. A little less expensive than the digital, but a little bit more of a hassle.

So, if you're going to go out and buy a thermometer, and $10 or so is not an issue, I guess, we would encourage to use the digital thermometer. Frankly, it's kind of fun in using it with young people. It's kind of neat to see the digital readout. But, the point is we need you to be able to have an accurate reading. And, the digital thermometer does allow you to read accurately in a little space.

Uh-huh?

DR. LICHTENSTEIN: I'm a little concerning about something, looking just at this package of the Temp Right. I can tell on the basis of the color whether my meat is at 130 to 140 to 160, or 160, 170. And, it says that you can tell, you know, how well done your food is. But, it doesn't tell me that I shouldn't eat the rare. It just tells me how to sense when the meat is rare.

So, there seems to be some disconnect between what I think the intention is with respect to making sure people cook to a proper temperature that then results in an safe product versus making sure the way they exactly like it every time they cook.

MS. FACINOLI: You are absolutely right. And frankly, if you looked at the label of a number of thermometers, you will see disconnects.

And, one of the roles that we hope that we're playing with this new organization is to have them get the right information on the label, the right safe information. The right information that consumers can understand.

I'll tell you right now this digital thermometer has nothing to do with food safety. This just has from a practical use. There's nothing on here that says, "By the way, don't put this in your sink or your dishwater to soak or get wet."

That happened in our household. And, you know, you had to be a little forgiving because at least somebody was washing the thermometer. But, they soaked it in the water and then the battery died.

So, they need to have more information on it. They need to have it be right. So, yes, yes, we do have a role to play there.

DR. LICHTENSTEIN: Well, also, who keeps labels? I mean, you know, if you buy something like this, the package gets thrown out and there's no indication on here to me what, you know, essentially —

MS. FACINOLI: What is safe or not safe.

DR. LICHTENSTEIN: Right.

MS. FACINOLI: You're right. And, there have been some design things. I don't know if Diane or Holly wants to — but, talking about magnets or something that would go on — in addition to our magnets and other agency's magnets. But, some information that would go on their stove, on their refrigerator.

MS. MCPEAK: One of the things that we're trying to stress to this association that has started, The Thermometer Indicators Association, is that we would like to have consistent USDA-recommended temperatures somehow located on the thermometer. Very often you can put temperatures right here on the shaft, and it would be set, cook to 160, and have exact internal temperatures on here.

And then, make sure that all the manufacturers are consistently putting the same temperature so that we don't have one manufacturer recommending one thing, another one recommending something else. And, maybe one's safe, one's not safe. But also, being consistent. And then, that's educating the consumer.

DR. LICHTENSTEIN: Just to caution you, it is actually on this shaft, and it's rubbing off rapidly. And, that's from here to here or if somebody's using it. But, it's clearly starting to get

difficult to read. So, there's got to be some better technology if the appropriate temperatures are going to be here.

MS. MCPEAK: Exactly.

DR. GARZA: Assuming that we can get the American public to adopt thermometers in the way that we're now considering, what would be the cost-per-episode avoided or per life saved of getting widespread use of these? Is it going to be a cost effective measure?

MS. FACINOLI: Well, if you are going to reduce food-borne illness or eliminate food-borne illness, based on these costs that we're aware of here, whether it's a $1.99 for a package of 10 T-sticks, or $19.95, I would like to think that it would be cost-effective. I haven't done that math. I don't know that.

DR. GARZA: I think it's an important calculation because it's $1.99, but you multiply it, by obviously, by the American population, multiple uses, three, four times a day, and the cost can be impressive. And, before we recommend this as something that should be adopted nationwide, we ought to know at least what the cost is going to be, because there may be more cost-effective measures.

MS. FACINOLI: But we're not — I'm hoping that the dietary guidelines advisory group will not recommend just the T-stick, a disposable item.

DR. GARZA: No. That we — I think that's safe. We may recommend thermometers, but it would be useful to have a range of cost-per-episode-avoided. I mean, I know that that would be an estimate, but it would be useful.

DR. DWYER: There's one other thing that we need to get information on, need to ge research on. And, that is, in addition to the food borne-illness, there are a lot of two-lard drums that end up in the waste — the garbage because people made a mistake and cooked things took long, or fish that drys out. So, there are some hedonics again that are important. I mean, thermometers, just the oven thermometers are useful from that standpoint. They really do make the food taste better.

MS. FACINOLI: Well, one of the things that we know that in talking with focus groups is that if we could

— if they know that you can have food that's — or meat and poultry that is higher quality as far as tender or not burned up, that interests them as much as the safety factor. And, we actually have asked those questions. We do have that baseline data.

I witnessed a focus group test recently in Raleigh, North Carolina, and it was very interesting to watch the reaction of the groups. Holly witnessed them in New Orleans. And, we had some focus-group testing November of '97. And, we watched the group react to the fact that it would allow them that to perhaps even have a pink burger if they wanted it if it was 160, or a juicy burger, or a piece of chicken fillet that wasn't dried up and hard because it was safely cooked to the right temperature.

We also witnessed their reaction as far as their concern for children. That was a motivation.

And, we also heard them say they basically haven't witnessed their moms use thermometers other than cookies and giant roasts, large roasts. And, if people were starting to use them and they understood that this would make a difference in safety and quality, that they felt like it would be adoption — it was a behavior they'd be willing to adopt.

DR. GARZA: Do we permit individuals on food stamps to buy the thermometers with their food stamps?

MS. FACINOLI: Do we — I'm sorry.

DR. GARZA: Do we permit individuals on food stamps?

MS. FACINOLI: I don't know the answer to that question.

DR. GARZA: No?

MS. FACINOLI: That's an interesting concept.

DR. DWYER: The specific issue that all of this has been about is what would you do about taking it out where right now it says, "Use a food thermometer to make sure foods are cooked to a safe temperature." And then, it references this Figure 3.

And then, there was talk on the phone call to eliminate the semi-colon which says, "preferably a digital thermometer or new disposable T-stick thermometers that can be used in thin foods." I

mean, that's the issue that we're trying to resolve right now.

DR. KUMANYIKA: I have a lot of questions. To prioritize, my main question is whether something similar that would help identify if the food is contaminated is being developed. And, where that question comes from is my personal experience in being unable to convince people to follow food-safety measures because they simply know from the intermittent reinforcement, that the chances that it's contaminated are low. And, they don't want to be bothered. And, these are, you know, fairly well-educated people.

They just think of thousands of times that they've done something that I'm telling them they shouldn't do, and it doesn't — they don't get sick. And of course, you know, there has be to be something in the food going to make you sick. And so, if people had something that they could stick in the food to tell if there's any salmonella in there, that — I'm just wondering because this strikes me as something that even though it's great and certain type of cooks will use it, I mean, for which foods — for every food, it would take you two hours longer in the kitchen because you'd be sticking something in every — I mean, it seems infeasible.

DR. DWYER: I saw people working on DNA probes. I've heard a little from my colleagues about — I think you're about five years ahead.

MS. FACINOLI: There's a number of things that are going along that way, but they're not here yet. And, this thermometer for $3.95 or $9.95 or $1.95 is here now.

And, I know I watched a demonstration recently of a scanner that scans for ADP. But, it's $1,500.

DR. DWYER: What is ADP?

MS. FACINOLI: Idenophene bi-triphosphate. It's the bi-luminescence scanning. But, that's not something that we're going to have in homes. It's probably not even something that we're going to have in small restaurants for awhile. But anyway, it does show for presence of some type of pathogen. But, that's just now getting available even into small processing plants.

So, you know, so I think as industry and researchers are aware of the need for something more consumer friendly and something to help consumers — I'd like to have something in my refrigerator. I'd like a little swab in my refrigerator that's affordable and easy for me to read to see what's in my refrigerator.

So, those — I think the dietary guidelines including information about food safety and the importance of that will go a long way in elevating the need for consumer-friendly, consumer-useable pests in the home, or tracking in the home.

There's one more little thermometer here. I don't know if you're sick of thermometers by now or not. But, this is a type of thermometer. It has a probe, goes into the food. It sits outside the oven or outside the grill, and you can test for it. These are available. All these things were purchased in stores.

Is there another question? I'm sorry.

DR. GARZA: With the thermometer, there's also a question about the use in refrigerators. Are there recommendations? I know — we see appliance thermometers, but are they in the same price range?

MS. FACINOLI: I think they are.

MS. MCPEAK: Appliance thermometers are much cheaper. They're about $3.99. And, they're very readily accessible. Almost every grocery store that I checked in, I found that they have appliance thermometers. And, they work good in the refrigerator and the freezer. So, they're very readily accessible.

DR. KUMANYIKA: Two more maybe quick questions. One is, for which foods would this thermometer use — to be recommended from a feasibility issue? And, the other is, how does it relate to microwaving?

MS. FACINOLI: Okay. Meat, poultry, eggs dishes. I know the FDA is now saying that they're recommending going for visual indicators of doneness.

(Thermometer beeps)

Is that me doing that? I'm sorry if I am.

DR. GARZA: It's overcooked!

(Laughter)

MS. FACINOLI: Did you set that? Why did you set that?

However, there is a recommended safe temperature for cooking seafood. So, that's what we're talking about. Meat, poultry, eggs, casseroles that are made up of meat, poultry, egg dishes, seafood, that use.

And, the second part —

DR. KUMANYIKA: Microwaving.

MS. FACINOLI: Microwave, yes. Absolutely. We're also including a use for microwaves.

Now, some of you may have microwaves. I used to have one like this. I don't have one now. It had the probe in it that you could — while it was cooking, you knew when, in fact when it got to the correct temperature.

There are new microwaves now that have different types of probes. But, taking the food out, testing it, allowing for a moments of standing time, which I know is a hassle and people aren't going to want to do that, but we are absolutely recommending that.

Knowing that it's a hassle is not going to stop us from recommending that people do this behavior. It's just like the seat belts. Seat belts are a hassle. They ruin your collar. But, we know that we made those changes in the years gone by, and we know that kids had a major role in making that behavior change. So, we're very interested in reaching children with these messages about using thermometers.

In fact, one of the focus groups said that if their kids harassed them in the kitchen, "Where's your thermometer, Mom or Dad," they'd absolutely be using it and a lot of messages about the interaction of children and this behavior and thermometer use.

No one, I will say, in all the groups that we talked to over the last couple years, indicated that price was a problem. And, we did have a spread of the economic group. I couldn't cite that for you right now. I have shared those studies with Dr. Dwyer and somebody else. Anyway, I'd be glad to share with these studies with anyone else that's want to read it?

Yes? Yes, sir?

DR. STAMPFER: I thought your analogy with seat belts was kind of apt. Seatbelts are shown to save lives in accidents, and there's actually data for that.

MS. FACINOLI: Yes. There's a lot of data for that.

DR. STAMPFER: And, do we have any actual data that widespread use of these thermometers has been associated with any change in human illness?

MS. FACINOLI: We don't yet. Though, what I'd like to say is that in the last couple of years, we have our baseline data. We think we have done a good job with the 1998 FDA/USDA consumer survey, and, we'd like to think with knowing about usage. There are a number of other focus groups, a number of surveys that we've talked about.

We'd like to think in a couple of years, we could provide that data for you. And, that's not going to help you with the fifth addition, but we'd like to think that with the campaign that USDA is getting ready to embark on with thermometer usage, with the information included in the dietary guidelines next year, that when we do the next surveys, we'll be able to ask questions, add questions to the USDA and DHHS surveys that will be able to get that information for you.

But, we're at baseline now. USDA has been recommending use of thermometers for years with turkeys and large cuts of meat. I don't believe I'm aware of any data that shows the amount of illness directly related to eating turkeys or beef roasts or pork roasts cooked with thermometers. We know — absolutely — it's data we want to be able to get. And, we feel very strongly that the educational campaign, getting the information out through the dietary guidelines, through the media, we'll make a difference. And, we'll be able to show some reduction.

DR. DWYER: Dr. Stampfer, I think you're too — in answer to your question, the answer is you don't know. The second answer is that of all of the measures that are currently being advocated and advertised, things like these sprays that people are using in their kitchen and so forth to spray surfaces and so forth. In my view, the best buy for the money if consumers want to do more than following those simple guidelines is to buy a thermometer. Whether it's going to save lives or not, I think is a question that's something that CDC and USDA and other agencies in the Federal Government need to get going on.

The other problem I see that needs to be dealt with is getting more information about food-borne illness in the home. Because as I understand it, a system that's based on passive reporting is not going to be very helpful in getting isolated food-borne illness accidents.

DR. STAMPFER: Well obviously, I'm for food safety. Nobody can be against food safety, but there's a limited number of messages we can get across to the public. And, I just question whether we should be recommending an intervention in these guidelines that there's no data available yet to — I'm not asking for randomized trials or even saving lives, just an association. Some kind of data of the nature that we have for all the other guidelines that it's actually going to benefit human health.

You know, it's reasonable that it probably would, but is that enough? We're supposed to have some science behind it. Is that enough to advocate an intervention? Just kind of makes good sense and it's reasonable?

I just raise this as a question.

DR. GARZA: Alice?

DR. LICHTENSTEIN: I would just caution that as these programs get developed and the material gets developed, especially with respect to children, that it be done in a very cautious manner because the first thing we talk about and we keep reminding ourselves is that we should be enjoying food. And, I would — at this point, I'm not convinced that if there's a swab for e-coli, that every piece of fruit needs to be swabbed before a child can take a bite. And, I think we want food to be safe.

We certainly don't want it to cause any disease, but I think there — depending on how it's presented, I think it could also create some unintended problems.

DR. GARZA: I want to make sure that we also get a chance to cover — there's a whole report, and we're spending — have about 25 minutes left on this one recommendation of thermometers. If there is your only concern on the guideline, that's fine. If you have others, then we need to make sure that we don't run overtime.

DR. DECKELBAUM: I have a fresh question and comment. It relates to fruits and vegetables, or perhaps other foods as well.

There is emerging literature that vegetables and fruits can be contaminated by parasites. Those would include gardeolamblia, cryptosporidium and cycosporin. And, there have been food-borne outbreaks associated with these parasites.

Now, in the — in the text of the guideline, we do mention parasites once. And, it is mentioned to wash fruits and vegetables. But, there's a lot of detail given to cooking. And, I just wonder if there's not multiple ways of the way people wash fruits and vegetables and whether there should be some consistency. Once we're making this kind of recommendation, whether it should be a little more well-defined.

How do you wash fruits and vegetables? I know how I wash them, but I don't know if that's right or the wrong way. And, how some of this literature is really emerging in terms of contamination with parasites and fruits and vegetables may be more appropriate to leave it in the Green Book rather than in the text of the guideline itself.

DR. DWYER: That's a good suggestion. I think the experts — we can solve it.

The reason there's so much emphasis on cooking is you cannot be sure of a safe temperature without a thermometer. You cannot be sure of a safe temperature without a thermometer. And, therefore, it's vital to use a thermometer if you're concerning about safe temperatures and their reasons to think that that's part of the chain of problems that are preventable which consumers can do something about.

In terms of the fruits and vegetables, is there text that you would suggest adding to the guideline. And if so, where would like to add it, Richard? As well as mentioning it in the Green Book. We can do that.

DR. DECKELBAUM: I can get you the articles on contamination, parasites, contamination of vegetables and perhaps fruits. I don't remember, but certainly vegetables by parasites. I don't know how well you have to wash them or how to wash them to get rid of them. I don't know how sticky they are once they're on.

But, within the guideline, there might be some input about how we should be washing our fruits and vegetables. I don't have an answer for that right now.

DR. GARZA: I am certainly persuaded, Johanna, because given the emphasis that we're giving to fruits and vegetables in the guidelines, giving people some suggestions as to how treat them. I mean, is water enough, or do you have to use a brush? And, if so, how do you keep the brush clean?

DR. DECKELBAUM: And also, a lot of vegetables are cooked. How should that be handled?

Could you have a little asparagus thermometers?

DR. GARZA: Kathryn?

MS. MCMURRY: FDA generally recommends washing vegetables with warm water using a brush to remove surface dirt as appropriate.

DR. DECKELBAUM: We should include some of that. I think there must be information on that available.

DR. GARZA: A very good suggestion. Alice?

DR. DWYER: If there's any information from FDA or FSIS on this, we'd really appreciate it as quickly as possible.

DR. GARZA: Alice?

DR. LICHTENSTEIN: Additionally, I think there's some rinses on the market now for fruits and vegetables, aren't there? Well, no. I'm certainly not suggesting recommending, but I think we have to give some guidance as they're out there. They're in all the supermarkets and they're sold in the fruits and vegetables section. And, I think, is there evidence that there's any advantage to using them if there's not? And, if there's evidence that it doesn't matter.

DR. DWYER: This came up on the expert phone calls we had in November and December. And, the experts that we consulted then did not feel that the rinses were warranted.

DR. LICHTENSTEIN: Well then, I think maybe that should be stated. What I'm just saying —

DR. DWYER: It was in the first set, but it was considered too long, so we took it out. But, we can put it back in.

DR. LICHTENSTEIN: There at the point of purchase, I think that the issue is going to arise in people's minds. And, the other issue has to do with you know, these salads that are pre-cut and these vegetables that are — carrots that are pre-peeled, can we say anything? Should people be washing those, rinsing those? Or, can they assume that because the salad greens have been cut up, that they can just pour it into the salad bowl?

Do we know anything about that? Can we give some — because this is practical guidance. I mean, we want people to be using this stuff. What do we say?

DR. GARZA: Shiriki and then Suzanne.

DR. KUMANYIKA: This relates to a broader suggestion I was going to make about the format. Right now, this is written — all the information is here, but it seems more like it's written for health professionals.

And, I was going to suggest organizing the text by food category, perhaps and by setting so that, you know, changing diapers or in the kitchen or packing your lunch. Things that would really pull the information out so that people could see in different situations what is it I'm supposed to be doing with food, and then perhaps the guidelines for different food categories, like put the meats versus the vegetables, some key points.

This one doesn't have a box like some of the other guidelines do that give those tips for really doing it. So, maybe not to replace the text, but a box of tips for those special situations that are most likely to be done wrong and user-friendly language like count to 30 while you're washing your hands, as opposed to 20 seconds which, you know, might think of how long is 20 seconds? And, then you don't want to waste water. So, just really thinking through to make it a little bit more consumer friendly.

DR. DWYER: Can you mark it up the way you want it, Shiriki, and give it to us before close of business today and we'll work on it tonight.

DR. KUMANYIKA: Okay.

DR. GARZA: I'm sorry. Suzanne?

DR. MURPHY: Actually, I was going to say I like the clean, cook, chill, separate. I never get them in the right order. But, I like the short, presumably memorable words. But, I don't think Shiriki was saying we have to drop that. But, maybe have a box that has some more practical tips in it. But, I think it's nice that the two campaigns, the fight back and this at least, sort of have the same format.

I did wonder why the information on washing fruits and vegetables isn't under "Clean". Is that — it seems to me it kind of gets lost as just a throwaway sentence at the end of the introduction.

Because I think it is an important concept that we don't want people — yes.

DR. DWYER: You're saying move on page 15 paragraph 3. You want to move it over to —

DR. MURPHY: I'd just put it down there under "Clean" on the same.

DR. DWYER: Fair enough. It's probably my mistake when I —

DR. MURPHY: And, then if it's expanded, it'll have a better home, so to speak.

DR. DWYER: Okay. And, expand the whole business on fruits and vegetables. Yes. That'd be the place for it.

DR. MURPHY: Can I come back to thermometers while I have the speaker or whatever it is I have?

I think maybe based on what we've been told, I would be in favor of keeping some reference to food thermometers. But, just to say perhaps a variety of inexpensive thermometers are available in markets, rather than say T-sticks or digital thermometers or endorse anything in particular, just tell people they might want to look for them. I think one of the valuable things I learned today is that they're available. I didn't even know that. So, maybe we can share that information via this booklet.

DR. GARZA: Roland?

DR. WEINSIER: I just want to be very careful that what information we do include is based on at least as sound as science as we have, recognizing that once it's in, it's practically impossible to get out or to revise. And, I say this seriously, particularly, the fruits and vegetables. If you're saying that we need to be washing our lettuce in warm water, scrub with a brush, then let's include it. If it's based upon evidence that this is a serious concern and a population-wide issue.

I don't see anything about cleaning fruits and vegetables in either of these sets of materials handed out from the ADA and the other association. I don't know that it should be or should not be included here. I just raise the question that we don't want to create food phobias to the point where people are using fingernail brushes before they eat an apple.

DR. DWYER: Let me just say that the references that we're looking at are not those. We're

looking at Federal agency advice. So, we're trying to review whatever is due us Centers for Disease Control prevention and the Food and Drug Administration and the President's Food Safety Committee — Commission — already had as their guidelines.

So, what these people have done is simply — spin-offs. It's not what we're relying on. What we're relying on is Federal agency-recommended. And so, we will not — we will look first unless you guide us otherwise through those Federal agencies to see what they're saying about things like washing fruits and vegetables in warm water. I honestly don't know what they say about it. Maybe some of you can cmopare with them.

DR. MURPHY: There is a statement at least in here that says, "Be sure to wash away all soil from vegetables by scrubbing them under clean, drinkable water." That's under — the problem is this one at least is done by pathogen. So, it's hard to find the practical step for all the details.

DR. GARZA: Alice?

DR. LICHTENSTEIN: I would find it helpful if something like perishables was more better defined because I consider fruits and vegetables perishable. And, the way it's — you know, I think it's okay to keep apples and oranges on the kitchen counter or the kitchen table. And here, it's telling you, well, refrigerate perishable foods promptly. It's sort saying, well, you know, hide all the fruit in the refrigerator. And, I think it's because traditionally, the perishable foods were to be considered to be casseroles with eggs and cheese and meat and that kind of thing. But, I'm just wondering if some of the language could be adapted to be more inclusive.

DR. DWYER: I think that the way — what I hear people talking about for those foods that you're calling perishable is special-care foods. Rachel and Lesley are both people who are in — better equipped to answer that than I am.

DR. JOHNSON: We defined them earlier, don't we? what those special perishables are? So, maybe the word "perishable" isn't the best term in that particular setting.

DR. LICHTENSTEIN: The first sentence under "Chill" on page 18? Some of this is common-usage versus how we're defining it. We have to distinguish.

DR. GARZA: Any other comments? Roland?

DR. WEINSIER: Should I stop eating sprouts?

DR. GARZA: I think we mean bean sprouts, because I didn't know they also meant brussel sprouts.

DR. DWYER: I think Dr. Johnson could probably answer that.

DR. JOHNSON: I don't know. I mean, I followed — wasn't it recently the FDA came out and said, "Don't eat sprouts?" I mean, they had a very clear recommendation.

DR. MURPHY: Wasn't it alfalfa sprouts?

DR. JOHNSON: Yes. It's the alfalfa and bean sprouts. You didn't take them to Japan with other kinds of sprouts.

DR. MURPHY: No, I didn't think it was bean sprouts.

DR. GARZA: That would also include brussel sprouts?

DR. MURPHY: A sprout is a seed product.

A problem, of course, is getting a seed to sprout. There haven't been good treatment programs that have come up yet. Your concern, if you are in a high-risk group, is that there is no guarantees.

DR. GARZA: Exactly. But that's —

DR. WEINSIER: You know, if the statement is left in, I think we need to be able to stand behind because they're widely used and served.

DR. DWYER: We can stand behind it. And, that's why we consulted with the expert advisors.

DR. WEINSIER: It's the underlined words under cook? Page 16?

DR. JOHNSON: I did highlight here Roland that maybe we need to be more specific and name them in parentheses, alfalfa beans. I mean, if you think it's confusing or something like a brussel sprouts. Is there more specific terms than sprouts?

The way I've seen it in the newspaper where USDA comes out with the warning is they just say

"sprouts".

DR. GARZA: "Bean sprouts" may be better.

DR. STAMPFER: Following on Roland's comment, this is a brand new guideline. And, you know, I'm sure Benjamin Franklin would be pleased with the degree of confidence in our Federal government if we're relying solely on their recommendations.

But, our charge is actually to use science. And, I don't think Federal recommendations come under that category. I think if we have a new guideline, it's got to be justified by science and maybe, you know, it's going to take a little extra work on the staff part to go back and find out what science, if any, those Federal regulations or advice was based on and cite — use the same standards as we're trying to apply to the rest of the guidelines. I don't think just somebody's recommendation is enough by itself.

DR. DWYER: That's absolutely — you're absolutely right, Dr. Stampfer. And, we can only rely on evidence-based research as we go through this. And so, in trying to generate a new guideline, what's also important in addition to the scientific evidence which, of course, Federal scientists use as the basis for public policy-making, the wording is also important. And, it's important, I think, whenever possible, to use wording that has already been vetted through the various sister agencies of the Public Health Service and the USDA.

And so, evidence-based first. Second, if there's wording that's already been found to be acceptable by the various Federal agencies that are involved in this endeavor, it's also very important in my judgment to use that, because it speeds up the process of approval.

DR. GARZA: Suzanne and then Richard. You're right.

DR. MURPHY: Thank you. I guess I feel that when you find that people get sick and die from eating a food, that's pretty evidence-based. And, I know that has happened with sprouts. But, my question to whomever is if we prioritize the foods that are causing illness in the U.S. today, I don't think sprouts would be up there at the top. I certainly think raw fish is near the top. But, I'm hesitant to put sprouts in that same list.

And, I think you can look at — at least reported — incidents to the CDC or whomever. My impression was, for example, foods like raspberries and strawberries were causing lots of food-borne illness. But, these are — you know, you do have to weigh that these are healthy, nutritious

foods. And, I'm not sure how much we want to put consumers off fruits and vegetables for a relatively small number of deaths here.

So, I would look to the Federal people for some guidance on how to prioritize the foods that are causing the most harm, and then let's mention those. But, I can't believe sprouts are up there.

DR. GARZA: Richard?

DR. DECKELBAUM: Johanna, I think when reviewing the science based, something that should be considered and probably mentioned in the Green Book is there's a major under-reporting of food-borne illnesses. And, there is documentation and literature on the under-reporting aspects. Sylvie B. in our group is published on under-reporting of cryptosporidium, for example, and the reasons behind it.

Even if the available science is sparse, there is literature on under-reporting, which I think would also be important for the rationale for this guideline.

DR. DWYER: Did you find in the rationale as we've written it — it mentions under-reporting several times. And, this business of having to have a partner to have food-borne illness, the way we count food-borne illnesses as outbreaks also leads to under-reporting, and we tried to say that. But, could you review the work in the Green Book and see —

DR. DECKELBAUM: I reviewed it a while ago and I actually forget parts.

DR. DWYER: Yes.

DR. DECKELBAUM: I'll look at it again.

DR. DWYER: Yes, it's certainly a good point. It's a point that Fred Jewel makes in his latest paper, and it's one that we need to stress if we haven't stressed it enough. Well-taken point.

DR. GARZA: Johanna, the only other point as we come to the close, there is certainly literature as we've heard in terms of chilling and most of this. I mean, one can go back to the food safety literature and be convinced on that point.

The one issue that has come up today is there's no literature that adopting the practice is going to be efficacious, and that the actual use of thermometers. So, the working group may want to

consider tempering the language to say that because there is no way of knowing whether is something thoroughly cooked, you know, you may want to consider buying a thermometer.

But, using the imperative "use" would suggest that, in fact, we have data that this is going to be efficacious. And then, we can certainly strengthen the language in the Green Book to say that we need that type of data to make sure that, in fact, the doctrine is practiced, would be helpful.

But, that — I think that in terms of — we all know that if you don't chill your food, you know, bacteria grow. There are practices that have, I mean, much better documentation throughout the guideline. But for this one, as we've heard from the Federal agency, there isn't any. And, facing a nationwide recommendation on an expectation, I think is chancy for the reasons that Roland — I think it was Roland.

Once we've put something in, you know, the presumption is that it's been documented and efficacious.

Is that the sense of the group, or am I not reading the group correctly?

DR. DWYER: No, that's fine. We'll do it. We need to do it for BMI, too. You know, for all of these things we subject.

DR. GARZA: Alice?

DR. LICHTENSTEIN: To go a little bit further, it may be — just for emphasis to buy and to use correctly, as opposed just to use them because .

DR. DWYER: I'm sorry, Alice. I don't understand.

DR. LICHTENSTEIN: And use the thermometers correctly.

DR. GARZA: I think Suzanne had some language already even before my comment that she'll suggest to the group.

All right. Then, Scott?

DR. DWYER: May I thank Joan and Kathryn for their help on this because —

DR. GARZA: We may still need your help. Scott has one comment.

DR. GRUNDY: I just had a question. Can you actually with fruits and vegetables, wash away the infectious elements? Is that possible? Can they be washed away?

DR. DWYER: I don't think we can always get them all off. But, I'm not an expert on it. It depends on the fruit, doesn't it? Or, the vegetable?

DR. GARZA: All right, then.

DR. DECKELBAUM: I would just bring that up as a recommendation because I have available literature combination. I'm not aware — not aware of literature on whether washing is efficacious. And so, that would actually be fairly easy to tabulate, all you would need is a few heads of lettuce and other vegetables.

DR. GARZA: Okay. Then, let's take a 15 minute break. We will be back here a few minutes before 10:30 so we can start promptly on salt.

(Whereupon, a short recess was taken.)

DR. GARZA: Can I get all Committee members to take their places?

(Pause.)

DR. GARZA: We can start now. If we can ask Scott and Alice to take your seats.

Okay, Johanna. Okay. Maybe since you're going to beginning with what we've agreed on, controversial area.

DR. KUMANYIKA: I did want to comment on the physical activity guideline. Is that your idea when you're thinking about physical activity, because it has some of the concepts that we were talking about yesterday for ways people could think about activity other than talking about it. If you don't have as clear a copy as I do, if you want to see it in a prettier form, I can pass it around later or you can get it from me. But, everybody has a black and white copy.

DR. GARZA: Is your mike on because we can't hear you?

DR. KUMANYIKA: The green light is on and it seems to be working. Okay. If I turned it right upside up, you think that would make it easier? Not that I've ever used a mike before. Better? Is that better? No? Sorry, you don't have earphones.

So, I was just mentioning the physical — Australian physical activity guidelines, which is an example of how another country is approaching the issue.

Salt. The way I've organized it is if you start by talking about the points of agreement. Of course, that's always dangerous because when we start talking about them, we may not still agree. But, I wanted to go over the two categories.

One is the nine changes because we certainly have spent as much deliberation on issues and comments that have been made. And, even if we decided not to change them, I think they really belong in the rationale. So, to go over the nine changes.

I thought they were of two types. One is — suggested fill-in, some of the current comments to — play down the sodium guideline. And, the other is to recommend a specific level. And, those are two things that we decided, not just to specifically change the current guideline. And, we'll talk briefly about the rationale for those non-changes.

The point for dropping or downplaying the guideline on salt and blood pressure, one is that the association of sodium and blood pressure is not firm, or that there's not evidence that sodium reduction lowers blood pressure.

There were three types of evidence that I think should be in the rationale, and I've actually drafted some of those in the text that's been circulated yesterday to the Committee. From the second phase of the Australian study, I'll go over those briefly.

And then, safety issues, possible adverse effects and other effects on quality of life were raised. The applicability of the sodium guidelines for the general population, whether there's enough consumer interest, if there is need of this guideline, if necessary. And, we do have some focus group information about that.

For the trial for hypertension prevention, I made a slide of a paper that we might even decide to include in the rationale itself. I made this table from the two articles that present the results of TOHP-I and 2. And, the reason I thought it might be useful to include the table with the actual data is because unless people have heard of the study or read the paper, then they don't really

know that there was a study done to examine the question of primary prevention. And, there's several points that you could get out of a table like this and the rationale.

One, is the levels of sodium intake that the people had coming in based on urinary measurements. How much their sodium decreased, what was the proportion — proportionate reduction in the development of new cases of hypertension under a couple of different scenarios.

So, I'll go over the table, and you have it — it's a document handout yesterday. This is page 2 of that document handed out to the Committee.

First, the baseline. TOHP-I was 18 months long, and it's in that first column. And, it had a sodium intervention that included both overweight and non-overweight individuals.

TOHP-II included only overweight individuals in the BMI range. I mean, some of them were very modestly overweight. The BMI range that was applicable is here.

And, blood pressure data for incidents were collected at 18 months, 36 months and 48 months.

I think you're able to find — right now I am fishing for stuff, so maybe wait till — right, okay.

The TOHP-II, because all the individuals were overweight, also had an intervention that tested the combination of weight reduction and sodium reduction. And, since weight is one of the major interventions for lowering blood pressure and it's mentioned in the guideline, I thought I would show the results for comparison of the combined weight sodium with the sodium alone.

So, for the levels of sodium coming in and the baseline in TOHP-I, it was about 3,500 milligrams. And then, TOHP-II because everybody was overweight, it was 4,200. So, that point is able to show that people who weigh more, eat more, actually consume more sodium. It might be of interest. Large for a trial, certainly larger than for small amount metabolic studies you might see.

And, the combined people were essentially similar because they were random, either into one or the other. They were consuming about 4,000 milligrams.

Okay. So, the net change in sodium, and this is a normal with the control change subtracted, for 44 millimoles in the TOHP-I study, the baseline blood pressure levels — you can see these are people in the normal range of blood pressure there. They're high normal for diastolic, you know,

84, 86, but they're — these are not hypertensive people.

And, the reduction associated with this change in sodium taken at 18 months net 25 percent reduction essentially, .76 relative risk of developing hypertension compared to the usual care and treatment control group or 18 months of follow-up. And the follow-up was 90 — over 90 percent or it may even been as high as 95 percent. So, they had blood pressure levels on almost everybody who was randomized.

This was not significant. TOHP-I was not to try to look at development of hypertension. It was part of the changes in blood pressure. But, you can calculate the incidents from the data that's been published. So, it's not — but the size of the reduction is about 25 percent in that population.

In the second phase, people started with a higher sodium intake. They reduced about the same amount, 43 normals. And, at 36 months, the reduction in sodium was about the same. There was not a urine collection at 48 months. The main reason for following people out to the bitter end was to get more blood pressure for the life table that showed the incidents of hypertension.

And, the reduction again, versus the usual peer group was .88 and .88 here. It was significant here — not significant here, but it was — there was more of a trend toward significance here probably because the control group was creeping up in their blood pressure more, and they — data points here said a — something might have given more, — the result is about a 14 percent reduction in the development of hypertension.

So, these data have been interpreted in many ways. If you'll accept at least the systolic and diastolic blood pressure, it's really the systolic finding that holds and the diastolic doesn't. But, you calculate how many people didn't develop hypertension who would have had they not had this reduction of sodium intake, the difference is a 14 percent reduction.

Now, in the combined intervention, they didn't reduce their sodium as much. The weight loss was — I don't remember the weight loss. I have the paper here, but you could also look at the amount of weight they lost. They didn't lose as much weight as when they were in weight reduction alone, but some weight was lost.

But, the point of this intervention is the combination of people attempting to lose weight and attempting to reduce their sodium at the same time. And, you've got somewhat less sodium reduction. But, the overall package of whatever they did, weight in sodium, you got a 71 percent

— 71 relative risk there, a .84 and a .85.

So, in the final analysis, these curves came together and the data points out here are getting thin. But, you have .86 for the sodium and .85 for the weight reduction alone versus weight and sodium combined, versus usual care, which is not dramatically different.

So, even this is only one study, it is — or, the two studies, it's two studies that were designed to inform policy at the end of a continual, and they involved hundreds of people and were very well-controlled and have been published long enough to be debated in the literature and so forth.

So, I thought it might be useful to include in the rationale that one of the reasons for not changing the — dropping the gun or de-emphasizing — is that the only major study that had come out with an intervention in normal people actually supported the idea there is a modest benefit in shifting a blood pressure distribution towards less hypertension. And, with that, one has to cite the benefits of the population approach using Jeffrey Rhodes-type arguments that you're really shifting the population distribution.

This is not clinical treatment of hypertension. This is reducing the number of people who are going to develop high pressure because you change the distribution. So, that's one piece of evidence.

The other two, which I don't have a slide of, I mentioned meta-analyses. And, there are I think three meta-analyses that have been published. We — some of us heard them discussed at the NHLBI conference — our subcommittee concluded that they didn't convince us that there was no case. So, it's a matter of presenting those meta-analyses. So, why do some people interpret them to the contrary and say why we don't feel that they're compelling evidence against this particular recommendation?

Finally, the DASH study is often cited in opposition to this recommendation. So, it's a matter of explaining that the DASH study could not test this question because it held sodium intake constant at three grams and held weight constant, and held alcohol intake constant. It was designed to test emerging strategies for hypertension prevention in addition to the proven strategies. And, the proven strategies were held constant.

We can mention the rationale that DASH-2 is under- way, which will test this fruit and vegetable, dairy, low-fat diet against 50, 100 and 150 millimoles of sodium. But, those results will not be ready anywhere near in time for the delliberations of this committee as far as I know.

So, that would be the package of evidence against retaining the guideline. And, why don't I stop there and get comments before going to the other issues that we considered as nine changes?

DR. GARZA: Suzanne?

DR. MURPHY: Shiriki, I'm sorry if I missed it. In the trials that you just covered, what was the reduction in sodium in the diet? Is it sort of what we're recommending in the guideline?

DR. KUMANYIKA: The reduction would have been to about — what we're recommending in the guideline comes up to be about 104 normals. In Take 1, the sodium group went close to that. It went from 155 to 44 of the women actually got down to 104 because within the — because of the body size issue. Women are actually more able to achieve an absolute goal.

We did not find any evidence with a lot of searching for a threshold effect. So, the guidance is framed to say that some reduction is better than no reduction because there's no evidence that you have to get down to a certain level to benefit. And, that's also one of the reasons we're not recommending a specific level except indirectly the way we did before.

So, we asked that it was reduced, in the combined group here, they didn't get near it at all from 179 to 29. They reduced somewhat. But, within combination with the weight loss, there was still a benefit. So, this is actually evidence that sodium reduction to a level that's above the level that we're recommending is associated with a greater response.

We tried to see if you could calculate how much sodium reduction you would have to get everybody's blood pressure below a certain level. And, we toyed with that for awhile. Just didn't seem to make any sense, because on the issue of whether there's a relationship, the best response seems to come out in a similar fashion of cross studies.

Nancy Cook presented this at the NHLBI conference. If you do all the fancy error corrections and so forth, you get a very similar data point for the dose response under different conditions. It seems to work in overweight people, so if they don't lose weight, they still reduce their blood pressure if they moderate their sodium intake.

If they do lose weight, they might not get an additive effect. We can't tell because we didn't get an additive intervention. You know, we didn't get the same sodium and weight loss in the intervention. So, we can't tell if you could actually get twice as much benefit, say.

So, the levels here are higher than 2,400 at

the — and, except for very small women who are eating lower calories.

DR. GARZA: Shiriki, you mentioned that the distributions had been shifted. Are the samples cited adequate to test whether or not it was only the right side of the table that was shifted? Or, did we actually shift the entire distribution to the left? So that there was a symmetric change, both at the left and the right tails?

DR. KUMANYIKA: There is — I believe that Jeff Coutler at NHLBI has published in another paper, in the ILSI supplement, I think, has published a distribution from TOHP-I. That could probably be generated by the coordinating center, by Nancy Cook. She might be able to generate a distribution.

But the gradient of reduction is across — it's not just the high people who've changed. I can't give you all the details, although it's been published in detail. But, it's not just a few people who changed. It's really everybody had a reduction. Of course, some people increased it. In the control, some people go down and some people go up. And, in the — for sodium intake, and also for blood pressure and in the treatment group too. But, the two distributions were pulled apart.

DR. GARZA: Is that still consistent with the idea that we have salt sensitive population among the larger or the general population?

DR. KUMANYIKA: It is not — it doesn't address the question of the salt sensitive population because there isn't any way to identify responders and non-responders in this kind of a situation. We have looked at — we haven't done a paper on predictors of response to this intervention. But, most of the salt — in fact, all of the salt sensitivity papers are much more drastic reduction where you're triggering a different type of physiological response.

So, I don't know if we're going to be able to make an argument on the basis of salt sensitivity because the analysis of these data hasn't been done. It hasn't been done for — let me think is this TOHP-I or TOHP-II. There's Steve Hunt's paper with the AGT gene type where it looks like having the AAG gene type or AG is better than having GG for a response to the sodium reduction. It also affects response to weight intervention, I think.

But, that's not a huge difference. It doesn't mean that the other people didn't respond at all. It's graded, and, that's probably not the gene type that answers the question. There are probably

several. You know, it's a polygenic situation.

So, I don't know if — maybe we should cite the Hunt paper as an example of efforts to identify gene types that might be particularly to people that are salt sensitive. But, it's not feasible, at least not in this round to make advice on that basis.

DR. GARZA: Johanna?

DR. DWYER: In the table, Shiriki, could you just say again, what the intake was in TOHP-I and TOHP-II, and what the blood pressure reduction was in terms of what was the ending blood systolic and diastolic blood pressure? And, then what was the weight loss because I can't make head nor tail out of this.

DR. KUMANYIKA: Okay. I did not put on this paper the ending blood pressure —

DR. DWYER: What was the ending? Two thousand milligrams —

DR. KUMANYIKA: — but the delta is about — yes, that's just there. Okay. Can you not find this? I put in millimoles and milligrams. It's from your examples. That's the baseline intake.

DR. DWYER: Okay.

DR. KUMANYIKA: And, the baseline intake for the overweight —

DR. DWYER: But, it says sodium or sodium chloride?

DR. KUMANYIKA: That's sodium.

DR. DWYER: Okay.

DR. KUMANYIKA: Okay? The baseline blood pressures are —

DR. DWYER: Yes, I got them. But, what about the —

DR. KUMANYIKA: The ending blood pressures were — the delta is about —

DR. DWYER: I wanted to know the —

DR. KUMANYIKA: Two millimole — the mean blood pressure change on average, the difference between the two groups is about two millimeters of mercury systolic and one millimeter or less diastolic. It's a very small delta, which is one reason the sample size is so big. It's significant, but it's very small.

And, when I turn — here, I could also add those blood pressure changes. What I chose to put here were the results in terms of the incidents of hypertension from the life table because that's relevant to the case of can we get prevent people from crossing the threshold since we have this arbitrary — somewhat arbitrary — definition of hypertension, which is the 140/90, the incidents data we calculated on that kind of a public health question.

DR. DWYER: Let me just ask, though. So, if 125/84 for TOHP-I, and it went down by two systolic and one diastolic —

DR. KUMANYIKA: Roughly, but it's — or —

DR. DWYER: — and then the same pretty much in TOHP-II —

DR. KUMANYIKA: It's about the same size. And, I have both of those papers with me. I can give you those before the end of the meeting.

DR. DWYER: Okay. And so, the risk of developing hypertension was either systolic or diastolic?

DR. KUMANYIKA: Right.

DR. DWYER: Either?

DR. KUMANYIKA: Either, or being put on medications by your physician.

DR. DWYER: And, how about the weight loss?

DR. KUMANYIKA: Well, the weight loss was not a factor in TOHP-I at all. They did not lose weight. It was not a confounder of the — there was not a meant difference in weight loss between the treatment and control groups.

Also, not in TOHP-II, and, in fact, in some — well, the analyses to look in subgroups or not are not published yet, but if anything, the blood pressure change was in — some of it was in spite of

the direction of weight change in some of the groups. The weight — these finds are not explained by weight as far as we can tell. But, where people lost weight, the weight is a more powerful influence on their blood pressure than sodium intake. But, there was no net difference in the results. It explains this finding.

DR. DWYER: How big were the weight losses even though they didn't differ between subjects?

DR. KUMANYIKA: The target in the — there was no weight — the weight loss in the sodium group was negligible. If there was any weight loss, it was plus or minus a kilogram. It was sort of natural history type weight loss.

In the combined group, the target was 10 pounds on average. And, I believe that they lost a little bit less than that, and they didn't maintain that as adults or over — by the end of the intervention.

DR. DWYER: And, the final systolic and diastolic were again a loss of about two systolic and one diastolic?

DR. KUMANYIKA: Yes, two or one. I'll get the data. And, that's probably rounding up. It may be slightly more or slightly less by subgroups. I mean, the point of that being that it is not — it is a population mean shift. It's not a clinical — it has nothing do with the individual benefit in this type of argument. It's just saying that the blood pressure distribution of the U.S. population if you were able to get this change in sodium intake would be lower, and fewer people by a certain age would get to the point where they develop hypertension.

DR. GARZA: Scott?

DR. GRUNDY: Shiriki, is the rationale for this guideline mainly spelled out in the rationale section in the Green Book under "High Salt Intake Associated with High Blood Pressure?" Is that the essential rationale for this kind of —

DR. KUMANYIKA: All that's there now is the rationale for not changing it. The original Green Book describes that, you know, the background that you suggested — you know, the animal, epidemiological evidence and so forth. So, that's — the case wouldn't be made on that basis, but the case has been challenged. And so, what I'm discussing there to focus the Committee on, is the new evidence that's come out since 1995, and whether that —

DR. GRUNDY: Right.

DR. KUMANYIKA: So, the two need to be blended for the ultimate rationale.

DR. GRUNDY: So, there will be — the Green Book will have the ultimate rationale —

DR. KUMANYIKA: What the original rationale was plus the new data that had come out.

DR. GRUNDY: Plus the new data.

DR. KUMANYIKA: Right.

DR. GRUNDY: Okay.

DR. GARZA: Are there other questions?

DR. GRUNDY: What are you — just can I ask one more question? What is — in terms of the ultimate rationale, you know, what would be the two or three major pieces of evidence, or does it have to — is that a synthesis of all different kinds of evidence?

DR. KUMANYIKA: What's usually cited are, you know, in order of the suspicion of the association coming from ecological evidence to begin with, of populations with higher salt intake. Animal studies showing the mechanism. Clinical studies showing that people with hypertension lowered their blood pressure by reducing salt intake, which has never been a point that's argued by any people who are against this guideline.

The question has become whether people who don't have high blood pressure have a benefit from reducing their salt intake, and whether the benefit is large enough to warrant a population intervention. That's the argument. And, in the meta-analyses studies, I think, including DASH, most things that lower blood pressure have a bigger effect in people with hypertension then they do in people who have normal blood pressure. In DASH, I think it was 11 in the hypertension versus six or something in the people without high blood pressure.

And so, studies that show blood pressure reduction or sodium reduction in normal tenses are then cited as a part of the evidence. And, those are the pieces. And, sometimes meta-analyses to see whether that's consistent across a lot of different populations, different studies.

And, the T-O-H-P evidence, the latest one is an addition because it's the longest study focusing on sodium reduction, although it doesn't have people of normal weight just because of money. It couldn't afford those extra arms because it's longer and it is in people with — it is in normal tenses essentially, people with high normal blood pressure.

It doesn't answer the question of whether people with very low blood pressure to start with would benefit. So, it doesn't say — you know, it's on the high risk strategy. It doesn't say that anywhere in the distribution you would benefit.

So, the other piece of that comes from the — I guess, the old public health ethic that if something is not harmful and it shows benefit, you can apply it to the population. And then, that point has been argued, which is a different point. Well then, maybe it is harmful.

So, you know, and I'll talk about that.

DR. GRUNDY: There is a continuous relation between blood pressure and risk for heart attack and stroke. Right?

DR. KUMANYIKA: Just as with — yes. Blood pressure with risk for heart attack and stroke and weight and blood pressure and sodium and blood pressure both appear to be continuous. And so, weight is one strategy, although weight's hard to lose. It's simply one important strategy. Physical activity reduces blood pressure independently apparently. And, sodium intake, is another strategy that's recommended, along with alcohol reduction.

So, the evidence is a mixture of specific evidence that it's related and public health concepts that this is the way to go about addressing the issue. I guess that's the best way you could say it.

DR. GARZA: Other questions or comments from the Committee? Why don't you go ahead and move on?

DR. KUMANYIKA: Okay. The other points — and, here again, I'm talking about the way we would do the rationale for the changes that we did not make. Safety issues have been reviewed — have been raised and reviewed since the last guideline. I really hadn't been — major safety issues when we did the last guideline at all. There's been a new theme in the debate.

Some of this of course could be viewed as

self-serving on my part since I was an investigator in

TOPH-I and TOHP-II, and I did one of the reviews on safety issues. So, you know, you all read this and rip it apart if you don't believe it. You all have to believe this, too, not just me.

I think that we agreed that most of the safety issues were not related to the general population, but what we've done is add some more specific guidance in the text because these might be consumer concerns. I'm not talking about the text changes, I'll talk about that.

But, I will discuss, along with the guidance from the Chair, in this rationale, we should mention these studies that have come out relating sodium intake or proported to relate sodium intake to mortality and describe what that evidence is supposed to be and why we think it's flawed. So, that — I would put that in the rationale so that we don't only present one side of the case.

For consumer interests and perceptions, I didn't find evidence that consumers think this guideline should go away, although I'm sure if you were motivated to, you could find such evidence. But, our focus groups, the one — the comment that I saw was that people felt that diets should be lower in salt. There are a lot of national survey data where people are trying to reduce their sodium intake.

So, whether or not it's the major thing on their mind, is one issue, but it does seem to be something that consumers believe. And, whether or not it's feasible might determine how strongly they go for it. But, I didn't find any problem with the consumer perception that is harassing or making their lives miserable or anything that would say that it's a terribly unhappy thing to have such a guideline.

Recommending a specific level. We had a phone call. We discussed this — putting a more aggressive recommendation of a specific level. And, it went down in flames based on the fact that there was no new evidence to support saying that a particular cut-off was the best

cut-off.

So, there wasn't any reason to change — I think, how did I put it in the rationale. It seemed appropriate to continue the reference to other federal guidelines than to introduce a new recommendation from the dietary guidelines committee as if we had evidence to make a new recommendation. We didn't want to base our recommendation simply on the consensus from other bodies and then treat it as if it was in the recommendation. So, that's where we came down

on that, and that might be worth discussing.

DR. GARZA: Any questions on any of those points?

DR. KUMANYIKA: The subcommittee is still going along with this. Maybe these were the other things that we had agreed on. Amazing.

DR. GRUNDY: Well, just on safety, that's a recurring theme. Right? The safety issue is a recurring theme?

DR. KUMANYIKA: I think it's sort of quieted down recently because there were, I guess, one study isn't published, three analyses from one group, one abstract presented at AAJ and one study from Scotland. Those are reviewed by Chris Simposed at the NHLBI conference. None of them was designed to address the issue. And so, it's quite easy to find alternative explanations for the findings. And, the findings themselves are not — there tend to be no findings that there's no benefit for mortality, more than they are findings that sodium is causing deaths from cardiovascular disease.

So, the latest reports — the evidence and the comments submitted are pointing out that if you can't prove that reducing sodium intake extends your life, then it's no reason for a guideline.

DR. GARZA: Shiriki, will you be discussing under safety the concern that by recommending lower sodium intakes we're going to run into some iodine issues or?

DR. KUMANYIKA: I'm going to bring that up later. That's one of the things we still have to discuss. And, we had a nice — handed out yesterday, I hope. No, we didn't hand it out to the whole group, but we have a few more copies from the FDA to help us get into that issue.

DR. GARZA: Are there any other issues that relate to either safety or any of those? Okay. Go on.

DR. KUMANYIKA: So far, we're moving along. Okay. So what changes are making now? I have a eye test sort of a chart. The Committee has it in front of them. And, I put it up here because it's neater than my handwriting, although I have some of this in a different form.

And, I just wanted to show the format of this to start with. So, in broad strokes, you can see what we are changing. Oops, wrong direction.

And, I did it similar to the way that — Roland had done his yesterday. We have the guideline. We have the subheads and the subsections, the box text and the advice for today.

And, perhaps as you can guess from the extent of the non-changes, it really hasn't changed very much. So, there's some subtle changes in wording. There's a couple of major additions, but I would say almost all the changes are for clarification. And, a couple may be as precautionary.

So we're recommending changing the guideline from choose a diet moderate in salt and sodium to choose and prepare foods with less salt. There are several changes in there. We took the word "diet" out, focusing on foods. Adding a reference to food preparation and dropping the word "sodium." And, this is not the first time the Committee has seen this. And I'm thinking this is a form of agreement. I'm thinking that this whole — anything, except a few highlighted items are actually points of agreement.

Going, going?

DR. GARZA: Let's pause here on the guideline. Are there any questions because the only one that I would raise is it gets us at least into a potential discussion of good foods versus bad foods in going from diet to foods. Can you share that working groups discussion with us in terms of that possible argument being raised?

DR. KUMANYIKA: I don't know that we discussed it. I was thinking about it quite hard yesterday when we were discussing the issue in relation to the fat guideline. And, because of the way sodium is distributed in the food supply, it might not be as problematic for salt as it is for fat. I mean, I'm going to be making some comments about that. Yes?

DR. LICHTENSTEIN: I would agree with that because frequently with respect to food, there are options. You can not add extra salt to foods that's being prepared. In the marketplace, there are a lot of options that you can get to — of food with different sodium contents of salt contents. So, I agree that it's less problematic.

DR. GARZA: It might be very useful to go over some of those — documenting some of those reasons in the rationale.

DR. KUMANYIKA: Right.

DR. GARZA: So that, in fact, we can share that with others and provide a — this sounds

perjorative a clear target for those that might disagree coming up with

counter-arguments as to why future committees may want a change.

DR. KUMANYIKA: I think that's a good point because we hadn't specifically addressed that. But, there are options and very little of the sodium is inherent in food, so you're not targeting a food necessarily. It's the way it's fixed or prepared or packaged, and so forth.

DR. GARZA: Richard?

DR. DECKELBAUM: I was just going to say the same thing that foods are not born with high salt unlike some foods are born with high fat.

DR. KUMANYIKA: Okay, write that down.

DR. GARZA: The prenatal type of argument.

DR. DECKELBAUM: Keep the pediatrics out.

DR. KUMANYIKA: Okay. Shall we go on to the —

DR. GARZA: Unless — I don't see any other comments right on the guideline.

DR. KUMANYIKA: Okay.

DR. STAMPFER: It's really just a question about the sweating under the — as part of the Box 20.

DR. GARZA: Okay. We're going to be going by the subheadings. So, if we could do this in an organized fashion, it may give us a chance to get through this.

Go ahead.

DR. KUMANYIKA: Okay. So, the subheads. We had four subheads in '95. It's on page 39 of the old booklet if you want to refer to it. And, we're suggesting four subheads for the year 2000 so — three subheads. So, this one is almost the same. We dropped the word "sodium". And, that's the only change in the first bullet. I'm not talking about what's under it, but that's the first change.

The second bullet, we changed sodium as associated with high blood pressure for greater accuracy of the statement that high salt intake is associated with high blood pressure because — sodium is associated with blood pressure, but high sodium is associated with high blood pressure.

The other factors that affect blood pressure have been moved to a box. So, it's not a subhead, but it is a boxhead at this point.

And finally, most Americans consume more salt than is needed, which was descriptive, has been changed to a behavioral statement of "Aim for a moderate sodium intake."

It might be good to just react to that — the new wording of these two before we talk about how we rearrange the text to go along with this. Any problems or concerns with saying "aim for a moderate sodium intake," for example?

DR. GARZA: Any comments on any of the — you want to take one subheading at a time?

DR. KUMANYIKA: Okay.

DR. GARZA: Or do it on the first subheading?

DR. KUMANYIKA: It's just dropping the word —

DR. GARZA: Are you doing the text under them as well?

DR. KUMANYIKA: No, not — I just think just because of some of the wording, it might be nice to just look at the bullets and the conceptual flow to see that it didn't change and see if — and, then talk about the changes which are actually relatively minor within those sections. It's more editorial.

DR. GARZA: Taking the first one, Shiriki, when we say high, unless we're going to give the consumers some guidance as to what high is, so we may want to — when we get to that, make sure that, in fact, that's going to be clear?

DR. KUMANYIKA: Yes. Are you implying that it should say something like higher salt intake is associated with higher blood pressure? Because there is no —

DR. GARZA: I know, but that's the problem. That if we say high salt intake is associated with high blood pressure, then I think we know what high blood pressure is because we've got some clinical guidelines for that. It's what's a high salt intake then.

DR. KUMANYIKA: That would be too complicated to address in this.

DR. GARZA: I know. That's why I'm raising it. That by having that heading, that would sort of be my expectation of the consumer. That you're going to tell me what a high salt intake is.

DR. KUMANYIKA: What about changing it to higher? Do we have to have — is that grammatically acceptable to put higher salt intake is associated with high blood pressure?

DR. GARZA: I would find that still as a consumer — my expectation would be well, are you going to tell me what higher is? I think these subtleties, at least — I have a focus group of an — equal to one at home generally, and I'm told that we scientists try to read tea leaves, and that most consumers just are not going to be focused on the ER.

DR. KUMANYIKA: I think that in the text if it doesn't say so now, and I'm not referring to it right this minute, but I think that in the text, we can make that clear. Because what it means in most populations, the people however — whatever the distribution is, the people who have a higher blood pressure — have a higher sodium intake, have a higher blood pressure.

But, it's hard to — it's more of a cross-

population association. It's hard to see that within a population. And, I have to think about —

DR. GARZA: Could we say something like blood pressure rises as your sodium intake goes up?

DR. KUMANYIKA: Well, let me just think about that now. I think — let me look at the text because the basis for the statement is primarily a cross-population comparison. It's been very hard to find this within populations because the distribution may not be across the range. See, I forgot to bring the —

DR. GARZA: Go ahead, Alice and then Richard.

DR. LICHTENSTEIN: Your blood pressure may increase with increased sodium intake. My blood pressure may not.

DR. GARZA: Well, it's a population, but that same thing would be true if you say high salt intake is associated with high blood pressure.

DR. KUMANYIKA: But may be —

DR. GARZA: It doesn't say may be in the heading.

DR. LICHTENSTEIN: There should probably be a may for either version of it.

DR. GARZA: I mean, we should have some discussion. I mean, perhaps I'm the only one — the only consumer that would be if you tell me high, then I'd like some guidance on what high is.

Richard?

DR. DECKELBAUM: I would think that going with higher could be helpful, and you know there are cross population studies which the — study, which suggest that it's continuous. And, that's a strong — you know — you can point out the type of study, but it is a continuous thing, so that higher is more —

DR. GARZA: That's why I rephrased it the way I did.

DR. DECKELBAUM: And so, I think that we're fairly safe in quoting some studies which show that it's a continuous variable, as you increase the salt intake.

DR. GARZA: Johanna and then Suzanne?

DR. DWYER: Maybe we could just say salt is associated with high blood pressure?

DR. KUMANYIKA: That's the way it was before. That's the way it was before, but I thought that this might be better because the fact that —

DR. DWYER: You were wrong.

DR. KUMANYIKA: Some salt — it's not just some salt, it's really this relationship of — but, if it's going to be confusing not to define it, we could drop it. It didn't bother anybody before the way it was.

DR. GARZA: But, when we look at the text, we can make that judgment. Suzanne?

DR. KUMANYIKA: We'll come back to the text.

DR. MURPHY: Well, I'm echoing the same concern that every single person can benefit from reducing their salt intake, which is the implication. And, I don't know — if it's group level data, I don't know that we can extend that to say it will apply to every single person. So, this seems to be too sweet.

DR. KUMANYIKA: That's what the bullet says to you, that it's too —

DR. MURPHY: Yes. High salt is associated with high blood pressure for everyone.

DR. KUMANYIKA: Okay. Then, I would think we take the high off and just leave it as salt intake if it's causing that kind of confusion.

DR. GARZA: Scott?

DR. GRUNDY: Let me follow up on what Richard said and what you commented. I think we have to look on this as a continuous variable and not a categorical thing because association between blood pressure and risk is across the board.

And also, something that Alice said that it may affect — not affect her, but it may affect Bert. Well, I think that is very difficult to prove that that is the case, because measurements of blood pressure are difficult to make. The changes may be small for individuals, but nevertheless, as a continuous variable, it could have an effect on everybody.

So, I wouldn't say that everybody would not benefit. I mean, it's a risk issue, more than it is, you know, a categorical thing. High saturated fat is in the diet. It's not going to kill everybody. It increases your risk. So, high salt in the diet, as far as we know, increases the risk for everybody, although there would be some variations from person-to-person. Nevertheless, on the whole, it would raise your blood pressure. So, I would be inclined to say higher blood pressure is what it's associated with.

Is that in line with what you were thinking, Richard?

DR. DECKELBAUM: Right.

DR. GARZA: So, you would go with high salt intake is associated with higher blood pressure?

DR. GRUNDY: Yes.

DR. DECKELBAUM: Higher salt intake?

DR. GRUNDY: Higher salt.

DR. GARZA: Oh. Higher salt?

DR. GRUNDY: Higher salt intake is associated with higher blood pressure.

DR. GARZA: So, higher in both places then?

DR. GRUNDY: Yes.

DR. MURPHY: So, my question would be, have we once and for all based on good solid evidence put away the concept of salt sensitivity? We can say with confidence that is no longer an issue?

DR. GRUNDY: No. I'd say that — I mean, that's like we know — let's just take the analogy to saturated fat. If everybody in this room we test — everybody in this room, there's a variable response to saturated fat, some will go up a little bit, some will go up a lot. And I mean, we've done a lot of studies that show that. I think the same thing holds for salt. Some may go up a little bit, some may go up a lot. And, it's going to be probably a bell-shaped curve of distribution.

But, the idea that there's two groups of people in the country, those that respond to salt, and those that don't, is probably erroneous. Isn't that — would you agree with that?

DR. KUMANYIKA: Yes, I agree with that. I said I think on one of our calls that for some reason this guideline seems to be held to a different standard from some of the other ones because the case is very similar for fat and cholesterol, but nobody seems to worry that everybody in the room isn't a dietary responder to fat. But, when it comes to salt, people want to exclude themselves from the target population immediately on the salt sensitivity issue.

And, I don't really understand that because I haven't seen any evidence that — I mean, the salt sensitivity literature is not very informative. It's not even as informative as the fat response literature because the protocols are so extreme.

DR. GARZA: Suzanne and then Johanna?

DR. MURPHY: Yes. Welll, I think it dates back to what many of us have taught for a long time that six out of seven people don't respond to salt. I mean, there — I don't know where that number ever came from. It's not my area of expertise, but it's sure out there.

And, no one has ever used numbers like that for fat responsiveness. I mean, I would assume — I have always assumed that everybody responds to a reduction in saturated fat.

So, there is certainly a perception, which I'm happy to be told that's totally erroneous, but it's been around a long time. And, that needs to be clarified if it's just plain wrong.

DR. GARZA: Johanna?

DR. DWYER: Just hearing on this, and I just don't know the answer and would appreciate guidance on this. I guess what — I'm not sure that the analogy is exact with saturated fat and serum cholesterol response, because I guess what bothers me and I need reassurance is first of all, is the size of the change as great with the sodium blood pressure connection? And, is the number of responders versus non-responders in a metabolic ward so that the adherence issues are taken out, are they the same?

I'm well familiar with your work, Scott, and those of others on the blood cholesterol response.

DR. GRUNDY: Right.

DR. DWYER: And, you know, I know Alice and Ernie and others that Tuft's have done wonderful work on that, as well. But, I'm not so sure about the sodium. And, are the — is that a direct analogy or isn't it, back to Suzanne's question?

DR. GARZA: WHy don't you respond to that, Shiriki, and then we'll go on to Alice's question.

DR. KUMANYIKA: I think that I need to look up some data and respond exactly. You're asking if in a control situation, are there some people whose blood pressure responds with a 15 percent drop to a certain level of sodium reduction as — and some people whose doesn't? Is that what — you're asking in a clinical situation which could you get a response?

DR. DWYER: In the patients that I see are dialysis patients. And, if you load them up with salt,

eventually, they'll all show a blood pressure — they all get blood pressure problems. But, these are sick people. And, the dietary guidelines aren't about people like that.

I want to know if the kind of distribution you see in your studies where you see a certain number of people who respond a lot, others respond a little, is that the same with the salt limiting?

DR. KUMANYIKA: Okay. So, you're asking —

DR. DWYER: Within the range of consumption, because those studies you people have done have been within the range of usual consumption.

DR. KUMANYIKA: So, you're asking —

DR. DWYER: I don't want to see salt loading of hemodialysis patients where you're giving them herring or something very high in —

DR. KUMANYIKA: So the question you're asking, for example, is what is the range of blood pressure response to a 30 percent sodium reduction? Is that — I'm trying to understand the question. I'm going to have to look up some data, but at least I want to make sure I understand what it is I'm looking for because we may already have some of the data put together. Like if you look in quentiles of people who reduced their sodium a certain amount, and you want to know what the spread is around a blood pressure change?

Is that the kind of question you're asking?

DR. DWYER: Yes. The number of people who respond and the size of —

DR. GARZA: Shiriki, don't you have that data? When you told us that the distribution shifted in these types of studies, that in fact, what you have is a similar situation. That's why I asked about whether you had a differential effect on the right or the left end of the tail, because in fact, if you have a distribution change, it would — the entire distribution shifting to the left, you would have a situation, I thought would be quite comparable where you had responses. Some people respond more than others.

DR. KUMANYIKA: Yes. Some people gain weight in weight reduction programs so that I mean a lot of these things are —

DR. DWYER: No, not on a metabolic ward.

DR. KUMANYIKA: Maybe not — I guess the question is what — which type of evidence are we discussing? Because if we go from population cholesterol reduction to dialysis patients, we can't discuss it. So, are we talking about population cholesterol reduction —

DR. DWYER: I would like to know about non-responders and whether the percent of — or minimal responders because as Scott has pointed out, everybody responds if you give them 200 grams of saturated fat. But, the point is nobody eats 200 grams of saturated fat. The point is, within the range.

DR. KUMANYIKA: And, how is that information going to help? I'm still not sure IF you're asking metabolic ward or population studies.

DR. GRUNDY: Could I ask a question in a way that might answer? Is there evidence for a dichotomous responsiveness, or is it a bell-shaped curve type of response?

DR. KUMANYIKA: It's a bell-shaped curve.

DR. GRUNDY: Yes, that's what I think, too.

DR. KUMANYIKA: But, that's — but, I have to look to see if I can specifically find. Most of these studies don't publish a distribution of response. But, there's never been — I mean, people have been looking very hard for salt sensitivity and can't find it without doing these other protocols because it's so polygenic I think what affects blood pressure.

The other problem is it's pretty hard to get an integrated measure of change in sodium intake from these measurements of one 24-hour urine every 18 months. So, there's a lot of noise in the data because even though — for example, with weight. If people come in weighing five pounds less, there's a pretty good chance that they weighed five pounds less for the period before they came in for the measurement.

For the sodium, when they come in for these studies, it's possible people in the intervention might adhere to the diet better than a few days before they're scheduled to come in and give the urine sample. And so, some of this, I don't want to give a false precision. You can't —

DR. DWYER: I'm not — I mean, after physiological responses in a situation where those

variables are subtracted, I agree with you, that would be not a good —

DR. KUMANYIKA: But, I'm not —

DR. GARZA: Let me interrupt. You've got 30 minutes to do this, and unless you think we're going to come to resolution, that it may be useful to say, "Well, let's get the data." And, one example — I mean, Johanna was just talking, that you may want to plop responses and see if they're bell-shaped, or if you have a big peak of no responders and then a tail of responders or something.

And, then we'll get the answer, but I don't think that —

DR. KUMANYIKA: Okay. I think I'm getting it. So, in the rationale, we want to be able to show that we can't pick out one set of people from the population who would benefit or not benefit. And, if we can't show that, then it only applies to this one — I never, I'll burn that textbook that you had that said six out of seven don't respond because I've never seen that in the literature.

DR. GARZA: — at Berkeley has been teaching.

DR. KUMANYIKA: Okay. Well, we'll move on from this for the time being.

DR. GARZA: Then, Alice. Alice has a question.

DR. LICHTENSTEIN: First, I have actually a comment on this, and then I'll move to my question. I think it's a lot more difficult with sodium. I agree. I think people have been looking for a long time for markers or responders, non-responders. And, I think for a lot of the reasons you pointed out, they haven't been apparent. Whether it's polygenic, that it's more difficult to measure accurately.

I don't think that it can be compared with fat and fat. Unsaturated fat, we can precisely measure pleasant cholesterol levels. We have found that, you know, E4 phenotypes types respond differently than E2. So, I think it's non-comparable.

But, the issue with respect to —

DR. GARZA: Let's move on because we've beat that thing to death, I think.

DR. LICHTENSTEIN: Oh, okay. All right. As far as may, there are possibly responders, there aren't responders. Maybe we're focusing a little bit too much on that. And, a lot of the discussion, I think, has persuaded me from that because, you know, we eat as units of people where usually certain dishes are prepared and everybody eats from them. A lot of times we don't prepare the food that we're consuming.

So, in a sense, if these are really guidelines, not specifically for individuals, but more for general consumption patterns, we're on relatively safe ground to say, "Well, yes, we know there is a relationship between sodium and blood pressure." Therefore, it does seem reasonable that we do focus on maybe reducing sodium contents in general of foods, and it's unlikely that anyone is going to be put at a disadvantage if that happens on a population wide, or even a family unit wide, or a college cafeteria wide basis.

DR. GARZA: So you're supporting high salt intake — the suggested change or the original one?

DR. LICHTENSTEIN: Sodium associated with high blood pressure.

DR. GARZA: So, you're going with the original?

DR. LICHTENSTEIN: Yes, I think salt is — dietary salt is associated with high blood pressure.

DR. GARZA: Okay. Then, can we move onto the next one?

DR. KUMANYIKA: I hope so.

DR. GARZA: I'm becoming a time wizard again.

DR. KUMANYIKA: No, that's fine. I never run out of patience with treading this ground yet one more time.

So, the other factors is that blood pressure has been moved to a box and there's reference to it in the text. So this is the final one for a subheads to consider. — for a moderate sodium intake.

DR. GARZA: Any concerns about that? It's obviously consistent with our aim for healthy weight. Okay.

DR. KUMANYIKA: Okay.

DR. GARZA: You want to move on to the text?

DR. KUMANYIKA: Yes, why don't we talk about the text changes in these sessions. And again, you all have this chart in front of you. And, the eye chart is just so that the audience won't have to count on my words too much.

The text in these section, if you look at it in comparison to the other text, mentions the role of weight in a different way. Some of the text about weight was in the other section before. So it mentions weight.

It says: "Your salt intake, along with your weight and other dietary factors." And, that is moved there because it was felt in the subcommittee discussion that the fact that salt is only one of the factors relating to blood pressure might get lost or needed to be very prominent because nobody thinks that this is the only strategy for blood pressure reduction. So, it seemed like a good idea.

And then the reference to the box that lists the other aspects for blood pressure is right there. So, it says, "Your salt intake, along with your weight and other dietary factors, may affect whether your blood pressure becomes or stays too high." And so, that's conditional that may affect.

And so the changes, it mentions role of weight specifically. Moves thing to the box. And, the text in this section after the box also mentions the calcium excretion and stomach cancer. And, the stomach cancer is new as far as I could tell. We didn't ultimately mention that in last year's guideline.

I don't have the references. I think Ann might have been looking into that from the subcommittee awhile ago. And, I didn't find the specific studies that we would cite that are recent to confirm that. So, I thought that might be worth discussion to see if, in fact, we do have that evidence and if we want to add that into this year's guidelines.

The calcium was there before. We have information from the DRI text about calcium and sodium excretion that we got, I think, in support the mention of calcium and sodium excretion and bone health, and justify it.

So, what about stomach cancer and how it's mentioned? What it specifically says is, "Populations that high salt diets have high rates of stomach cancer." That's the way it reads at the moment. It did say, populations that consume very highly salted foods, but now it says that

have high salt diets.

DR. GARZA: Okay. Alice?

DR. JOHNSON: I would say higher again. I would say higher again.

DR. GARZA: Alice and then Rachel and then Meir.

DR. LICHTENSTEIN: Is the association with high salt foods or fermented foods that are high in salt?

DR. KUMANYIKA: Well, that's why I said before the various salted foods because most of the time when it's come out in the cancer literature, it's come out in association with foods because people perhaps are not sure whether exposure to certain very dense foods or whether it's the total sodium intake. And so, I had actually preferred the other wording.

DR. LICHTENSTEIN: But some other component associated with fermented foods?

DR. KUMANYIKA: I mean, first of all, this is stated as population as ecological evidence. It's not stated at — and, that's why I say, which evidence are we using? And, if we don't know, we have to go back to where we had done a literature search, and we identified some new studies, but I didn't find a reference to where we had resolved this. And so, I'm flagging it because I'm not sure we have it nailed down.

DR. GARZA: All right. Rachel and then Meir?

DR. JOHNSON: No. I just think it's a continuum, and that's why I recommended saying higher again, rather than high because we don't really define high and it's just in comparison.

DR. KUMANYIKA: Well, this is a case of something that's very high. I mean, this is something that it's in a different domain, I think, from the general continuum.

DR. JOHNSON: Then, should we say very high?

DR. KUMANYIKA: Well, it said before as you can see it on the text.

DR. JOHNSON: Okay.

DR. KUMANYIKA: The question is, do we have evidence? And, then the next question is what's the wording?

DR. GARZA: Meir?

DR. STAMPFER: Well, I think there are data that support that, especially ecologic data. But, we really haven't gone to ecologic data as a sole support for other recommendations. And, in terms of individual data, say, analogous to what we would have for fruits and vegetables or whole grains where you have data on individuals and their risk, there I don't know how strong it is.

So, I guess I'm not sure we're being even in terms of how high the bar is for what sort of evidence we would require to make a specific comment. For example, another analogy might be in the alcohol guideline. There's some evidence that higher intake is associated with — well, no, I guess that's not a good analogy.

But, I think the evidence is really mostly ecological. So, I guess we'd have to decide whether we believe that sort of evidence is credible enough to include in the guideline as opposed to the rationale.

DR. GARZA: You mean that's specifically for cancer?

DR. STAMPFER: Yes. The stomach cancer — high salt stomach cancer data.

DR. GARZA: Johanna?

DR. DWYER: I thought there were two lines of evidence that led us to say it. The first was studies from Asia and particularly, Korea where they have very high stomach cancer rates and for years, and also down in the south in this country, they were thought to be associated with salt intake.

But, after the discovery of hecalbacter pilori and some of those other relationships, a lot of those relationships were rethought. And, the hecalbacter central role in causing atrophic gastritis and maybe setting up a cascade of changes that led to stomach cancer with nitrates and also salt, perhaps facilitating that, but not being the primary thing. I thought that's where we stood on that.

The other evidence that's — and, there's a lot of data on that, but I don't know if it's strong enough for what we want. The other data that I'm aware of, Meir, you may know better. You may know these studies better than I do.

I believe the man's name is Jack Juisance from Luva, but I may have the name wrong. And his studies are of Belgium, different parts of Belgium, especially the Flemish speaking parts. He's Flemish. So, maybe it isn't Luva. Maybe it's the other university.

And, looking at different levels of salt intake and rates of stomach cancer. But, those data — he's quite an old man now. I think he's in his '80s. And, I don't know if he's done any work in the past few years on that.

DR. KUMANYIKA: Well, we had some recent citations that we looked up, but my impression is that they were still ecological studies. I mean, once in while, something comes out, but this is not on any more solid ground than that. So, the question is, is it worth mentioning in this guideline? I mean, the cancer literature mentions it, but it tends to — it's mentioned the same way. I don't know of any other type of study that have ever — that's ever really supported this. But, you know, it gets mentioned when you talk about foods of a high salt concentration that are typical in some diets in some countries.

DR. DWYER: Well, his studies were really not of as much foods as it was — I thought it was diets plus beverages. And, the salt is very — I think it's very high in the water of that part of Belgium. So, it's more of a total diet issue than any specific food being —

DR. KUMANYIKA: Okay. I have probably the old and the new stuff. Why don't you look at it again?

So, what's the feeling on this? If it turns out that even if the evidence is good and recent, it's only ecological studies. Should this statement be in there? Should some version of this statement be in there? That's the question.

DR. GARZA: The sense is I'm looking at body language around the room is no, that if it's just ecological, that's it very difficult to base national policy on it. Is that the sense of the group? Anybody that doesn't know or something.

I think that's the sense, Shiriki.

DR. GRUNDY: I don't think we can set that criteria. If it's only ecological, you can't base national policy on it.

DR. GARZA: Well, I mean in terms of sodium for this group. I mean, what the nation wants to do I think is fine.

But us at any rate, we will base our recommendations on more than ecological data.

DR. KUMANYIKA: Well, it also raises the question whether every statement in this book is policy or whether — if the question is, has high sodium intake or high salt intake ever been associated with any other health problem in a way that's consistent, this statement is not misleading because it consistently had association. We don't know if it's causal, we don't know a lot of other things about it. And, that's the question about it being ecological.

DR. GARZA: My sense is that, if I remember the data correctly, that stomach cancer rates are falling. Have there been similar changes in salt intake in those populations or not?

DR. DWYER: It's much closer to the south of the U.S. with helicalbacter. Isn't it?

DR. GARZA: That's right. That's what I'm saying. It's that, I mean, plus the ecological nature of the data that makes it more difficult.

DR. KUMANYIKA: I mean, if I had to vote, I would vote to take it out right now just because I don't think that we're on solid ground with what we're trying to tell consumers about this. That they could find out somewhere else that this association has happened, but in here, it's giving it more — it's implying something that we don't have any — that we're not ready to imply because we don't have enough information. If it turns out there's some other factor that's really driving this whole thing, at least currently, we'd be in —

DR. GARZA: I think we agree, so let's move on to the next point then.

DR. KUMANYIKA: Okay. The other thing that has been changed in this section, bringing up the statement about there's no way to tell who might develop high blood pressure from eating too much salt. However, consuming less salt or sodium is not harmful and can be recommended for the healthy normal person. It used to say healthy, normal adult, and now it says healthy normal person, which was a specific change so that it didn't appear to exclude children.

And, the literature supporting that for children needs to be added to the rationale.

DR. GARZA: Okay. Suzanne and then Richard? I think you both had your hands up.

DR. MURPHY: Yes, I really like that wording, but it seems to me to contradict the last sentence on page 55, the previous page that says, "You can reduce your chances of developing high blood pressure by consuming less salt." I wonder if we could just omit that sentence and let this last paragraph stand on its own?

DR. KUMANYIKA: Yes. That sentence on page 55 is a revision of something else that was trying to help people personalize the information. And, that what's subtle there is — what's maybe not working is that it's the risk that's reduced. It's not a certainty. It's the chances that are reduced. And, in fact, that's true as a definition of risk. But, it might not be — that might not be clear enough to put it in there.

So, whether to eliminate it, I just want to look back at what was in there before. Before it said, "Most evidence suggests that some — that many people at risk for high blood pressure, reduce their chances of developing this condition by consuming less salt or sodium."

So, one alternative is to go back to that. And then I was thinking after this discussion, that we probably should move that. There's no way to tell right up behind that text because it relates to that. So, why don't we — with this discussion, we might rework that piece of it and see if you like the way it comes out. Okay.

Let me refer to Box 20, which is the box added on safety issues. And that box now mentions — you have to know which box. Says Box 20. It's — yes, can salt intake be too low. This box was added to increase consumer understanding of safety issues, emphasizes that guidance does not replace medical advice, discusses split losses of sodium. Right now, it mentions iodized salt. It does not mention pregnancy. And, I highlighted the mention of iodized salt and the no mention of pregnancy because those are things we need to discuss.

So, why don't we open up that text for a discussion. I know, Meir, you had a sweat comment.

DR. GARZA: You mean, you want to do Box 20 now?

DR. KUMANYIKA: I think we —

DR. GARZA: Well, that's what I'm saying. I think we're going to start skipping, which —

DR. KUMANYIKA: The only reason I wanted to — well, okay. We don't have to do it now. It's because we were just referring to the safety issue, I thought it might be easier for people to think of the box where it occurs.

DR. GARZA: We can do it as long as people are prepared. I mean, I know that Alice has a question on Box 19, so that doesn't mean that we're not going to come back to that box.

DR. KUMANYIKA: Right. Oh, okay. I see what you mean. I'll take your — if you want to —

DR. GARZA: Let's just finish the text because what we might have to do is break for lunch and then come back and do the boxes together as a —

DR. KUMANYIKA: Okay. Let's finish the text. Forget Box 20. Forget Box 20 for a moment, okay.

So, text. Most Americans consume more salt than is needed aim for a moderate sodium intake. This section rephrases to give specific behavioral guidance in the title. And, it continues the same recommendation for the — you know, it mentions that the daily value is 2400. So, the people who wrote in who really wanted us to be more specific and deliberate on that point, will not be satisfied with the way we've done it, but that's where the Committee came down.

There's no other substantive change. This is the box where we're trying to help people understand the difference between sodium and salt. And, I'm very pessimistic about our ability to do that. We've dropped the word sodium in some other places. Now, they'll be directed to food labels to get the information about sodium, and that's something to consider. But otherwise, what's in that text, the essence of it, is about is very similar — it mentions eating out and ready to eat foods. It stresses that a little bit more, but not really different from what we had before so.

Comments? That's on page 57 of the draft guidelines.

DR. GARZA: On that text, Alice?

DR. LICHTENSTEIN: I'm wondering if with the example that we couldn't put in maybe at least a couple examples so we just don't single out one food? I was a little bit uncomfortable with that and maybe — yes, so to include maybe pretzels or a microwaveable taco or something like

that also because they'd all be sources of a lot of salt.

And, then the other thing is, and this is sort of a discussion point. Would it be worth reiterating that there may be lower salt options available and read the label, or read the front of the package?

DR. GARZA: Okay.

DR. KUMANYIKA: I might ask Carol Suitor to comment on this. There is a detailed box now I think that's better organized about how to do this. And, whether or not the examples in the text are helpful and how you do that is a judgment call. I think the purpose of putting this in was to try to explain — to help interpret this amount of sodium to someone who might pick up a particular product.

DR. DWYER: Are you talking about —

DR. GARZA: Well, hold on, Johanna.

DR. KUMANYIKA: So, that's the purpose. So, do you need to do that in this here and change the way we do it, or do we not need to do it here?

Carol, did you have any comment on this because you had questioned this whole section before when we were working on it?

MS. SUITOR: I think it's a judgement call. But with your decision —

DR. GARZA: Okay. All right. So there are other examples given in other boxes. So maybe we can take up the boxes and see whether, in fact, we can eliminate this one and just refer people to that box.

Meir and then Johanna?

DR. STAMPFER: Two things. First, I think it is important to — even though it's not going to be that easy to relate the salt to the sodium because that's what they have on the food label, the sodium. So, they need to have that.

Just a really small point. In the example that's given, you say — or the text reads — provides

900 milligrams of sodium, more than one-third of what you'd need for the whole day. But actually, what you need for the whole day is about 600. So, it's not — it's sort of what what you're — it's more than a third of what your upper limit ought to be.

DR. KUMANYIKA: Of the daily value.

DR. KUMANYIKA: Right, that's a good correction.

DR. GARZA: Johanna?

DR. DWYER: I wasn't clear, Alice. Were you talking about putting in some other foods just other than soup —

DR. LICHTENSTEIN: Yes.

DR. DWYER: — or, were you talking about taking the whole thing out and putting in —

DR. LICHTENSTEIN: I think it can be either way. I just don't think we should put in one food. So, it could either go into a table would be fine or include a couple of examples.

DR. GARZA: Suzanne?

DR. MURPHY: Yes. I'd take out the sentence that says, "On average, the more food you eat, the more sodium you consume." That sort of makes me despair of ever solving this problem. And, although I agree it's true, I don't know that it's helpful to say that.

DR. KUMANYIKA: Because we put that in partly for the reason that makes you despair. We put that in to point out that it's going to be harder for some people than others.

DR. MURPHY: But, fruits and vegetables, you know. I mean, the foods we're recommending are low sodium foods, generally speaking.

DR. KUMANYIKA: Well, okay. What do other people think about this?

DR. GARZA: Can you then summarize for the group, Shiriki, the changes that you heard, that we came to consensus to in terms of either the headings and then the text? And, then we'll break for lunch, come back at 1:00, and do the boxes.

DR. KUMANYIKA: Okay, okay. Okay. What I heard is — I've got to find my chart here. Okay. We actually, we didn't — it's not clear to me that we discussed the text under —

DR. DWYER: Advice for a day?

DR. KUMANYIKA: The first. No, under the first. We didn't do the advice for the day.

DR. GARZA: We'll do advice for the day when we come back from lunch.

DR. KUMANYIKA: Okay. The first block of text under salt is found mainly in processed and prepared foods, there were no changes suggested to the bullet. And, we didn't discuss the text. We skipped that by mistake. But, it now mentions restaurants. And, it's otherwise editorial for clarity. The content is almost identical to what was there before. There was no reason to change it, but there was a lot of interest in putting more emphasis on —

DR. GARZA: I'm sorry. What do you think we missed by —

DR. KUMANYIKA: I'm going back to the beginning of suggested text to go through —

DR. GARZA: Going to the first paragraph.

DR. KUMANYIKA: — discuss the text — I'm saying the changes are almost entirely editorial with the exception of making a point of mentioning restaurants. If you compare — if you put the two, old and new side by side, it was — it's not — this text was not discussed in comments. It doesn't seem to be controversial, and it's been edited.

DR. GARZA: That's the introductory paragraph for 481.

DR. KUMANYIKA: That's the introductory paragraph under the first bullet.

The second bullet, one of that the change was to consider higher salt intake is associated with higher blood pressure, or to consider just dropping the high from the salt and say, "Salt intake is associated with high blood pressure." We didn't vote on which of those two options, but that it would be re-reviewed after making certain changes to the text that would attempt to clarify around issues of salt sensitivity and to get specific rationale that shows that this is not a dichotomous variable. That we're certain — only certain people would be targeted in this recommendation.

DR. GARZA: Is there a preference in the group for either of those headings, for the old one or the new one? Because I sensed there was. I mean, but maybe I'm — we're going with the old one, right?

DR. KUMANYIKA: The old one was sodium, so —

DR. GARZA: Well, we're going with salt, but just saying salt is associated with high blood pressure.

DR. KUMANYIKA: Okay. Okay. So, did I — is that it for this section? Any other —

DR. GARZA: Any others on the text, or was that the feeling of the group?

DR. KUMANYIKA: We will — that's on page 55.

Then, from page 56, we're going to bring the last paragraph that says, "there's no way to tell" up next to the text on whether you can reduce your blood pressure by reducing your salt intake.

And, in the other paragraph, we're going to delete the information about stomach cancer. Delete that sentence.

There is an open question. Some editing needs to be done to tie the calcium excretion to bone health more directly. And, we have the references due, and it just hasn't been done yet.

And then on page 57, the aim for a moderate sodium intake. We're going to see if we can give an — you can change the example if we give one to make it clear that it's more than a third of the daily value. And, we're going to see if we can do that without picking on one particular food.

DR. GARZA: Okay. Are there any other changes that — then, I'm going to suggest that we break for lunch. Come back at 12:45. That gives you 50 minutes to get there, have a leisurely lunch, and return. So, that's 12:45. And, we'll finish advice for today and get in the boxes.

(Whereupon, at 11:55 a.m., the hearing was recessed for lunch to reconvene that same day at 12:45 p.m.)

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AFTERNOON SESSION

(12:50 p.m.)

DR. GARZA: So, Shiriki, you're on.

DR. KUMANYIKA: Okay. So, we have to now go to the boxes. Right? Okay.

Okay. The first box that we can discuss is Box 14, which was some good sources of potassium. It has been deleted. If you remember, we pointed out that it was particularly poorly positioned because it made it look like it wasn't clear what the purpose of having it where it is on page 37 of the old booklet, since it's a sodium guideline and not a — fruit and vegetable or potassium guideline.

So, one question is whether there's anything in that box that you think is not said elsewhere in the guidelines. Have we lost anything that we need to make sure to pick up some place else?

I thought I was going to put that it had moved to fruits and vegetables. I didn't actually see if the potassium is mentioned in the old fruit and vegetable text, but the guideline to eat fruit and vegetables is certainly in the new box that's been suggested for Box 19. — steps, may prevent high blood pressure.

So, the question on the table now is to reiterate that we deleted Box 14 and see if anybody thinks that something is going to be permanently lost there.

DR. GARZA: As I recall, we got — there are two places where we talk about high blood pressure now. It is mentioned in the food and vegetable guideline that increased consumption of fruits and vegetables is related to high blood pressure — I mean, to lowering your risk for blood pressure.

DR. LICHTENSTEIN: I don't think so.

DR. KUMANYIKA: I looked in this —

DR. GARZA: I thought that it was in the text, not in the box that we said one of the benefits.

DR. LICHTENSTEIN: Well, I'll look.

DR. GARZA: Yes.

DR. KUMANYIKA: Because I do think that — I mean, the two DASH diets that are so widely talked about as having a role I think one, mention of the fact that diets that are high in fruits and vegetables because the fruit and vegetable diet in DASH was fruits and vegetables, that was the main modification of that diet. Then, there was the combination diet that was also looked at, high in fruits and vegetables and had high dairy, mostly for lowfat dairy. I had more protein.

So, both of those diets reduce blood pressure in that study, including F and V, just not as much as the combined. So —

DR. GARZA: I don't hear any objections to dropping the box. Meir?

DR. STAMPFER: I don't object to dropping the box, but the point at the bottom of that old Box 14 about cheese often having added salt, maybe that should be stuck in some place. I'm not sure where. Maybe where we talk about sources of calcium in the adequacy guideline.

DR. KUMANYIKA: We might come to that when we talk about Box 21 because we're a little bit on — on the food groups in Box 21. So, I thought we could go to that. Okay.

So, this box is gone. I just want to make sure you didn't wake up in the middle of the night once and realized you lost Box 14.

Okay. The next box is Box 19, following these steps may prevent high blood pressure — they help prevent high blood pressure. This text is meant to agree with the current policy guidance on high blood pressure, which is — for which there's evidence and put sodium reduction in a broader context.

The essence of the text was in the other — in the prior version under other factors affect blood pressure. It's just been put in bullet form and then put in this box. It's on page 56 of the draft.

DR. GARZA: Any questions? Leslie and then Scott?

DR. TINKER: I have two small questions or comments. On the first bullet, keep a healthy weight, would it make more sense to use the terminology consistent with the weight management guideline, say, aim for a healthy weight?

DR. KUMANYIKA: Fine with me.

DR. TINKER: The second one was suggesting that we not use the exclamation mark at the end of the third bullet, if you drink, do so in moderation.

DR. KUMANYIKA: I noticed that. I don't know who put that in there. A non-drinker probably.

Other comments?

DR. GARZA: Scott and then Alice?

DR. GRUNDY: My comment was — are question's of more general one about talking about high blood pressure as a distinct entity. And, it's on page 55 where he said high salt intake is associated with high blood pressure and then on that table, on Number 19, too.

Wouldn't it be better to talk about levels — higher blood pressure and higher salt intake, rather than saying that this is about preventing high blood pressure as an entity? It seems like it's more of a public health approach would be to talk about — make it more of a continuous thing because it's almost as though if you don't have high blood pressure, you don't have anything to be concerned about. And, I'm not quite sure what the best strategy on that is, but I think it ought to be across the board recommendation like we talked about earlier.

There is one statement that says, "You can reduce your chances of developing high blood pressure by consuming less salt."

DR. KUMANYIKA: And we talked about that, that's going to probably be revised closer to the older version of that text. That's in the part we discussed before lunch. And, we're going to talk about that because the other text was before general talking about the risk in populations or something so that —

DR. GRUNDY: Right. But, then it goes on to this Box 19. It's the same concept that these are way to prevent high blood pressure. You know, there's two kinds of people, those that have normal blood pressure, so-called normal blood pressure and those that have high blood pressure and are getting medication for it. So, there's not really much in between. And, I'm just wondering if the concept that it lowers your blood pressure with sodium control as part of an overall strategy or keeping blood pressure lower, rather than making it categorical like it's in Box 19 and in the other places.

That's a general question.

DR. GARZA: Johanna?

DR. DWYER: Maybe Shiriki, because I've got it right in front of me, maybe — would it meet your concerns, Scott, if we said — if the box was entitled something like, "These steps may keep blood pressure healthy?"

DR. GRUNDY: Something like that, yes. Something more like that, yes.

DR. DWYER: And, then say, "Salt intake, weight and other dietary factors affect whether blood pressure becomes or stays — affects blood pressure."

DR. GRUNDY: To go to the idea of a more continuous rather than categorical, that's my point.

DR. KUMANYIKA: I think that wording — I was thinking about wording — if that would work. There probably is a lot of consumer recognition, and a lot of effort has gone into consumer recognition of the term high blood pressure, and even though everybody knows that it's a continuum.

So, I just wonder what the rationale would say because actually it becomes a broader recommendation for policy. It's actually saying that there's been too much emphasis on the cut-off. And, I'm not sure how the NHLBI will view that ultimately. Because there seems to have been an effort to get people to recognize it even though it's a continuum. There's a number that says you should think about it differently. So —

DR. GRUNDY: I guess my point is this. What's happening in the blood pressure field as I see it is that you either have normal or high blood pressure. And, if you have high blood pressure, you get medication to treat it. I mean, that's the paradigm that we're living under now.

And, the dietary approach to it is then put over in a tiny little box and it's not very important. And, even — you know, even the JNC people don't — they may give lip service to that. They don't pay much attention to it. It's, which drugs do you use? And, what I'm trying to do is suggest a way to reassert the dietary approach to controlling blood pressure.

DR. KUMANYIKA: Okay. I think I get it — I get it now. So, one of the points of the rationale, that it would avoid having people automatically kick in a pharmacologically treated condition

when they see that term since we haven't been able to overcome the perception of it as only a drug-treated condition.

DR. GARZA: Johanna?

DR. DWYER: Well, it seems to me that if we position it as like we did aiming for a health weight, we're emphasizing the health promotion aspect.

DR. GRUNDY: Right.

DR. DWYER: So, we're talking about things that keep blood pressure or can help keep blood pressure in healthy range just like physical activity and moderation in diet keep weight in a healthy range. So, it's a little tweek, but it's —

DR. GARZA: Meir and then Richard?

DR. STAMPFER: Maybe we can just for Box 19 use the heading that was used last time around, "Other Factors Affect Blood Pressure."

DR. GRUNDY: Something like that, yes.

DR. GARZA: Richard?

DR. DECKELBAUM: I just — I think, you know, in our aim for cutting across guidelines, it would be useful in Box 19 to mention when — keep the healthy weight and the physical activity, to say that both of these also affect other risk factors for cardiovascular disease and perhaps other chronic diseases as well, just as another positive point for inclusion in this — you know, in the guidelines as overall.

DR. GARZA: The only other point that I would raise, and we'll go to Alice, if you change the heading to something that's similar to what Meir suggested, then I think the list you have is fine. If we leave something that is more general, then we have to add lower your sodium intake or something, because it's — when you read the heading, when we emphasize the health promotion aspects, you're sort of struck by the fact that sodium isn't there. And, that's the whole —

DR. KUMANYIKA: Right. And, it is omitted because it was in Other.

DR. GARZA: And, then you can say, "See Box 20 for specific guidelines," but including it in the — in that box, it'll stand alone may be important.

DR. LICHTENSTEIN: So, is it going to stand like this and have the sodium included? Because I was going to say if we go to the other title, I would just suggest say, "Factors other than salt that might affect," so that we don't lose it.

And, then I have one small point, but I think it's sort of a residual of the last addition where everywhere you're saying low fat, low fat, low fat. Just to me it seems to be — complicate things about the fresh fruits and vegetables. Yes, they're low in sodium. They're low in fat. They're low in calories. They're low in a lot of things, but I don't see why the fat is in there, specifically there and not in other places. So I would just say sodium because that's what the focus is here.

DR. GARZA: Yes. Okay. Let's move on then to Box 20?

DR. KUMANYIKA: That statement, by the way, do we need a reason to take out stuff from before because that sentence is verbatim from the prior guideline?

DR. GARZA: We can say that it's for clarity.

DR. KUMANYIKA: Well, I guess the issue is that people have felt so strongly that weight control has to be almost as prominently featured in the sodium guideline as sodium.

DR. GARZA: She's referring to fat, saying the best way to lower fat. But, that may not —

DR. KUMANYIKA: But, that's the only reason you would say they help with weight control. That's what I mean. So, I just want to make sure.

DR. WEINSIER: The low energy density displaces other higher energy foods, so you don't have to highlight fat.

DR. KUMANYIKA: Then what I want is rewording — okay. So, you're saying that they may help with weight control without saying why. That's going to be misleading because lowering sodium and help with weight control, some people think that their weight is because they're holding water, instead of fat.

DR. GARZA: The concern, Shiriki, is that we're not trying — we've changed the fat guideline to

moderate. And so, it's not just fat that's of concern, but low calories. And so, you can say just lower in calories. High energy density would be difficult for most consumers to —

DR. WEINSIER: I'm not saying we introduce that. What if we simplify it and say that fruits and vegetables are helpful for blood pressure and weight control, and not even go into the sodium, because fruits and vegetables may affect blood pressure in ways other than just the low sodium content. The high potassium being one example, but there may be other factors.

DR. KUMANYIKA: Well, that's — we just mentioned that.

Well, okay, so, I don't want to go by this so fast that I don't know what people want. One possibility that's been suggested is to change the word "fat" to calories. That would be the simplest change.

DR. GARZA: I think that's the one that's favored as I look around the room.

DR. KUMANYIKA: Okay.

DR. GARZA: I'm getting a feel for this group. Listen, I'm into mind reading these days, Scott.

DR. KUMANYIKA: Okay. I like that, one word.

Okay. And, for the title, we have several options for the title.

Should we vote on the options for the title of this box, or should we suggest that subcommittee suggest something and then we come back the next round?

DR. GARZA: I think that the subcommittee can make — I think you've got choices as to what to do with the box depending on what title you select, so that's fine.

DR. KUMANYIKA: Okay. Shall we go to Box 20? Can my sodium intake be too low?

We had at one point thought that we could actually find enough data to put a lower limit to keep people from overdoing it because of some of the safety concerns, but we didn't — I think the solution to that was to talk about requirements and contrast to daily value without ever saying what a lower limit of every day intake should be.

So, the first bullet in there, that is not a concern for healthy people. And, if you have a chronic health problem, ask your doctor if reducing your sodium intake might cause problems. Probably should say salt there.

So, comments on that one? This is —

DR. GARZA: We'll start here and then just go around. Roland?

DR. WEINSIER: Yes. I didn't know what the second bullet, how that matched with low sodium intake?

DR. KUMANYIKA: The first bullet — we're on the first bullet. The second bullet, that's much more difficult to discuss.

DR. WEINSIER: Yes, but — I mean, does it belong in this box?

DR. KUMANYIKA: That's why we're going to discuss it that we should move it. Let's talk about the first bullet.

DR. WEINSIER: Oh, you want to stick — I'm sorry.

DR. GARZA: What you might consider, look at the title. It may be pre-empted discussions — if we say, "Is lowering my salt intake safe or something?" And then, you could put iodine and everything else in there.

DR. KUMANYIKA: Okay.

DR. GARZA: So, with that possible change, let's look at the first bullet and then go bullet by bullet.

Leslie?

DR. TINKER: Did the subgroup look into the literature about people that were hypotensive normally, have low blood pressures under normal circumstances? Those are the folks that clinically I hear ask about "Well, can I get too little salt? Will my blood pressure go to low?"

DR. KUMANYIKA: I would say that people — that fits just a definition of having a chronic

health problem, right. There are several people — several health problems that — you know, if you have something wrong with you that your body isn't functioning the way it normally should, then you shouldn't be following a general dietary guideline. You should be asking your health professional.

DR. GARZA: Scott?

DR. GRUNDY: But, I wonder if that's not too general. Everybody has a chronic health problem.

DR. GARZA: I think that tells us the age set that you're mixing with, Scott.

DR. GRUNDY: I'm just wondering if you could be more specific to help people there.

DR. KUMANYIKA: Have any of these guidelines actually mentioned conditions? Once you start with a list of conditions, it starts sounding like a clinical guideline. So —

DR. GRUNDY: I understand, but you might be a little — somehow more specific. I don't —

DR. DWYER: Well, could we say if you have hyper or hypotension? Those are the two things that are involved in blood pressure, aren't they?

DR. KUMANYIKA: Yes, but some of these guidelines they'll mention cystic fibrosis or some endocrine problems relate to sodium conservation. So it's not something that would be friendly in this booklet. I'm trying to think of how to do it.

DR. GARZA: Scott, could you live with — if you're under the care — if you're being treated for a health condition?

DR. GRUNDY: That might be better, yes.

DR. KUMANYIKA: If you're being treated for a health problem. The other thing we're concerned was people on lithium, being managed on lithium, they shouldn't be monkeying around with their sodium intake and this wouldn't be helpful to —

DR. GARZA: What is it — rather than having those words — if you'll take that under advisement and see what we can do.

On this side? No questions on this side.

DR. LICHTENSTEIN: This is just point one, right?

DR. GARZA: This is just point one. All right. Point 2, we'll start with this side. And, you had a — there is an August 18th — I think it's the August 18. It says, "Dear Kathryn".

MS. MCMURRY: There are some questions raised by the subgroup about sodium intake in the population and iodine intake. And, FDA provided some information.

DR. GARZA: Can you summarize what they've sent you? We just got it. I don't know whether anybody — did you have a chance to see this?

DR. KUMANYIKA: Well, people got it yesterday, but they probably didn't read it.

DR. GARZA: No, it was passed out today.

DR. KUMANYIKA: Oh, the iodine was only —

MS. MCMURRY: Some people got it yesterday.

DR. KUMANYIKA: Okay, sorry. So, maybe only the subcommittee —

DR. GARZA: Did you have a chance to see —

DR. KUMANYIKA: I can — yes, I can summarize it.

Essentially, the issues for iodine were whether the — that it used to be too high, and so, therefore, it was not considered an issue of whether people would lose some iodine because they didn't use table salt. Then, measures were put into place to try to reduce the contamination of iodine in the food supply. And, those measures were successful, and CDC published some data showing that the certain proportion of people appeared to have lower iodine intake. And the data were tentative so that monitoring of iodine intake was recommended. And this document points out that the one measure would overestimate the people with a low intake and so forth.

However, this FDA comment also notices that because of the food safety concerns, some of these measures that put iodine back in the food supply are on the upswing again. And so, nobody has

any idea of what that will do to the iodine and the food supply.

It mentions the other sources of iodine, the fortification of a bread stabilizer and gives the impression that iodized salt is not necessary to meet iodine requirements. That there's no evidence that there's a problem now, that monitoring is taking place. And, that if anything, they'll go up. I mean, that's what I got out of reading this document.

So, it's actually a little bit different because of the food safety issues than it was the last time we talked about it, because we only knew about the monitoring. And now, we have evidence that it might actually increase again in the food supply for food safety reasons.

So the two issues of whether to say something about iodine and where to — well, three issues, whether, where and what to say. And, I think the Committee was convinced that we should say something.

The first suggestion that we had put in or that I had put in was to say that indeed, some salt contains iodine, but that there are other sources of iodine in the diet. And, this statement is one that Johanna felt that we should put in. If you use salt, use iodized salt.

But, now the way this is stated, it doesn't really address the safety concern. I think Johanna, as you put it, if I can dare to paraphrase you that if we didn't say it the right way, we would be undermining the public health measure that's involved in iodizing salt. And so, what we said, we had to be careful that we didn't imply it wasn't a good idea to have the iodine and the salt to begin with. So, that's my summary.

DR. GARZA: Okay. Any comments concerning — Alice, you had your hand up.

DR. LICHTENSTEIN: This was a modest comment that just we should point out that if we feel it's appropriate that when you buy salt, buy iodized salt. Just, it's an opportunity to indicate that you have a choice when you go to the supermarket and you should pick the iodized.

DR. GARZA: So you would recommend continuing with the statement? Where would you put it?

DR. LICHTENSTEIN: Purchase iodized salt for home use.

DR. GARZA: Could we put it under aim for a moderate sodium intake and put it into that text

and say, "When you buy salt, you know, buy iodized salt?"

DR. LICHTENSTEIN: Yes, just somewhere.

DR. GARZA: Johanna?

DR. DWYER: I think — I don't know if this is appropriate. Iodized salt is a reliable source of dietary iodine, but iodized salt is not used in most processed food.

We could put it there, Alice. Put when you buy salt, buy iodized salt. If you use salt, use iodized salt.

But, do you think it's a good idea to put in something about multi-vitamins, some of the FDA statements that many multi-vitamins contain iodine? People who are on a salt-restricted diet should consult your healthcare professionals for ways of obtaining adequate from other sources.

And, I don't know if you want to put in anything about — I guess maybe that would be helpful. I don't think it fits there, though.

DR. GARZA: Should we put it in the first one? In the first guideline where we deal with other supplements or —

DR. KUMANYIKA: I guess — I'm worried because I've talked to a lot of consumers about salt issues. And, if they actually think that this is something they need to prevent a deficiency, they will interpret this in a different way than the way we mean it.

So, I think we should get clear on whether we think consumers need advice about getting enough iodine or whether we should leave it to the natural course of things. Because anything we say that you need salt for iodine, I think can be interpreted that people have to make sure they use a certain amount of this to get their iodine requirement. And, the FDA update doesn't indicate that that's the case. And so, I think we're going beyond where the situation is right now to say that. That's what worries me.

DR. GARZA: Well, should we just flag it is a research issue that needs to be followed?

DR. DWYER: Flag what?

DR. GARZA: The iodine.

DR. DWYER: — about iodized salt?

DR. GARZA: That we don't know what intake is at the present time because the data are old and their fluctuations in the food supply in terms of sources of iodine.

DR. DWYER: Well, I have a problem with that. I know that Lou Braveman, in University of Massachusetts, has like 5,000 iodine urine samples. So, I'm not sure that that's true. I don't think that this issue is going to go away, but I may be the only person on the Committee who thinks that.

DR. GARZA: I'm just responding to this, not from any personal knowledge. I mean, that's what this seems to be saying.

DR. DWYER: Yes. I think consumers are going to need to know something because the New England Journal's feature article two or three weeks ago was on this and pregnancy. And, it's not necessary — it's not an alarm. I think that actually the Salt Institute letter is quite good. It says, it's not a big alarm issue, you know, just mention it in passing.

DR. GARZA: Where would you mention it then?

DR. DWYER: I think down below in the salt guideline, but I'm willing to do whatever the committee thinks is appropriate.

DR. GARZA: Under aim for a moderate sodium intake? Is that the paragraph you would fit it into?

DR. DWYER: Yes.

DR. GARZA: Or in decrease — that would be it, yes.

DR. KUMANYIKA: The only other place I thought you could move it to, which is what I had made a note of, is in the Box 21, there's now these settings oriented, sets of advice about how to decrease the salt content of your diet. And, there's one that says, "If you salt foods and cooking at the table, add small amounts." And so, my question was, is that a place to say something about iodized salt?

DR. GARZA: Meir?

DR. STAMPFER: I don't think we can go halfway. I think if we mention it, we're raising it as a potential problem. And, I think a natural interpretation is that people need to get iodized salt to get iodine.

So, if we're going to raise it as an issue, I think we have to add a couple words about other places, eat and get iodine. You don't have to add iodized salt to your food to get iodine.

I think either we should just drop it or say enough for the consumer to not go to the solution of adding iodized salt to solve their iodine problem.

DR. GARZA: Would you think it would be more appropriate to put it in the first guideline when we discuss other sources of micronutrients?

DR. STAMPFER: If we have it in there, I think that's a natural place for it.

DR. GARZA: That would be a natural place?

DR. STAMPFER: Yes.

DR. KUMANYIKA: Under adequacy.

DR. GARZA: Under adequacy. Johanna?

DR. DWYER: I think to rely on environmental contaminants and unintentional food additives is the way to get iodine, doesn't make much sense. I mean in other words —

DR. GARZA: That's not what we're saying. We can give advice under that adequacy guideline.

DR. DWYER: I think that's good advice for Boston, but I'm not sure it's going to fly in Dubuque, Iowa.

DR. STAMPFER: Well then, we need to give advice that will fly and it's not just iodized salt.

DR. DWYER: I agree. Vitamins are one —

DR. GARZA: Johanna, I think that the — what I'm hearing is, yes, we should mention it. The issue is now where? Do we put it here or in the adequacy guidelines?

So let me turn to Suzanne and see what she thinks, and then we'll come back and see if we can get a consensus on that.

DR. MURPHY: Well, first of all, before I talk about where it goes, I want to say something about what we say. Although NHANES-III found what? Eleven and a half percent of the people had low urinary iodines, notice they found 5.3 percent had high. And, I'm a little worried about a blanket recommendation to always without exception, which this seems to be saying, use iodized salt. Because I don't think we know what it will do to the distribution if people took us literally.

So, I guess since I don't necessarily want to tell everybody to use iodized salt, where you don't say that is irrelevant.

DR. GARZA: So, you're concerned with that five percent? I think the concern that I see is that the toxicity problems are much less worrisome than the problems of deficiency. And those are real —

DR. MURPHY: Could we compromise and say something about during pregnancy? I mean, I agree that it's a problem during pregnancy.

DR. GARZA: Well — I'll let others speak too. Richard?

DR. DECKELBAUM: We may recall at our first meeting when we had various introductions, it was mentioned that these guidelines that were going to produce, also get published and used internationally. And, I think it's important to remember that internationally, iodine deficiency remains a major problem. And, to give the naysayers in other areas of the world another tool for objecting to fortification of salt with iodine, I think would be a misstep.

I know we have an obligation to the American or North American population, but what comes out of here is also going to be picked up by naysayers elsewhere, and I'm concerned about that, to just drop it.

DR. GARZA: Other points of view? Johanna?

DR. DWYER: Suzanne, who do you think should use iodized salt, and who should not? And,

how are we to tell consumers who is who?

DR. MURPHY: I think it's a good idea to use iodized salt, but I don't think it has to be — every package of salt you buy doesn't have to necessarily be iodized. And, I think there are consumers that sometimes do it one way, and sometimes do it another.

I don't have a problem with saying — certainly, it's true. Iodized salt is a reliable source of dietary iodine. But, if I'm taking a supplement of iodine, I don't have to buy iodized salt.

DR. GARZA: Would you condition that if we put it in the adequacy guideline that if you're not taking a supplement, then limiting your salt intake —

DR. DWYER: So, did you agree that we should add something like, "Many multi-vitamins contain iodine?"

DR. MURPHY: Yes.

DR. DWYER: And then, you also wanted to add that some — that kelp is also a source of iodine?

DR. MURPHY: I don't know that that's a big concern. I'm worried about saying you have to always use it.

DR. GARZA: Assuming that we meet some of those concerns, where would we put it?

DR. DWYER: Why not "adequacy"?

DR. MURPHY: I think it could go there, sure.

DR. GARZA: Okay. Next? How is that for taking consensus?

DR. KUMANYIKA: Well, that's fine. I got some ideas about ways we might phrase some things from listening so we'll see. Some of my point is that we think it's important to address the issue in this guideline, and it's got to be in there somewhere. Okay.

DR. GARZA: And, adequacy seems to be the —

DR. KUMANYIKA: Okay. The next bullet is about sweat. And, we've had a couple of versions

and some things, I've consulted a couple of sports nutrition textbooks myself, and they weren't particularly enlightening as to what we should tell the average consumer.

So, does this — how does this work as it's phrased now?

DR. STAMPFER: I had trouble understanding what this means, "so make changes gradually." I mean, I'm going to go out for a run on a sunny day. Should I start off walking and then gradually pick up speed? Is that what that means? Or — honestly, I don't know what that meant, "make changes gradually."

DR. KUMANYIKA: What about the text that —

DR. STAMPFER: — gradually? I don't know. Maybe that's what I — I didn't know.

DR. LICHTENSTEIN: I agree. I have no idea what that —

DR. KUMANYIKA: What about the text that's in strikeout as it was before? Is that any better?

DR. STAMPFER: Well, I think the, you know — I think a reader who's worried about that somebody who exercises a lot in a hot climate wants to know whether that person should be having, you know, eating more salt. Does that 2,400 — is that still a good target for a person who sweats a lot? And, I don't think that answers that.

DR. GARZA: If we see sudden changes, this doesn't include individuals that do that habitually. It's sudden changes in exercise pattern. And, if you add — where is it? So, make changes in your salt intake gradually.

Would that take care of it? Is that what the intent was?

DR. KUMANYIKA: Okay, so you're — what I'm actually hearing is that there needs to be something that says people who are doing things habitually don't need to worry. This is fine. Sudden changes — something like to put it in context because you didn't — the sudden came out of nowhere. Is that —

DR. LICHTENSTEIN: I actually thought it might have to do with the weather, that if it's — you know, if it suddenly became hot or something and you were sweating more while you were running. That's how I interpreted it.

DR. KUMANYIKA: People who are conditioned are putting on a very dilute —

DR. LICHTENSTEIN: Your reasoning is a little well-grounded.

DR. KUMANYIKA: And, people who really are into athletics won't be listening to us anyway. They're taking other advice.

So, these are things people have in the the back of their mind, do they need to take salt pills? And we're trying to address that.

DR. STAMPFER: And a lot of those repletion solutions have sodium in it like Gatorade. Is that a good thing for people to do who sweat a lot? I don't know. But, I think we should have that — I think there are enough people like that that we should have some kind of guidance.

DR. DECKELBAUM: Is there a science base on this?

DR. GARZA: Yes.

DR. KUMANYIKA: When we looked for it, Johanna circulated something, and I looked in a couple of books. And, they talk a lot about hydration, much more important than taking a salt tablet. And, that's what drives the rest of it.

DR. GARZA: At least if we go to military reports in terms of salt use, and Johanna, help me. I mean, most of that is if you're taking very — the military committee has I thought looked at this issue several years ago that if you're into the ranger-type activities and trained for life in the Sahara, it might be in those exceptional circumstances, salt is needed. But, if you're a habitual runner and you have a day that goes into 80 or 90 degrees, that generally you've already adapted to low-loss — low sodium losses in sweat.

Now, if, in fact, you've moved to the Sahara, and they're going to be there permanently, then likely there you might want a salt — to gradually change your salt intake. I mean, that's the way I — that's what I read in the literature, but I don't know whether — I'm certainly not an expert, I mean.

Roland?

DR. WEINSIER: I haven't reviewed it recently either, but that's my understanding that these

— this is more of an exception rather than a rule.

DR. KUMANYIKA: Right.

DR. WEINSIER: And, I wonder, unless there's new data that other people know about, if the comment shouldn't be to the effect that other — then, in exceptional circumstances of you know, sudden increases in physical activity, most people do not need to take salt supplements for exercise and sweat, or something to that effect, which comes back to the point that generally you do not have to. Not a blanket statement, do not, but generally do not have to.

DR. GARZA: The danger is that by increasing your salt intake, you also increase your water requirement.

DR. KUMANYIKA: Right.

DR. GARZA: And so, because you get into problems and hydration much more quickly than you do with salt depletion that you then exaggerate your need for water with the added salt.

DR. WEINSIER: Yeah, but presumably, I think the problem —

DR. GARZA: You take it in appropriate circumstances, there's a risk in making a recommendation. There's a whole literature going back to Conzolazio in the '50s in Colorado that looked at this. And so, it's just a matter of passing whatever language we use by one or two individuals who we might know this area very well and make sure that we're on solid ground.

Okay? The next one?

DR. KUMANYIKA: Okay. So, that does it for the box safety. And, the last one, before the advice for the day is "Decrease the salt content of your diet".

The changes in this section, first, the title of the box is changed. It used to say, "To consume less salt and sodium." And actually, I don't remember where we got this new title from. I don't remember if I did it or it came up on a conference call, whatever. But, this is much more behaviorally directive. In fact, I was a little surprised when I saw it because it seemed strong than the Committee had been willing to do before.

Do we have other ones like that? Like, in fact, decrease the fat content? I just want to make

sure if somebody's going to react to it, that they do it now so we don't go forward and then find out in fact, you didn't like it.

DR. GARZA: Well, we did talk about the desire to be rooted in fact, for the document to be more directive. That's in keeping with that, but I honestly don't remember if the same term "imperative" appears in other boxes.

Johanna and then —

DR. DWYER: It seems to me it's hard to — you know, it all blurs in your mind. But, it seems in some cases we're using a lot of subjunctives, and you might, could, ought and so forth. And then, in other places, we're telling them what to do. And, if they don't it, they'll be put into the nutritional jail.

And, I think we need to be consistent, and I hope Carol, we can get something from the editing. But, I know the guidelines are not equal in terms of the degree to which we're being directive.

DR. GARZA: The guidelines or the boxes?

DR. DWYER: The guidelines and the boxes. I don't think we — I think we need to be very careful on that or we're implying that some guidelines are not very important like this fat guideline, whereas, others are very important and we're more direct.

DR. GARZA: Meir?

DR. STAMPFER: Yeah, I think it would be better not to be as directive since there's a limit or there's a daily value target, and some people are meeting that. So, why not have something like what was in the guidelines. To consume less salt in your diet.

DR. KUMANYIKA: Or, you could put your — half your decrease, which is much softer than decrease.

DR. GARZA: Ways to decrease.

DR. KUMANYIKA: Ways to decrease, right.

DR. GARZA: Okay. We go with ways. What about the content?

DR. KUMANYIKA: In the text — okay. So, the changes — which by comparison to the older box that was there, which used to be Box 15, is organized now by eating occasion, in spite of some of the interest in making it clearer to consumers because we — I mean, I find in general, the guidelines tend to scramble a lot of advice into a very nicely-reading narrative, but it's hard to go back and find the advice you want when you see it. So, I'm all for this kind of changes, grouping it by different eating occasions. So, it's at the store, at home, eating out, any time.

Guidance for eating out is expanded. Specific amount of salt and foods labeled low-sodium. This came up on a conference call of the subcommittee that we had to define it somewhere. And, because the food-labelling law is so complicated, the one that was chosen, which I agree with, is the one that's actually fairly straightforward. That if a food says it's low sodium, then it's supposed to have 140 milligrams or less.

And, then we added here the advice to consume water. There was a question about a prior statement we had about water is — whether water was low in sodium, which is other beverages. We have given to some of you a printout from the nutrient data system showing that most waters, I think, average around 50 milligrams per cup. But, what the statement says is that it's usually low in sodium. And, the point of it, I think, is the chance to advise people that water is a good beverage to use.

So, those are the changes. The stuff that's underlined here are questions that I had for the Committee about things that might need to be done to this box.

DR. GARZA: Rachel?

DR. JOHNSON: I just had a couple of points under the cooking and eating at home. We talk about learning to use spices and herbs, and then I know we haven't gotten to it yet, but under advice for today just for consistency, to use spices, herbs and fruits to flavor. I mean, I'm not really sure how we use fruits to flavor food. Maybe it's just the way that I cook.

MS. LYON: Juices?

DR. JOHNSON: Juices, marinades? Lemon? Okay. That's fine.

And then, under water, I would just add because I think we mention water a couple of other places, and we talked a lot about encouraging the use of water as a beverage in terms of an energy balance issue. So, maybe we could just add that it's usually very low in sodium and low in

calories.

DR. GARZA: That's a tough influence. That's why we brought water.

DR. JOHNSON: What?

DR. GARZA: It's a tough influence.

(Laughter)

DR. KUMANYIKA: Well, it's definitely usually low in calories, but — although some of those flavored waters are not.

DR. JOHNSON: Right. No, honestly, because there are a lot of bottled things now that look like water. And, when you look at the food label, they're not.

DR. DWYER: Vodka.

(Laughter)

DR. GARZA: Johanna?

DR. DWYER: Just a question of formatting. If we're going to have a ways to decrease the salt in your diet in five sort-of places, then it seems to me we need to be consistent throughout the guidelines and to have the same thing under fat and under weight and under food safety. It seems to me we need a decision on that.

DR. GARZA: But, before we do go on, I want to make sure that we don't — just a critique. Rachel made a very important point. And, that is, at least — I'm familiar with European data — but bottled water, in fact, can be very high in sodium. And, there were advisories going out, because it was being used in children's diets quite a bit. And so, they were increasing their water requirement because of the high salt content of bottled water.

And so, I'm not familiar with American data, whether we've done the same analysis.

DR. DWYER: What about water softeners?

DR. GARZA: Is that an issue, or do we not need to worry about it because —

DR. KUMANYIKA: We can say read the labels. In some bottled water, I see labels that say it's zero on everything. I've seen European waters that are very high in calcium and so forth. If we could add, read the label on bottled water.

DR. GARZA: I think that may be preferable than what we have. I sort of got detracted by the tough contingent.

DR. LICHTENSTEIN: I'm wondering if for advice at home, say don't automatically put the salt shaker on the table. You know, if it's not there, people may get at it, for households that are in the habit of automatically salting, maybe that's one approach. Simple, cheap.

DR. GARZA: Any concerns about that? No? Okay. Then, can we move to advice for the day? Or, today, rather?

DR. TINKER: As I'm looking at Box 21, the header, "Decrease the salt content in your diet", and then the first thing is choosing the vegetables except for — because they're low in sodium. And, I know that in the guideline explain the sodium and the salt relationship, but I wonder if it needs to be explained early on very clearly. Because the first sentence — if you back to the very beginning, it says, "Salt, sodium chloride is the main source of sodium in our foods." But, if I'm not a consumer and I'm not sure what's going on, I have to go farther till I really get the aha, sodium and the blood pressure.

And, then I go to the Box 21 that's talking about decrease the salt, and there's an interchange of salt and sodium —

DR. KUMANYIKA: Without explaining.

DR. TINKER: And I understand why, but I don't know if it's clear enough to a consumer about how we're using these somewhat interchangeably.

DR. KUMANYIKA: Yeah, we had talked about possibly putting a label to show a relationship. We've haven't figured out how to do it. I have a list of unresolved issues and how to deal with that labeling issue is one of them. I don't think that's been done here, and it's going to be very confusing unless we figure out a way to approach it.

DR. GARZA: Okay. Roland?

DR. WEINSIER: I know you discussed the text section called "Aim for Moderate Sodium Intake" earlier, but I'm just having trouble recognizing the "aim for moderate sodium intake" and "decrease the salt content of your diet".

DR. GARZA: We've changed that.

DR. WEINSIER: So, the other one is — I thought moderate was still in there.

DR. GARZA: We're going to aim that the title for that box we've changed —

DR. KUMANYIKA: To ways to decrease.

DR. WEINSIER: Yeah, I know. I was getting at one way to decrease, and the other is aim for a moderate. And, they seem like they're going opposite directions to me. Even under that paragraph, it says, "Moderate your sodium intake. Sodium has an important role in your body". I get the feeling it's being encouraged as an important nutrient, and yet, you turn to the next page, it says, "Ways to decrease."

Am I the only one that's seeing that —

DR. KUMANYIKA: It says later that most people consume much more. And so, maybe under the aim — that sentence has to go up higher. It use to be the title actually, that most people consume more sodium than they need. On page 57, it's buried in that paragraph that, the direction of moderation is lowering.

DR. WEINSIER: Yeah.

DR. KUMANYIKA: Does that help?

DR. WEINSIER: Well, maybe moving it up, that would certainly help.

DR. GARZA: Most people consume too much and you moderate to go down.

DR. WEINSIER: Yeah, that would help.

DR. GARZA: Any other points? If not —

DR. KUMANYIKA: It's only 1:40.

DR. GARZA: We're at 7:30, folks, for a day.

DR. LICHTENSTEIN: Under advice for today, perhaps — assuming that there are a few people that still cook, just practical advice saying, "If you're" — you know, "when you cook especially when using older recipes, start with half the salt and adjust if necessary?"

DR. KUMANYIKA: It says that in cooking, doesn't it? Well, it says something about cut it in half.

DR. GARZA: Let me make a suggestion because we are not going to get through this. The recommendation of this type are important, but are ways to express things that we've agreed to that send those suggestions onto the chair and make it incorporate in boxes because they really don't require a group-wide discussion. Otherwise, it's going to be rough. And, I don't want those guidelines that we take later on today to be shortchanged because we take the ones early in the day and feel like we've got lots of time.

DR. KUMANYIKA: Okay.

DR. STAMPFER: Just to help speed things along in that line, maybe you can just take a minute or two to tell us your vision of how things are going to go, so we'll know what level of detail we should bring up here versus what we should save for e-mails for later.

DR. GARZA: I think that if, in fact, there are issues that you feel don't relate to things that we've agreed to, that it's very important to raise those. The reason I use this one, I thought it was a good example, it's how do we — what's another way to decrease your salt intake? It isn't whether, in fact, that ought to be in a box. It's ways to decrease the salt intake. And, that's — that's a distinction I would make that perhaps it's clear to me, but not to anybody else.

DR. KUMANYIKA: Okay. I think that's —

DR. GARZA: Advice for the day then.

DR. KUMANYIKA: I think that's a good distinction. Let me just mention about this underlying

text that it does deal with standardization of the content, because we mention only certain food groups. We don't mention others. And, at some point maybe in the refinement stage, we have to decide whether we're going to be uniform. So, I'll keep that flagged until we get to that.

Okay. The advice for the day is unchanged, and it's in nature of — it mentions weight control because I couldn't talk Johanna out of mentioning weight control there. But, it's underlined to say that it's been suggested and maybe not agreed to.

I think the issue there for trying to control your weight is that because it's a sodium guideline and not a blood pressure guideline, do we need to mention blood pressure control throughout, or should we just mention it in one place? So, you know, we can open that up for discussion. I think that's the only potentially debatable point here. This is where the cut-in-half actually shows up. It mentions restaurant foods. It's editorial. least I think it is editorial, you can read other things into it.

DR. GARZA: Okay. Johanna, do you want to defend yourself?

DR. DWYER: Yeah. I think it is a blood pressure guideline, and that the most effective way to reduce blood pressure under our control without, you know, a doctor's intervention, is weight control. And then, these other things are also important.

DR. GARZA: Okay. Is there a strong feeling for its including or omission? Suzanne?

DR. MURPHY: Well, I'd like to argue for its omission because it seems so jarring to end the whole text on salt with, "Oh, and before I forget, try to control your weight." I mean, we don't say anything about alcohol. We don't say anything about alcohol here and that's also another —

DR. DECKELBAUM: Is there a Bloody Mary mentioned?

DR. GARZA: Okay, Richard. Can you repeat that?

DR. DECKELBAUM: Is there a Bloody Mary mentioned? I mean, that's very high in salt.

DR. MURPHY: I don't think it's unimportant, but it seems like the wrong place for it.

DR. DECKELBAUM: Or, it should be put in the middle.

DR. GARZA: All right. So, you would recommend its placement within the paragraph?

DR. MURPHY: I'd leave it out, but if it stays, I'd like it to be somewhere else.

DR. GARZA: Okay. Do other people have strong feelings regarding its omission or inclusion? Richard?

DR. DECKELBAUM: It shouldn't be at the end of advice for today.

DR. GARZA: But, we can say omission or inclusion and then we can let Johanna and Shiriki decide where they put it because they've heard the objections to the jarriness (sic).

Meir?

DR. STAMPFER: I would vote for omission because the whole thrust of advice for today is what you should do to lower your salt. And, weight control is part of that.

DR. GARZA: Well, we heard, the more you eat, the more you're salt.

DR. WEINSIER: As important as I think it is, I think it should be omitted here unless there's considerable re-writing and greater emphasis on the blood pressure relationship to sodium and other factors. And, I think that's not appropriate for advice for the day. So, under the circumstances, I think we have to omit it.

DR. GARZA: Okay. There seems to be a sentiment towards its omission as opposed to its inclusion. Does anybody want to object to that? Well, we know you do, Johanna.

DR. DWYER: I'm changing my objection that it should also include alcohol (laughter), and the whole of that paragraph where it says, "Choose fresh fruits and vegetables" should go down to the bottom. And, then that sandwich in the middle would have weight and alcohol in it.

DR. GARZA: Okay. Is there a sentiment? Does that change anybody's sentiment as to its omission that we include alcohol and therefore, should also include weight? Or, would you just omit the alcohol and weight?

DR. DECKELBAUM: Seconded.

DR. GARZA: Okay. Sorry, Johanna.

DR. KUMANYIKA: Okay. To wrap up — this was my checklist of unresolved issues that I actually think we covered with the exception of pregnancy and whether do a comment that sodium restriction is no longer advised for pregnant women needs to in there somewhere.

And, I don't know if we need to resolve it now, but I'm sensitive to the things that people have in their heads that they may still — some of them still may have that. And, that was the thing — there's literature on that. We could try to figure out how to say it if — whether we should add that to the safety box. And, if you don't want to vote on it now, then we'll put a draft statement in there that could be taken out the next time. But, I don't want to forget that because some OB-GYN's are probably still telling pregnant women to restrict their salt intake.

DR. GARZA: Johanna, you look puzzled.

DR. DWYER: I think most of those obstetricians are dead.

DR. KUMANYIKA: You think so? (Laughter.) Okay. So, it may not be necessary to put it in. We'll discuss that in the subcommittee.

Future research issues, these were the ones that I came up. They are not — they have not been discussed by the subcommittee, but I thought we should — the Chair asked us to mention these topics. So, I took the topics that we had come up with and the discussions that we couldn't really resolve and mention them as possible future research issues.

The other one that is unresolved that could get here is the food-labelling issue of whether people can actually understand the difference well enough to have sodium on the food labels if we're going to give guidance in terms of salt.

We still don't know — have a good handle on actual intake. We have to track food supply changes. Iodine needs to be discussed. The actual link of sodium intake to osteoporosis as an end point is not well described, although some bone metabolism issues are described, but not the end point.

Asthma is something that — it's interesting to it's interesting to me, but probably — it's not on the same level as gastric cancer in terms of the etiological, but the amount of literature is very scant, and it's not enough — it's considered by the subcommittee not enough to support a

recommendation. But, it definitely has some theme. And, I think that research on that topic should be encouraged because asthma is on the rise. It was just discussed in the press the last couple of days that asthma's rising, and people can't seem to get a handle on it.

And, upper and lower limits for children or adults. I still think that's an area maybe the institute of medicine is already on top of this, but just to make sure that we eventually we can say something about what we think people should eat in a more specific way.

DR. GARZA: Are there any comments, additions? Johanna?

DR. DWYER: I'm not aware of what the putative mechanism is for asthma-salt connection. I mean, to me, that —

DR. KUMANYIKA: There have been vascular hyperreactivity for the people who look — I mean, there are different theories of what causes asthma, but when there's -it's a smooth muscle, sodium retention and hyperreactivity and the data are not bad. There's just not a lot of them. And, for some reason it's not pursued perhaps because of fashions in the asthma-etiology literature. But, I think it should — you see, there's good — some good etiological data . And, there's been some trials, published trials, Peter Birney and guys from England.

So, I just mentioned it for pursuit as a research issue. Also, as a trigger. As a chronic, but also as a trigger.

DR. GARZA: Any other issues that have been omitted that you would like to see included?

DR. DWYER: Pre-aclampsia.

DR. GARZA: The role of salt in pre-aclampsia?

DR. DWYER: Uh-huh.

DR. GARZA: Okay. Thank you very much, Shiriki.

DR. KUMANYIKA: Okay.

DR. GARZA: Then, we will move ahead then.

And, our 10:30 item is grain guidelines. And, let me — while Richard is going up there, I would prefer that we err on the side of mentioning too many things than too few, if you're in doubt because this will be the last time we'll have a general discussion on these. I didn't mean by my comment to stifle discussion.

(Pause.)

DR. GARZA: Okay. Dr. Deckelbaum?

DR. DECKELBAUM: Okay. Well, you will notice that my audio-visuals were somewhat primitive having just come from Alaska and having a total of about six hours in my office between Alaska and here. So, we did what we could.

And, I'm going to follow Bert's outline in presenting the sort of things that we supposedly have agreed upon first. Then, go on to issues and concerns that have been raised. And then finally, turn to directions for research.

And, it's actually quite interesting. When I looked at our notes from the first meeting re: issues that we brought up in terms of modulating for this Committee, most of them actually happened. And, I believe we have a good science base for them. So, if we look at the different areas where there's been substantive changes and so-called — general agreement, we can look at separation, choosing of the name of the guideline, benefits of whole grain, some issues or points relating to grains and then at the bottom, there's advice for today. And, I'll go through each of these individually now.

So it was actually Alice that pushed forward strongly with separating the grains guideline to make grains, fruits and vegetables into two guidelines, grains and fruits and vegetables. And, I think that not only she but the science base certainly justifies that in a very strong way.

If we look at the intake of grains as a whole group, the intake in terms of number of servings and following the pyramid are actually better than fruits and vegetables. Fruit intake is especially low, but in the grain category, the intake of whole grains is very low. Generally, lower than one serving per day per person.

So, that there's — with evidence that I'm going to be showing below later, that there is a need to beef up, not only fruits and vegetables, but certainly grains — whole grains in the grain category. There's also an ability to increase fiber intake by dividing the guidelines and giving

better implementation advice for different categories really of these foods.

A major reason that we'll discuss as we go along is that particularly in reference to whole grains, the science base has changed markedly, I would think, in the last five years. Perhaps, some of the other nutrients we've been discussing.

And finally, I think something that's quite important is that generally the public comments that we've received as well as the reports on the focus groups, I think, were unanimous. I think unanimous if I'm not mistaken in agreeing with this separation of grains from the fruit and vegetable guideline.

Can anyone point out where I may be wrong? I think it was pretty unanimous.

DR. LICHTENSTEIN: Unfortunately, it wasn't unanimous. There were a couple of comments in the Blue Book indicating that why add another guideline, but I'd say the majority.

DR. DECKELBAUM: But, they were referring to the other guidelines.

(Laughter)

DR. LICHTENSTEIN: Wishful thinking.

DR. DECKELBAUM: But anyways, there was an overwhelming majority in favor of this, I think that's fair to say. Alice will have to agree with me on every point here because we want to do this together.

As well — I mean, some of the organizations that provided comments like the American Diabetic Association were very positive about splitting them into separate guidelines. And, as well the public comments were generally I say — the majority, maybe not unanimous and maybe not an overwhelming majority, but the strong majority were in favor of emphasizing whole grains in the guideline itself.

And so, the second point here is the guideline as we're currently considering, which is choose a variety of grains daily, especially whole grains. So, we'll note now that in the grains guideline and the fruits and vegetables guideline, we maintain this word that we discussed a lot yesterday, variety.

And the rationale for that is actually given in the Green Book and in the text itself, is that the nutrient content of different fruits and vegetables and the nutrient content of different grains have varied markedly. And Alyson Escobar provided us with data early in the summer, giving specific examples. And those are listed in the Green Book text of how different whole grains — and of course, depending on fortification or enrichment of fine grains, you can have marked differences in nutrient content. So, that the word "variety" seems very well justified.

What about especially whole grains? And, at our last meeting, we had a discussion of whether it should be especially or including whole grains. And, we actually voted upon that. And, I don't remember what the number was in the vote, but the vast majority came out favoring "especially", rather than "including whole grains". Again, that could be subject for discussion later on.

What I'd like to do now is actually turn to the evidence and science base of why we need to emphasize more whole grains in the guideline. So, are there any questions up to this point? Good.

DR. DWYER: I have one. What is a whole grain? Is it defined by FDA as 51 percent grain?

DR. DECKELBAUM: Well, you asked that in your comments, and that's actually something I was going to ask a little later because there are different definitions, both within the scientific literature that studies whole grain, what makes up a whole grain and what the FDA may classify it as.

DR. GARZA: And, it wasn't 51 percent as a I recall.

MS. MCMURRY: No. There's no specific definition, but it needs to be the characterizing ingredient of the product.

DR. DECKELBAUM: Sorry?

MS. MCMURRY: It needs to be the characterizing — a characterizing ingredient of the product. There's no specific content regulation.

DR. DWYER: What does that mean?

MS. MCMURRY: There's no specific percentage of ingredient that's required.

DR. DECKELBAUM: Well, I actually looked up that in the articles that I was reviewing to see if I could find an answer. Generally, the articles, at least when they refer to cereals, call the cereal a whole-grain cereal if it was greater than 25 percent whole grain, unrefined grain. But, that's actually something that could be considered. We need perhaps a better definition if we're going to be emphasizing it more strongly.

DR. GARZA: Let me ask, Carol. In the pyramid, when we look at grains and whole grains, is the distinction made between what was considered a whole grain versus —

MS. DAVIS: Yes.

DR. GARZA: So, what definition of whole grains did you use in the calculation?

MS. DAVIS: (Inaudible).

DR. GARZA: If it was 25 percent or the whole grain or serving.

(Multiple speakers.)

DR. GARZA: So, if a product has whole oats at any percentage, then that's considered a whole grain product? There's a main ingredient? Carol, can you help us? Because I think that's the question that Johanna had.

DR. DWYER: I'm not trying to be difficult.

DR. GARZA: No, I think we need a —

DR. DWYER: I'm just saying if you're recommending something, you need to define it.

MS. MCMURRY: It's usually the first ingredient.

DR. GARZA: It's the first ingredient in the label in the ingredient label. That's the characterizing ingredient.

DR. JOHNSON: So, an oatmeal cookie that might have flour as the first ingredient wouldn't be considered a whole grain?

DR. GRUNDY: That's dessert.

DR. DECKELBAUM: Can I ask then, are there guidelines for the people who write food labels as to

(End tape 3A)

DR. GARZA: Meir, does this issue specifically —

DR. STAMPFER: Yes. We define whole grains. It's right in there, Box 11, the first line. And, our job is to come up with dietary guidelines. And, if our job was to define the food label, you know, we'd have a few more meetings. But, that's not our job.

DR. GARZA: So, Johanna, do you —

DR. DWYER: I don't find that's a satisfactory answer.

DR. GARZA: But, in Box 11, I mean, the Committee does say that if one of these is listed first on the label, that, in fact, this is a food — is a good source of a whole grain. Is that sufficient guidance for you?

DR. DWYER: No, it isn't.

DR. GARZA: Okay. Well then, let's come back to that.

DR. LICHTENSTEIN: I think it's actually extremely important issue because if we're defining it one way and foods are labeled another way, somebody could actually be purchasing something that says whole wheat bread and actually it's not what we intended it to be. So, it's critical.

DR. GARZA: Let's come back to that, Johanna.

DR. DECKELBAUM: So, what I'd like to turn to now are the evidence for benefits of whole grains, in particular. And, I'll divide that. I'll spend most of the time on the evidence that's been accumulated since 1995, and then briefly mention the evidence before 1995 that the previous committee had available to it.

So, I think the strongest evidence is emerging in prevention of coronary heart disease. And, there's been two major studies that have come out, namely, where the primary endpoint is the effect of whole grains on — in one study, coronary heart disease mortality, and in the other, coronary heart disease mortality and morbidity.

If you combine these two studies, the population, which were all women totaled close to 110,000 women. And, both studies used a similar approach at looking relative risks or odd ratios of coronary heart disease, endpoints as a function of quintiles (phonetic) of whole grain intake.

The thing that I think is remarkable in the studies is that it's really only when you get to the upper two quintiles, that you get close to two servings a day of whole grains. But, what is apparent in both the studies is that in overall general population is about a 30 percent decrease in coronary heart disease endpoints at the highest quintile. And, in certain subgroups, for example, non-smokers, the effects can even be higher at the highest quintile of whole grain intake.

The other thing that's important I think to note is that it does not appear to be a threshold effect, but it's continuous across increasing whole grain intake through the quintiles.

In addition to these two major studies where whole grains and coronary heart disease were the primary linked points or variables, I found and reviewed seven other studies where, although not the primary endpoint necessarily or the primary factor in the x-axis, you can pull out of those articles that whole grains had an effect on — strong effect on coronary heart disease mortality. And, if you add up again those studies, I think it brings it up to over 60 or 70,000 men. I did it earlier so that the — maybe the number of total studies are small, but the number of subjects studies are rather large.

It's important to note that these are observational association studies so that there's no intervention studies available. Nevertheless, there's a very strong set of data that support the concept that high intake of whole grains will decrease risk of coronary heart disease, both in men and in women.

Something that I found that is a bit worrisome is both the women's studies, higher intakes of refined grains — there were suggestive data suggested that they're associated with higher risk of coronary heart disease.

If we look at the studies before 1995, most of those — most of the studies actually focused on the

effects of fiber in whole grains or other foods, fruits and vegetables and showed beneficial effects of fiber. So, the endpoint was coronary heart disease link with fiber intake. And, also a number of studies with lipid lowering.

I think it's important to note that in the studies that have come out since 1995, that there's been a major effort from the two major groups, the Boston Group and the Iowa Group to dissect out possible confounders to these results. And, whole grains comes out strong even when you control for fiber intake, other kinds of nutrient intakes, other lifestyle variables, night nutrient intake, et cetera.

So, I'll stop here just at this point and ask if there's any discussion to bring up right now relative to the coronary heart disease links.

DR. GARZA: Scott?

DR. GRUNDY: Well, I raised a few questions in my notes to you as you know —

DR. DECKELBAUM: I'll get to them, too.

DR. GRUNDY: You will get to them later or is that in the rationale?

DR. DECKELBAUM: Yeah, mechanisms and —

DR. GRUNDY: Yeah, you want to comment later on that?

DR. DECKELBAUM: Yeah.

DR. GRUNDY: Okay, fine.

DR. GARZA: Richard, if we look at the consumption data in terms of the small percentage of the population that uses whole grains, then issue of confounding in observational studies are a particular concern. I mean, because of the other characteristics of populations who, in fact, may be selecting whole grains.

Do you feel that those observational studies that you've looked at adequately control for confounders such as economic status, weight? I mean, all the sorts of things that we think of when think of populations that presently consume whole grains. And that, in fact, we're not

seeing whole grains as a marker for a variety of other behaviors, but that, in fact, we can be reasonably assured that it's whole grains that are responsible for the benefits.

DR. DECKELBAUM: So — I think that's a major possible confounder. So, both the major studies actually include that kind of data within their analyses, and perhaps Meir, do you care to comment on that because you were involved with one of the studies?

MR. STAMPER: Yeah. I'll try to be brief. The two that you specifically mention, socioeconomic status and weight are not too problematical in these studies because in the nurses — they're all nurses — and weight is very well measured and easily controlled. Obviously, one is concerned about other potential confounders that are harder to measure like other aspects of diet or lifestyle.

We did adjust for everything that we could think of, that we could measure like physical activity, vitamin intake, intake of other nutrients and foods and so on, and it did attenuate the relative risk, but not very much. So, obviously, we can't rule that out, but if the relative risk had jumped a huge amount, then we could say, well it's because if we had measured everything perfectly, it would have gone all the way to null. But, it only changed modestly, so it gives us some measure of confidence, but it still — you know, it's observational data, and the concern you raise is legitimate.

DR. DECKELBAUM: So, the —

DR. GRUNDY: Can I comment on that?

DR. DECKELBAUM: Scott? Sure.

DR. GRUNDY: You know, when you presented that unrelated to mechanism, it made me think a little more about what we would call a beneficial association. And, what I think you could say is that higher intakes appear to be safe relative to their effects on cardiovascular disease. In other words, you found no adverse effects from higher intakes like we would find with saturated fat. And, in one sense what we're looking for are foods that are safe relative to a disease.

And, to take the next step and say they prevent disease, that's much more complicated. But at least across the range of what you found, the higher intake, you found no evidence of increased risk. And so, therefore, that would be a good kind of calorie to include, one that appears to be safe.

So, maybe that would be one way to get around the causality issue.

DR. DECKELBAUM: Well, I'm not — I think I would propose mentioning the association with the benefit. I think the evidence in two very well-controlled studies and seven other studies are strong in showing a beneficial association. Higher whole grain intake with decreased cardiovascular — cardio — coronary heart disease risk.

DR. GRUNDY: I guess that implies — association is right. But, to take a step and say causality is another problem, isn't it? I mean, when you say benefit, that implies a causative factor, doesn't it?

DR. DECKELBAUM: I'm not sure. Do we have to have a cause and effect?

DR. GRUNDY: When we use the word benefit — usually with efficaciousness of a drug or something, we use the term benefit. It goes along with that. That's why I'm a little concerned about that term.

DR. DECKELBAUM: I think in the actual text, we don't use the word "benefit". I just don't remember. I can look it up here. But association.

Well, I can — you want me to address the mechanism now because it's on the next overhead?

DR. GARZA: I think the language you use is "decrease risk", if I recall correctly. That's it's associated with a decreased risk.

DR. DECKELBAUM: I think the language we use is "higher intakes of whole grains were associated with decreased risks."

In the guideline, actually, it says, "may reduce the risk." I think we were careful there. In the Green Book, we write or associate with decreased risks. In the guideline itself, we wrote, "may reduce the risk of cardiovascular diseases."

DR. GRUNDY: That's going one step behind the associated with. I think to say may —

DR. DECKELBAUM: May reduce.

DR. GRUNDY: I mean, you know, that's pretty weak, I guess. Maybe that's okay.

DR. DECKELBAUM: Well, we're careful.

DR. GARZA: Meir and then Alice?

MR. STAMPER: I think that's the right level of hesitation. We don't say, "will reduce the risk." We're saying "may". It's unproven, but there's some positive evidence there. The magnitude's pretty strong. So, I think that's about the right level of waffle.

DR. GARZA: Alice? No? Let's go on to biological mechanism. Is that what you were going to —

DR. DECKELBAUM: No. Well, I'll do that — I want to keep my order.

So, the next — I'll use a different word other than benefit, potential association. It related to some cancers. And, in the guideline itself, we write, I think, "may reduce the risk of cardiovascular — coronary heart disease and possibly some cancers." So, we were very careful in there. And, that evidence relating to cancer is essentially all case control studies.

And, what I did is I looked at four major ones that have been published since 1995 from both United States and from Europe. And, when you add up all the cancer cases, there was about 13,000 of the whole variety of cancers. And, these case controls included 23,000 control subjects when you bring all the subject together.

One of the studies was a meta-analysis of 40 studies, most of them before 1995. And, the others were a combination in a single center or bringing cases and controls together from a number of centers. And overall, when you look at these case control studies, the decrease risk varies depending on the type of cancers, but it can get down as low as 60 percent decrease in risk.

The two cancers that stand out as not having — this is with higher whole grain intake. The two cancers that stand out as not being effected in more than one study by whole grain intake are prostate and breast cancer.

So, the other point relating to Scott's comment just a couple of minutes ago is that in terms of safety, I did not find evidence of adverse effects of higher intake of whole grains that were in the literature or contained in these articles. So, there seem to be no adverse effects of increasing whole grain intake. But, I still think certainly more studies are needed in both these health spheres of cardio vascular and cancer.

The other change in the text of the guideline itself relate to a paragraph that is entitled, "Enriched Grains are a New Source." Folate, and this goes with the fortification in which were fine grains and they relate to folates. And, the previous set of guidelines in 1995 referred to a folate and neural tube defects, and the very positive association there. We've tentatively added, I think, a new guideline, "may reduce the risk of cardiovascular disease and possibly certain cancers."

And, when we reviewed the data there, let's do coronary heart disease. There are a large number of papers of the effect of additional folate or higher folate intakes from supplements or diet — and/or diet on what you see plasma homocysteine levels. The bulk of the literature. So, therefore, we have to take a leap forward to state that lowering homocysteine levels by way of increase folate intake will end up in reducing cardio vascular disease.

In fact, there's, I think, only one major study again from the Boston Group which shows that with additional folate and B6 intake, that you will reduce coronary heart disease in women. So, there's a leap there of going from folate to homocysteine to reduction of coronary heart disease.

Any comments there?

DR. JOHNSON: There was a study in JAMA. Bouche was the first doctor. It was from the University of Washington. And, she looked at homocysteine and coronary heart disease. I can get you the citation. It's a meta-analysis.

DR. DECKELBAUM: But, there's studies looking at homocysteine coronary heart disease good connection. There's studies looking at folate and homocysteine — good connection. But, folate directly to coronary heart disease, you have to use logic.

DR. STAMPFER: There's only — there are a few observational studies that have looked at folate and heart disease. And, they point in that direction of lower risk. But, there's no randomized trial data with clinical endpoints. There's a trial going on in the U.S., and there's a couple that are being initiated in Europe. But, there's no randomized trial data to prove causality. But, there's a fair amount of observational data.

There's folate studies looking at folate, either intake or blood levels in relation to future events of — future coronary events.

DR. DECKELBAUM: So, I'm asking the group if we'd agree that we can maintain the current

wording of the text, which I think says "may reduce the risk for cardiovascular disease."

DR. DWYER: Just a question. Do you call folate --- grain that has had folate acid added to it — "enriched", or do you call it fortified?

DR. GARZA: Fortified.

DR. DECKELBAUM: I'll call it whatever you want me to call it.

DR. DWYER: Fortified.

DR. GARZA: Fortified.

DR. TINKER: The text right now says "may help protect against coronary heart disease and possibly some cancers."

DR. DECKELBAUM: Right.

DR. TINKER: So, are you suggesting that we change that to reducing the risk?

DR. DECKELBAUM: No, no. I didn't read it exactly, but I was happy with that.

DR. TINKER: Okay.

DR. GARZA: Go back Johanna's question. I mean, the reason I said fortify was because it's my understanding that if you add a nutrient beyond the level in which it's normally found, it's fortification. If you just replace things, it's enrichment. And, somebody just said, "No, that we're slipping in our use of that terminology." But, as far as I know, that's still the correct terminology. So, we probably shouldn't perpetuate errors by being sloppy.

DR. TINKER: Well then, this isn't entirely correct because it implies that you have to eat whole grains in order to reduce the risk of coronary heart disease. If we're talking about folate, it's all grains are now fortified, it really applies to all grains, not just —

DR. DECKELBAUM: Well, they're separate because the studies on whole grains where that was the primary variable with coronary heart disease as a primary endpoint controlled for folate intake. And, you can actually go through folate intake —

DR. TINKER: Page 36.

DR. DECKELBAUM: Actually, if you look at the tables, you can see that folate — it's very unlikely that folate could have been a major determinant because they weren't that different from the different quintiles.

DR. LICHTENSTEIN: With respect to the heading on page 36, right now it says, "enriched grains are a new source of folate." And, although technically — they're labeled as enriched. And, that's what people see.

DR. GARZA: I know. That's the slacking —

DR. LICHTENSTEIN: Yeah, I understand that, but I think we have to be consistent what people are going to see in the supermarket.

DR. GARZA: We should actually get to a decision on that while we're here right now, to take a second or two.

Kathryn, what should we call it?

MS. MCMURRY: The text says that it's added to enriched grain products. The label of the products says they're enriched.

DR. GARZA: But, fortified with folate?

MS. MCMURRY: They left out the details.

(Multiple speakers.)

DR. GARZA: Shiriki?

DR. KUMANYIKA: That was the comment.

DR. GARZA: Okay.

DR. DECKELBAUM: The studies linking higher folate intake and reduction of cancer risk are actually weaker. A number of these are laboratory studies or the associations with higher folate

intake. Because again, multiple cancers are being studies both in animal models and in humans. So, in some articles, there's no effect. In some, there is a, I think, generally, a minor effect. It's not a major effect. There's the whole grain itself seems to show in the case control studies.

So, there is a possible link with cancer, and there is a mechanism that has — one of the mechanisms being proposed is the role of folate in protecting DNA from damage and the things that are related to carcinogenesis.

DR. GARZA: Scott?

DR. GRUNDY: I wanted to ask if it wouldn't be worthwhile to go back and look carefully at the DRI for folate which has come out and a group of people studied that carefully and extensively and developed language. I mean, we fought and discussed over that language extensively, and maybe linking your language to that language might present a consistency because I know all these questions have been gone over and careful wording developed related to it.

Would that be worthwhile doing?

DR. GARZA: I think it would be. It's an excellent suggestion.

I'd agree we have to be very careful here.

DR. DWYER: I don't remember what those recommendations said about cancer, but is it strong enough? I mean, coronary heart disease evidence sounds like it's much more human based. And, can we use animal data and etiological evidence for this if we threw out the stomach cancer one for salt?

DR. GARZA: There is some — isn't there some folate data in one trial that leads to cervical cancer, Richard, that suggested it's protective? I would be hesitant to say that it's just etiological data. There may be flaws with it. But, there are studies that suggest there is a relationship.

DR. DECKELBAUM: There's a number of studies. You have to pull them out of the literature. They're not in the major impact journals as of yet. And, the current text, I think, reads "may help protect against coronary heart disease and possibly certain cancers."

DR. WEINSIER: I wouldn't go so far as to say that they're not impact journals because one of the original articles on folate supplementation producing progression in cervical cancer was in

JAMA, early '70s.

DR. STAMPFER: This is a whole grain — or not a whole — this is a grain guideline, not a folate guideline. There's lot of other sources of folate. I don't think we should confuse those two. I mean, there's good evidence for folate and cancer at various sites that when you look at the evidence for whole grains and cancer, it's weaker. I don't think it would support anything strong than possibly —

DR. DECKELBAUM: Okay. And then, the other changes that were made, I guess we should have mentioned earlier on that there were major changes made by putting fruits and vegetables in a different guideline than grains. So, that doing these kind of tables for — what Shiriki showed for the salt guidelines were a little more difficult here because we sort of tore the two guidelines asunder and then put them back together so that we don't have a previous guideline that we can compare to the separate grains and the separate fruits and vegetable guidelines.

But, I think in the — what we did do in the advice for today section is give particular attention to the number of servings of grains and whole grains and to serving sizes, once again, because of the concern of overconsumption, which we'll return to again.

As well, in advice for today, we stress that whole grains should be or can be prepared with other food groups, if you will, peas, beans, vegetables. And, it is emphasized again that when fat is used, it should be small quantities, and avoid saturated fat and avoid added sugars in the preparation of the whole grains.

And, I would suggest that we add to advice for today that we should include at least two to three servings a day of whole grains in our diet based on the studies which showed that these levels where, in fact, you showed — whether were highest effects both in terms of coronary heart disease and reduction of cancer risk in the case control studies. So, that's the summary of the major and substantial changes that have been made in the grains category.

DR. GARZA: Should we go through the text? Are there any changes to that? Are you ready for —

DR. DECKELBAUM: I'm ready for it now or I can bring up the other concerns or questions.

DR. GARZA: Okay. Well, let's hold off on that and see if we can go and do it one paragraph or some sequential way.

Any issues with the first — with the introductory paragraphs? Rachel and then Alice?

DR. JOHNSON: The last sentence we see in front we see small to moderate portions per day. I would just say aim for at least six servings per day and then refer to Box 2, which tells you what a survey is, to be consistent.

DR. GARZA: That's in the introductory paragraph?

DR. JOHNSON: Uh-huh. And, the last sentence of that section. And then, also, later on, I know it's under advice for today, but it's the same thing. We have only six servings of sensible sizes daily. I don't really have a problem with sensible sizes, but again, we define the serving size in Box 2, so we can be more descriptive by just referring people to that box.

DR. GARZA: Okay.

DR. DECKELBAUM: Johanna actually had similar comments, and I have your comments on that here. And, you pointed out the same thing.

DR. GARZA: Meir and then Alice?

DR. STAMPFER: On that same sentence, I'd like to just delete the "aim for at least six portions a day." We're talking about all the grain products. And, this is a micronutrient major source of calories. I don't think we should push — I think this is a way of pushing calories to say at least six portions of grain a day. I think we should just leave that out.

And, for advice for today, just say — you know, have it at least two or three servings of whole grain because that — I think that whole grain should be the emphasis. You can see in that handout, you know, how small the proportion of grain products are whole grain that are in the market. So, I don't think we need to worry too much about increasing that. But, the rest of the grain servings that we're promoting is basically just calories. And, I think we shouldn't do that.

DR. GARZA: Alice?

DR. LICHTENSTEIN: I disagree that it's basically just calories. I think mostly grain products right now are enriched and folate's been added. And, a major issue that I still have not gotten resolved in my own mind is that although the folate level between the whole grains and the enriched products may be similar as far as availability, I'm not convinced that they are similar.

And, we did get some of the material from the DRI Committee, which actually went through that in a methodical way and suggested that the viability was not equivalent, was actually better from the enriched products.

We just had that article. It was published a couple of months ago in the New England Journal showing the impact of just fortification, not shifting the proportion of whole grain to enriched. But, to assume that any grain product is enriched essentially, just a source of calories, I can't accept.

DR. GARZA: All right. Johanna, and then we'll come back to this side.

DR. DWYER: I don't see how we can provide the number of servings that people are to eat unless we define the dose and what we mean by whole grains. So, that's the first problem I've got with the first paragraph. And, I think we've got to define it in a way that's consistent with other use that's out there.

And, the second question, I wondered if we could get a little more detail on the sentence that begins "whole grains differ from refined grains in the amount of nutrients they provide" and so forth? Would it be possible to add a little box defining — showing the different grains because there are only five that are listed in Box 11, and showing how different they are between the folate, B2, B1, niacin and iron.

It's just — how big is the difference? It is a lot or a little? I don't know. And, maybe you want to put fiber down there, too, or non-starch polysaturates.

DR. GARZA: Okay. Roland and then Scott?

DR. WEINSIER: Yeah, two comments. First, is in the first paragraph, and I agree with Johanna. That was one of my concerns. The sentence, "whole grains differ from fine grains didn't tell me anything." And, I've got a revision that I wrote in as a suggestion, but I think it needs to be dealt with. One, perhaps is that whole grains different from refined grains and that the outer fiber nutrient rich layers not been removed or something to that effect to explain what you're getting at.

But, the more important comment I think is in the second paragraph where you refer to portions. And, don't we mean servings there? Portions, aren't they what people put on their plate? Servings is what we deal with on the pyramid. So, I think that's a — if I'm correct, that's

a big distinction.

DR. GARZA: Scott?

DR. GRUNDY: One question about overall carbohydrate. Why don't we get more quantitative with carbohydrates the way we did with fat? I kind of calculated here that the average person may take 400 grams of carbohydrate a day. How should that be proportioned among the different components? Like, how much should come from whole grains? How much should come from other grains? How much from fruits and vegetables?

DR. DECKELBAUM: I was going to address that on the next overhead, but Johanna just brought that up, too. And I think, you raised it in your comments on the guideline and the Green text, I think we've got a bit of a problem here in that unlike fat, the studies have looked — the science that we have available is based on servings. And, I don't know if any of the studies then went into the components of different types of carbohydrates, complex versus simple, versus special unique carbohydrates that some of the whole grains may have.

So, that the evidence is really based upon servings, which meets what the pyramid does. But, to my knowledge, we don't have the available data where we can quantitate this in terms of grams or calories. If I'm mistaken, I'm willing to be corrected.

DR. GRUNDY: Well, we do know that total number of calories that would come from carbohydrate, right, and let's say you have 2,200 calories a day. You know 55 percent of that would come carbohydrates. So, how would you proportion roughly the different categories? Can't we come up —

DR. DECKELBAUM: Based on science or based on our intuition?

DR. GRUNDY: Well, just for our recommendations. I mean, I'm hearing more of this, plenty of fruits and vegetables, but I'm not sure how they're relative to one another in terms of —

DR. GARZA: We should be able to provide estimates based on a serving. We can give ranges for each of the components of the pyramid and then get to the estimate that you want. But, they're not going to be discreet. They'll be overlapping, I think, in the ranges. Because again, we want people to be somewhat flexible.

DR. DECKELBAUM: Nor will they have been tested. Like fat has been tested.

DR. GARZA: They will have been tested to the point that, in fact, they assure nutrient adequacy. All right. So, that to the degree to which nutrient adequacy it's related to health, that at least those ranges between those different categories of food will give you that assurance. But, in terms of being able to document the type of information which I think Richard is alluding to that says, well, if you consume 45 percent of carbohydrates, you're better off if you consume 55 percent of carbohydrates because it's going to impact on your cardiovascular health or cancer.

I don't know whether we can give people that type of assurance.

DR. DECKELBAUM: No, but I think it goes further than that. If we consume 60 percent or 50 percent of our calories as grains, what percent of that should be whole grains? And, I think that's going to be the —

DR. GARZA: And, that's why I think you could get — if you want half of it to be whole grains, and that's what — we're saying six servings of grain based on the data that you reviewed for us, you said three was a threshhold.

DR. DECKELBAUM: By serving up to —

DR. GARZA: Well, I know, Richard. We could be purists about this and confuse the public totally. I mean, to give them some range, say, 50 percent of your — 25 percent of your calories, whatever the calculation is, but I think it's — aside from giving people a rough indication, getting it to calories may be very difficult because people don't usually count calories.

DR. GRUNDY: I'm not even asking we do it in calories, but we ought to do it ourselves so that a recommendations — .

DR. GARZA: I'll ask Carol.

(Multiple speakers)

DR. DECKELBAUM: Based on the calculations that went into the pyramid?

MS. DAVIS: We just use three servings — no matter whether it's six to eleven, you get the requirements that you need.

DR. DECKELBAUM: Meir, are you familiar with any of the literature that brings associations

of whole grains into sort of grams or percent of calories?

DR. STAMPFER: Grams of food?

DR. DECKELBAUM: Whole grain.

DR. STAMPFER: Dried grain. I mean, you know, it's — all those data are based on certain.

DR. DECKELBAUM: Yeah.

DR. STAMPFER: I guess I don't see that as a problem because servings is what people eat.

(Multiple speakers.)

DR. GARZA: Let me try to guide us. We're not going to resolve this one today. We can ask the group that develop the pyramid to give us approximate calorie estimates, and we can, among ourselves, get a sense of what we're asking people to do in terms of portioning their diet. That I think we can do because it's not going to be in decimal points, but we should be able to get a range.

Suzanne?

DR. MURPHY: Well, I was wondering if we can't predicate it somewhat on fiber. I mean, I think that's one of the reasons we're trying to get people to eat whole grains. And, if you have three servings of whole grains, we know from the handout that you get 17 grams of fiber. And, that seems — this is actually a handout from last meeting, but we could — sorry. I have found it enormously useful.

So, your three servings of whole grains give you about six grams of fiber. And, together with your fruits and vegetables, you get up to about 17. And, we should be able to say something about that being a healthy level of fiber intake.

DR. GARZA: Would you put that in the rationale, or do you want to put that in the consumer portion? That's for us to understand the rationale.

DR. DECKELBAUM: But, I just wish to add, though, that the recent studies on whole grains are independent or separate from the effects of fiber so that in terms of these positive health —

potential positive health associations, they've been controlled for fiber intake.

DR. MURPHY: Yeah, I realize fiber is not the whole story, but we're looking for something to justify, I believe, a recommendation. And, I'm with Johanna and others that it would be nice to make it more concrete than just eat more whole grains. And, if we could tell people to aim for three or half their grain servings as whole grains, that would be a justification for it. It's the nutrient adequacy justification that helps get your fiber intake up.

And, I would argue that's the justification for six servings as well. That's how you get your iron and your zinc and your B vitamins up, is you need six servings of either enriched or whole grains.

So, for consistency, I would plead that in this second paragraph of the introduction, we repeat the serving sizes and reference Box 2. But, I don't think it hurts to give them again here and remind people they aren't really huge to help again with the overconsumption problem.

And, I would move the sentence that's over in advice for today about if your calorie needs are low, have only six servings. And, I understand the point we're trying to make. But, this would be back here at the very beginning, would be the point to make that if your calorie needs are low, you need six servings. Then, you can refer back to Box 1, which we've agreed is now going to show the different calorie levels and the different servings.

So, it would all fit in very nicely if you took some of the information that's in the advice for today. I would argue take it out of there and move it back to this paragraph. For example, the serving sizes that you list there.

DR. DECKELBAUM: Or, we do want to emphasize it, have different versions of it in both places?

DR. MURPHY: I think it's not necessary.

DR. GARZA: You have to remember the length. Can we move on then to the first paragraph under "why choose whole grains?" Roland?

DR. WEINSIER: Yeah. I think technically there's an error in the last sentence of the first paragraph . It reads, "The high fiber content of many whole grains may also help to heal folic-less food." It really, to my knowledge, does not reduce the way a food intake. I would replace it

with less calories, and that would be by way of two mechanisms.

DR. DECKELBAUM: What would you say exactly?

DR. WEINSIER: Everything exactly the same except that it ends with —

DR. DECKELBAUM: With less calories.

DR. DWYER: Is there any evidence to that statement?

(Multiple speakers.)

DR. GARZA: There is.

DR. LICHTENSTEIN: For the fiber? For the fiber?

DR. GARZA: No, for the less calories. Go ahead, Roland?

DR. WEINSIER: Yeah. I think the basis is in part upon Woodenson's data that date back to 1937 to 1939, which specifically for comparing whole grain and refined grain products and a variety were used. But, at least one that I recall was bread. And, it reduced calorie absorption by an average of nine percent. So, you could argue on that basis alone that if you weigh from the base of the pyramid let's say seven or eight servings a day of whole grain versus refined, it would make a difference of about 60 calories a day absorption.

The other potential effect could be by way of its reducing energy density.

DR. GARZA: Are you referring to Barbara Rawls?

DR. WEINSIER: The second comment. That would be more rolls and stubs type data. Yeah, but the first was —

DR. DWYER: I think if that's true, and as I remember, what they extracted had very high levels of fiber, but maybe I don't remember the right experiment. It seems to me that it must be cited in the Green Book if there really is evidence that the fiber is leading to less caloric intake.

DR. WEINSIER: Not intake. It was actually absorption is what they were —

DR. DWYER: You're saying they may absorb on a high —

DR. WEINSIER: Yeah. That's why I took out the word — I didn't put in the word "intake." I just said with less calories just to —

DR. DWYER: But, does that really have it in three servings when we're still not too —

DR. WEINSIER: Yeah. As I recall, they were using test meals of either refined or whole-grain foods. So, I don't know what it would be translated for a whole day because I think they were using test meals of a number of servings, and I don't remember.

DR. DWYER: I'm just a little — it has to be in the literature —

DR. GARZA: It has to go back to undigestible fiber. I mean, as I recall, that's the basis for that.

(Multiple speakers.)

DR. GARZA: You've got more digestible fibers, and it will absorb it.

DR. DWYER: Well, I'd just like to see the document and the cite or cites in the Green Book if we're going to say that because I'm not sure that I agree.

DR. DECKELBAUM: The whole grains separate from fiber also have what's called resistant starches, starches that don't get digested and metabolized in the small intestine, then get to the colon and they're broken down. One of the products of metabolism in the colon is short-chain fatty acids, which —

DR. DWYER: Which of the four different kinds of resistant starch are you talking about?

DR. DECKELBAUM: I don't know enough about the different kinds of resistant starches to answer that.

DR. GARZA: Alice?

DR. LICHTENSTEIN: On that same sentence, do we have adequate documentation that the high fiber content helps you feel full with less food?

DR. DECKELBAUM: Roland?

DR. WEINSIER: That's a little bit more of a stretch--

DR. LICHTENSTEIN: I think maybe it shouldn't be there.

DR. DECKELBAUM: Well it may be still —

DR. DECKELBAUM: It is best to sit tight on this, and I can actually ask —

DR. GARZA: If we go back to the rationale in the section on the weight control, and you go through the fact that people appear to regulate their intake based on the amount of food, does that provide you a rationale?

DR. DECKELBAUM: Yeah. That's why I say, it's a little bit of stretch because — I mean, Alice is right. Those studies were not addressing fiber — high fiber/low fiber, refined/unrefined. They were looking at energy density. And, there are lots of ways to change energy density, one of which is probably — you could with adding fiber. So, that's why we could extrapolate to say it may work, but those studies do not specifically address that.

DR. GARZA: If, that's the only one, I'd move on.

DR. DECKELBAUM: We'll look at that and I'll also check with a couple of my society colleagues, ask them. And, if we don't find strong evidence, but some evidence, we will modify that to soften it, or remove it.

DR. GARZA: Okay. Any other questions under, "Why choose whole grains?" Johanna?

DR. DWYER: Well, what about foods that have fiber added to them? Doesn't that come under here, too? Does the food that has fiber added to it become a whole grain?

DR. DECKELBAUM: No. I don't think so. Because whole grains have a lot of other components, as we'll discuss in a couple of minutes like phytochemicals, antioxidants, different micronutrients in terms of vitamins, metals. So that, adding fiber does not take a refined grain and make it into whole grains. It also doesn't rebuild the structure of a whole grain, which includes the germ part, the bran cover and the endogerm, unless there's some magic that do all of this easily.

DR. GARZA: Is there a big category, Johanna, that you're concerned about? I mean — I'm trying to think of — other than cereals.

DR. LICHTENSTEIN: There's a whole line of foods now with added sodium ensembles.

DR. GARZA: But, more than cereals?

DR. LICHTENSTEIN: It's cereals, it's chips, it's pasta, frozen entrees. And, our people going to end up seeing more of it, so it's actually an important point, at least to discuss.

DR. DECKELBAUM: In Europe and Asia, it's very common to find fibers out of fruit juices.

DR. GARZA: It's interesting that during the French Revolution they use to add sawdust to bread.

All right. Any other questions with the first or second paragraph?

DR. DWYER: I'm still very uncomfortable that I don't have a definition that I agree with.

DR. GARZA: But, we're going to get to the box, Johanna. We'll get to that. I'm assuming that we'll get to that, anyway. But, unless you forget to raise it, we'll get to it.

DR. DWYER: Why choose whole grains? I'm still not exactly sure I —

DR. GARZA: So, would you like that paragraph just omitted or both paragraphs just omitted?

DR. DWYER: I think —

DR. DECKELBAUM: Well, the box — it says, "What are whole grains?" Box 7.

DR. GARZA: We'll get to the box. I'd like to stay with the text because I found that if we don't do this in some organized fashion, then the discussion is longer. So, if we can just stick to the text and then come back. Johanna's question is an important one, but I hope we'll deal with in the box.

DR. WEINSIER: Well, it is important, but in the — I'm just reading through the rationale, and if Richard and his subgroup are correct in their rationale, in at least two places they're

indicating that it's not just the fiber that explains the beneficial effects on a number of disease, processing food and cancer and hypertension. And the text points out, you know, fiber. And then, it says — in the second paragraph, it says vitamins, minerals and other substances contribute. I don't know if that answers Johanna's question.

DR. DWYER: It doesn't answer the question. I'm not opposed to whole grains. I'm just trying to figure out what it really says. It says fiber, and then it says there are a whole bunch of other things. And, in observational studies, the fiber effect doesn't explain it all.

DR. DECKELBAUM: Yes. So, I can add a list of fenullic compounds or different vitamins. I mean, we could add that there, but you don't — but, I don't know if that'd be helpful.

DR. GARZA: Johanna, what is it that you think will confuse consumers? Do you think the detail is missing because I have to confess. I don't understand the —

DR. DWYER: Ideas.

DR. GRUNDY: I think you raise a very good point because I don't have it clear in my mind why I should use whole grains yet. And I think that — I mean, you know, you presented some epidemiologic data and so forth, but what is it? I know you're going to give maybe the mechanism, but don't you think the consumer ought to have some idea of what it is and how it's good for you? That's what you're asking, right? I think it's a very valid question.

DR. GARZA: So, Scott, are you suggesting that we ought to just drop, especially whole grains and not — I mean, is that what we're back to?

DR. GRUNDY: Either that or say that they contain multiple — biological factors that appear to be beneficial.

DR. GARZA: I thought that's what it said.

MR. MURPHY: It says vitamins, minerals and other substances and whole grains, et cetera. That seems to me —

DR. GARZA: Would you just like other factors instead of substances?

DR. GRUNDY: Well, I guess that's what I don't know what the other — I mean, you know, you

get vitamins and minerals from a lot of other places, right? So, what's being implied here is something unique.

DR. DECKELBAUM: Well, I suggest rather than —

(Multiple speakers.)

DR. DWYER: And the other stuff, you're just waiving a wand.

DR. DECKELBAUM: Well, what I suggest that we will do then is rather than give a list, and it's a long list. I mean, most people include — some people — this group have never heard of some of these things. And we can detail it a little or quite a bit more if you wish in the Green Book in the justification.

DR. GARZA: The difficulty — well, we can do it in the Green Book, but I don't think that's the objection that I'm hearing. Now, the question that both Scott and Johanna helped me and both of you address is I don't think we're going to find that, in fact, there are functional studies that'll tell us. It's this is a component that provides an explanation for why we see the effects that we do.

I expect when Richard describes for us the biological possibilities, it's going to be areas of research because I don't know of anyone that can give us an itemized list of what it is about grains that appear to have the effect that Richard described.

DR. DECKELBAUM: This is part of my next overhead, but I'll address it now because it keeps on coming up. The mechanism is that if you'll look at folic acid and its effect on neural tube defects, you cannot define a definitive mechanism, but that did not hold back this whole field of fortification of grains with folic acid. That was the primary mover.

DR. GARZA: Richard, they were some double-blind studies, so I think that's a bit of a —

DR. DECKELBAUM: No, I'm talking about mechanism. What's the mechanism whereby folic acid decreases neural tube defects?

DR. GARZA: I agree that the mechanism is —

DR. DECKELBAUM: It's not known.

DR. GARZA: But in the absence of that mechanism, there were double-blind trials.

DR. DECKELBAUM: Right.

DR. GARZA: There's something about folate, we don't have that in the whole grains.

DR. DECKELBAUM: No, but I've been asked actually by Scott to define mechanisms here. And I'm just saying that there are other examples where nutrition policy has had major changes without an exact biochemical mechanism being defined.

DR. GARZA: Yes, go ahead.

DR. GRUNDY: I have just one question. What I see you moving in the same direction as we're going with fruits and vegetables. There's an epidemiologic association with other factors that are contained in those that we have not defined. It's a body of evidence that's supporting multiple factors that are contained in grains just like in fruits and vegetables, and we should look at them in the same way.

Is that what you're saying? Maybe we are going to have to develop some kind of a way to say that for both.

DR. DECKELBAUM: And it may be difficult to dissect out the individual component effects.

DR. GRUNDY: There's all kinds of things that appear to be on the whole — there was a whole report that came out from the National Academy of Science about fruits and vegetables and their beneficial effects. And they considered all the factors and they still couldn't come up with it. But at the end they said, still the evidence is quite strong that fruits and vegetables have beneficial effects and maybe you relate these multiple mechanisms.

Now, that's what you're saying here in the same way with whole grains. Is that right?

DR. DECKELBAUM: I would agree with that.

DR. GARZA: Rachel?

DR. JOHNSON: I think just have to think about scurvy and limes. And they knew in the 1500s that limes cured scurvy. It do no harm. They didn't know the mechanism until, what, 1700?

And then I think a little bit of it is are we doing any harm and looking at it from that viewpoint? We don't know the mechanism. We don't know what it is in fruits and vegetables. They've done some clinical trials with beta carotene and it doesn't seem to be that. So, what is it? We don't know. But they do seem —

DR. GARZA: Johanna, would there be any information that you've heard today that would persuade you that we should choose whole grains? I mean, that might help. I mean, if you're saying that we should rewrite this, or this should be rewritten in a way that would take information that's being discussed that would be more convincing, or that we're saying, "Scratch this one because, in fact, there isn't any data that supports why I should choose whole grains."

Because the approach is something very different. I mean —

DR. DWYER: I think laxation is one reason.

DR. GARZA: Okay.

DR. DWYER: And probably the beta bucans (phonetic) in oatmeals and probably the fiber. But beyond that, this is an area where, as you well know, we've worked for many years. So, it's not as if I don't know what a phytochemical is. It's just that I don't see —

DR. GARZA: You're not persuaded that in the epidemiological study —

DR. DWYER: — not ripe enough to go that way. And without — you know, I think you can demonstrate, and there have been some demonstrations and randomized trials at least of the effect of laxation. I don't know how you say this in polite company.

DR. LICHTENSTEIN: Regularity.

DR. DECKELBAUM: Is that whole grains control for fiber, or is it the fiber effect?

DR. DWYER: It's probably both. I hear some intestinal hurry things in fiber, or in whole grains other than just the fiber. I thought there was some chemicals like there are in prunes.

DR. GARZA: You're not persuaded then that the epidemiological data that looks at the cardiovascular outcomes controls for fiber and still sees a residual decrease associated risk is convincing. I mean, that it's not fiber. It's one of these others and we don't know what it is.

DR. DWYER: No, I don't agree.

DR. GARZA: What is it about that that you find not convincing?

DR. DWYER: The problem of residual confounding. I'm not an epidemiologist.

DR. GARZA: That's why I raise residual confounding.

DR. DECKELBAUM: But both the major studies again, you know, if you have men and women together or close to 200,000 people, they state that they don't — they can't explain the mechanism. They can say that it's not due to fiber or other like nutrients that control for other socioeconomic factors.

DR. GARZA: It may be useful for Meir to review again why you don't think it's residual confounding. And then, if Johanna's still not convinced, then we will have to take a straw poll with that. Do we go with this, or do we not?

DR. DWYER: I pass. You know, we're not going to resolve the issue of residual confounding by —

DR. GARZA: You already explained it. This is — should we take — how many of you are comfortable with "choose a variety of grains daily, especially whole grains"?

DR. DWYER: I don't have any problem with that. What I have a problem with is when you get into doses where you have a definement.

DR. GARZA: We're now under why choose whole grains, which I thought you said we don't have any reasons to say why.

Did I misunderstand?

DR. GRUNDY: That's what I said. I think at least you ought to give some reasons here in the text that there are apparently additional protective factors. That's what you're going to have to say with fruits and vegetables, right?

DR. GARZA: Right.

DR. GRUNDY: So, why not say the same thing?

DR. GARZA: You think that it's just what is said, not that there's the evidence to support it. It's how we built the paragraphs that are of concern.

DR. GRUNDY: I'm skeptical of the evidence, but you know, the evidence is suggestive anyway.

DR. DWYER: It is. It's suggestive.

DR. WEINSIER: So, other protective factors instead of other substances would be helpful?

DR. GRUNDY: Right. Something like that. Whatever language used for fruits and vegetables could be used here as well.

DR. LICHTENSTEIN: Or vice versa since we don't have a — for fruits and vegetables.

DR. GARZA: I think it speaks about that from what I'm hearing. Before going on to the text because it seems to be an enormous sticking point, let's go to Box 11.

DR. DWYER: The problem I have with this box is that we've been told about these studies that relate health outcomes to numbers, absolute amounts of servings of fruits and vegetables or grains, and that these outcomes are associated — in other words, B3 or 2 or whatever, you have less of these bad health outcomes. And I can't understand how that data set relates to this definition.

I can understand it if it's popcorn, but I have trouble when you get over to things that are not eaten by themselves where you just cook them up, oatmeal, boger wheat and so forth. When you get into the grain and flours of the world or the whole rye and whole wheat, most of us don't run to the cupboard and grab the whole wheat and stuff it in our mouths. We might do that with popcorn, but we don't do that with these other things.

And so it can't — I have trouble imagining how those two data sets can possibly be valid in terms of the serving sizes.

DR. GARZA: Okay. Will you address that issue? Meir, Roland or whomever?

DR. DECKELBAUM: Well, I think the science — the papers that have been published actually

define what they consider whole grains to be. With cereals, it's 25 percent or more of the content is whole grains. I think the popcorn is obvious. For oatmeal, it's semi — almost obvious, and brown rice.

So, these studies have taken this into consideration. I think part of the problem may be in certain kinds of prepared foods, cookies, which are a mixture, and cereals. But the science is based on 25 percent or more cereals. And I guess the things that come up very strongly in these studies is cereal intake.

Meir, would you like to add to that?

DR. STAMPFER: That was well done. The only thing I would add is the number of servings in these studies that even the extreme, the high levels as you might expect is pretty low. So, I agree with you that in the sense that it doesn't provide us really crisp data on exactly the dose/response effect, but the reduction in risk was seen in say, the highest quintile where the intake of whole grain — total whole grain servings was only around two or so.

DR. DECKELBAUM: It didn't reach three in either of the big studies.

DR. STAMPFER: So, even though we don't have it exactly, the dose/response exactly figured out, I think the fact that we can see it despite from this classification, plus the really low levels of consumption in the country at large and in those studies, means that I think we're on pretty safe grounds to suggest increase in intake even though we can't say — specify exact grams or say have another — have a piece of whole grain bread instead of white bread, that sort of thing.

DR. DWYER: And that whole grain bread is defined as 25 percent or more of whole grain?

DR. STAMPFER: No, that was the breakfast cereal.

DR. DWYER: What's the whole grain bread?

DR. STAMPFER: Whole grain bread where the first ingredient is whole grain. The first flour ingredient.

DR. GARZA: Kathryn might be able to help us. She has a classification on the regulation.

MS. MCMURRY: For whole grain breads as a standard of identity, that it must be 100 percent

whole grain. For other products, it's not strictly defined or regulated because there's no way to analyze for whole grains in products. But it should be the characterizing ingredient, which is over 51 percent by weight, which sounds like it's higher than the standard used in your studies that was 25 percent.

DR. DWYER: And is the 25 percent that was used in the nurse's study also an FDA regulation, or was it just something that you used for cereal?

DR. STAMPFER: That was just used for cereal.

DR. DWYER: Does FDA have a standard for cereal, what a whole grain cereal is?

MS. MCMURRY: For cereals, it would generally go by the characterizing ingredient. But also there's a new health claim that's been authorized through the Food and Drug Modernization Act that is for whole grain cereals. But to meet the criteria for the whole grain, the cereal must have two grams of fiber per serving. It's related to the fiber content in order to make the claim.

And I have a colleague from General Mills that might be able to answer more questions. But generally, I've been told that the cereals that do make this claim in order to have that level of fiber would have 70 to 80 percent of their — of the whole grain as — of the total grain as whole grain. So, they would generally be higher. The ones that are making the claims for heart disease, I believe it is, would be on the higher end.

But there are questions that would come up in terms of snack foods and cracker products that strictly they should contain more than half whole grains. But there's not a real good way to regulate that right now, as I understand it.

DR. DECKELBAUM: I think it'd be helpful actually maybe to put a summary in the Green Book of what these different definitions are.

DR. DWYER: I think it'd be helpful to put it here.

DR. DECKELBAUM: We can think about that more. I just — I'm concerned about getting too confusing.

DR. GARZA: I think Johanna's trying to make the point that consumers have to be able to understand that we're going to be making recommendations between grains and whole grains,

try to help them select those products.

DR. DECKELBAUM: So if you can get a summary of all that, I'll try to digest it into a very non-confusing form. No pun intended.

DR. GARZA: But leave the fiber intact.

DR. DECKELBAUM: With as minimal laxation as possible.

DR. LICHTENSTEIN: Just to add to what Kathryn said, my understanding at least with making a health claim for cardiovascular disease is you can take a grain, and if there's not enough there, you can add some back. So that would ensure against — it's naturally occurring. You can mix two grains, one high in betaglote (phonetic) and one low, so at least that would avoid the issue of concern that there might be other components besides the fiber that would be important.

And just as a suggestion for how to give advice that would be useful to the consumer, I think it would be saying things like when you choose a whole grain, if you're looking for a whole wheat bread, the first ingredient should be, or look for 100 percent on the label or just some very practical things.

DR. GARZA: Perhaps we can look at the boxes.

DR. DECKELBAUM: So maybe we can include some of that either in this box or actually have a separate box for the different food categories to help consumers. That also gets to another point later whether we should include an ingredient figure. In a way, this strengthens the argument for including an ingredient figure within the guideline.

DR. GARZA: You mean, a modified Figure 6 so that you can accomplish both aims with what is now Figure 6 on page 35?

DR. DECKELBAUM: Yeah.

DR. GARZA: Okay. Now, can we move on to the last paragraph before the advice for the day? Enriched grains are a new source of — Alice?

DR. LICHTENSTEIN: I'm wondering if we need the last sentence because it's Federally

mandated that the folate be added. Therefore — or maybe this is a question. Do people need now to read the labels?

DR. GARZA: Well, I don't think that folate is added to whole grains. Is it now, Kathryn? I thought it was enriched.

MS. MCMURRY: Not at that the present.

DR. LICHTENSTEIN: But isn't there something that it's not — it's intentionally not?

MS. MCMURRY: I think there was an oversight in the regulation.

DR. LICHTENSTEIN: Is that what it was?

DR. STAMPFER: Is it optional?

MS. MCMURRY: Not at this time, not for bread products and flour products.

DR. LICHTENSTEIN: So, it should stay in. This is an accurate —

DR. GARZA: For right now.

DR. DECKELBAUM: But we can still have a product which is 52 percent whole grain, which is then called a whole grain product which is made up with refined carbohydrates or without folate added, because it's added to the refined flour.

DR. LICHTENSTEIN: But then you don't need to read the label.

DR. DECKELBAUM: Yeah, that's what it says.

DR. GARZA: Johanna?

DR. DWYER: Doesn't it need to be explained to consumers? Is it the case that we get enough folic acid from the — if there were a hypothetical three servings of whole grains, what's left is enough to give you 400 micrograms of folic acid?

DR. GARZA: Well, the issue is if somebody were to consume more of the whole grain — you

know, the reason we get ourselves I think into a circular argument is that enriched products take the folic theoretically and put it back at the level that it was before you peeled the coating off. Then you're fortifying the enriched product.

MS. MCMURRY: It's at a higher level.

DR. GARZA: Exactly. But that's what I mean. So you get to that higher level. So to say that they're interchangeable because the whole grain is whole and the enriched is not, is not accurate because the folic acid in an enriched grain product is much higher than the original food stuff.

DR. LICHTENSTEIN: And it's more bioavailable.

DR. GARZA: And it's more bioavailable. And so I don't know whether I'd want to confuse consumers as much as I'm confused by it all, but unless you think that gives misinformation, all we're telling people is read the label if you're worried about folate, is the way I read that.

DR. DWYER: But my problem is a different one, Bert. What I'm concerned about is folic acid is not added to whole grains. Okay.

DR. GARZA: Not necessarily. People can elect to add it.

DR. DWYER: But it's not required to be added to whole grains. And I think we need to say that.

DR. GARZA: Okay.

DR. DWYER: And then say that there's — you get enough if you eat these other things where it is required.

DR. GARZA: So you would add that right before the last sentence before it says, "Read the label"?

DR. DWYER: I would add it under the enriched grains.

DR. GARZA: It says, "folic acid is now added to all enriched grains." And we can say, "It is not required in whole grain products and read the label."

DR. DWYER: Fine.

DR. GARZA: Any other comments for that paragraph? Okay. Scott?

DR. GRUNDY: As I read the label, that doesn't give me much advice. Does that say don't buy it if it doesn't have it?. That's what I would conclude from that. Read the label. If there's no folate there, then what is that?

DR. GARZA: I think that's a pretty big concern. I think, Scott, for young women that are at risk of becoming pregnant who are very concerned about their folic acid, so I don't know that we can say, you know, "Don't buy it or buy it." It's just if you're concerned about folate. That's the way I'm reading it, but perhaps others — you want advice added, "Don't buy it"?

DR. GRUNDY: Well, no. I'm not sure you have to — if it's enriched, then it's in there. Is that just something added on that's not necessary? Is there a reason for people to start looking for their folates in labels?

DR. GARZA: The concern that I saw was because it doesn't — if people want to consume all their servings of grains as whole grains and you're young and at risk of being pregnant, then my advice to them would be, read the label because in fact, you may not be getting enough folate.

But that's what I liked about Johanna's suggestion that we insert that. But maybe I'm the only one that is —

DR. STAMPFER: I think they should be taking a supplement. Women who are likely to become pregnant should be taking a folate supplement. They shouldn't rely on diet.

DR. GARZA: Well, if it's fortified, Meir, it's the same compound, whether it's in a pill form or —

DR. STAMPFER: But it's not fortified to the extent of getting sufficient folate.

DR. GARZA: Well, that's actually not accurate. You can look at the FDA analysis. You can get about as much now.

DR. STAMPFER: No.

DR. DECKELBAUM: I would suggest we table this last argument because this is a major argument.

(Multiple speakers.)

DR. GARZA: It's the same compounds. I mean,

that's — and I think we ought to give people the choice as how they want to take it. I mean, I'm not for or against it. I mean, as long as you take it, that's fine.

MR. MCMURRY: And my other technical point on whole grain products, folate isn't part of the regular nutrition panel unless it's added, fortified.

DR. DECKELBAUM: I think Alyson did or someone did or Carol, analysis over sometime early summer to look at potential effects on micronutrients, which I'll bring up also in the next overhead and showed that increased intake of whole grains, I think up to three servings a day, did not result in displacement of major micronutrients. And I can't remember what they were. Actually, I think it may be listed in the Green Book section, which micronutrients were looking at.

DR. GARZA: Any other suggested changes for that paragraph before we move down?

DR. DWYER: Under advice for today?

DR. GARZA: Yeah.

DR. DWYER: Yeah, I don't think that all of those examples are necessary if your calorie needs are low. Have only six servings of sensible size a day. There must be some other way to do that in less words.

DR. DECKELBAUM: Well, earlier on we had the discussion to move that actually to the introductory paragraph.

DR. DWYER: Why not cut it out and just put it in Box 2?

DR. JOHNSON: Well, Box 2 defines servings.

DR. GARZA: Suzanne?

DR. MURPHY: I'm sorry. I've been momentarily distracted. We're on advice for today?

DR. GARZA: Advice for today.

DR. MURPHY: And on the format of the first bullet?

DR. GARZA: Yes.

DR. MURPHY: My suggestion would be eat at least six grain — servings of grain products daily. And then take the whole second half of that bullet and move it back where we talked about it before.

DR. GARZA: In the introduction?

DR. MURPHY: Right, right. But I think you need to say six somewhere in advice for today.

DR. GARZA: Okay.

DR. MURPHY: I had a —

DR. GARZA: Go ahead.

DR. MURPHY: My second suggestion is to take the whole last bullet and also put it back in the text somewhere. That doesn't seem to me to be the concluding take-home message of this whole dietary guideline. I mean it's nice, but it's —

DR. DECKELBAUM: Well, I think it stresses. I think it's nice in that stresses grains, whole grains. But it also shows that it should be integrated into a whole diet.

DR. DWYER: Well, I don't find that tasty at all. It sounds horrible.

DR. DECKELBAUM: What? What don't you find tasty?

DR. DWYER: Whole grains with cooked dried beans or beans and other vegetables. I mean, to me that is not a typical snack. I don't think we need that. I think it can be cut out.

DR. MURPHY: I can cut it, also. I wouldn't have that for take-home message, Johanna.

DR. GARZA: With those of you that would like something like that, do we need a third box here

to say how to increase your whole grain intake? I mean, give people various suggestions. I mean, one would be through strategies of this type or through others.

Would that work more easily where we now have it located? Alice and then Johanna and then Suzanne?

DR. LICHTENSTEIN: I'm concerned by doing that in addition to changing the wording of the guideline, which I agree with. I think — I'm concerned there being an overemphasis on whole grains. I think whole grains are great. I think if people choose to eat lots of whole grains, I mean, I think that's terrific. However, I still think there's a lot of value to enriched grain products.

And I just am getting the feeling as I read this that it's almost — the idea is, well, whole grain products 100 percent are preferable, and then everything else is in a separate tier.

I think they're important and there should be a good distribution, but not that we're going to start creating — I don't think the evidence — we have the evidence at this point to create two different classes of grain products. And if we have yet another box emphasizing whole grains, I think we're going to be —

DR. GARZA: So you'd just eliminate that bullet altogether and not try to replace it anywhere? Okay. Alice? I'm sorry. Rachel?

DR. JOHNSON: The bullet that says, "prepare or choose grain products with little added saturated fat." Are we talking about butter? Are we saying don't put butter on your bread? I'm not sure what we're saying there.

And also I want to know if we're talking about choosing grain products, and I'll defer to Alice on this, if we should say add transfatty acids because my understanding is one of the major sources of trans other than spreads is bakery products. So should consumers be looking for grain products that are low in trans?

DR. LICHTENSTEIN: I think this is residual confounding from the prior guideline where the emphasis was on low fat, and we saw it every single guideline. I don't think we need to say anything about fat. If we want to do that, then we should say something about salt, you know. There is something about added sugar.

I think those kinds of — I think fat issues should be in the fat guideline and grain issues should

be in the grain guideline. And if the one message we want to get across is there should be variety in the grain guideline and there should be a mixture of whole grains —

DR. GARZA: Should that be the take-home message, the advice for today? Take a variety of grain products with at least half of them as being whole grains, full stop. Obviously, I think some words missing, but rather than the extensive advice we have there.

DR. DECKELBAUM: I'd say — I'm not sure, at least half because if you take —

DR. GARZA: I'm sorry. I'm talking about 6. Go back to the —

DR. DECKELBAUM: Including two to three?

DR. GARZA: Yeah.

DR. DWYER: On what basis?

DR. GARZA: Well, the two to three — I'm sorry. I didn't mean —

DR. DECKELBAUM: Two to three is where the science is.

DR. DWYER: Is it?

DR. DECKELBAUM: Yep.

DR. GARZA: Well, that's as far as we can go. I mean, there are two avenues I think we have. One is to give no advice. And again, I mean, I'm right back to the guideline. If we're going to say especially whole grains, I think we owe the consumer some advice. And the only evidence that we've seen or reviewed are those two major studies with light sample sizes that —

DR. DECKELBAUM: And seven other studies.

DR. GARZA: — as being two to three servings as being associated with a low-risk reduction. So that's the rationale for the two to three.

Now, if there are serious concerns about that rationale, then I think we need to go back to this because this guideline hinges almost exclusively on that rationale.

DR. DWYER: Yeah. I don't know how firmly — I don't feel very comfortable about the quantitative recommendation. Maybe if it's phrased with a consider or something like that. If it's done, I can live with Suzanne because what she's saying is she's saying three servings of whole grain provide six grams of fiber, consider including these. So you get to where you want to go, but you're not saying that it's because of this other reason. It's just a fine point.

DR. GARZA: All right. Why do you think the fiber — what evidence do we have that 18 grams of fiber is so good? If you're hanging on that rationale.

DR. DWYER: Yeah. I would hang it on laxation, as I said.

DR. GARZA: On laxation?

DR. DWYER: Yeah.

DR. GARZA: That 18 grams gives you better laxation than 10 grams?

DR. DWYER: Yep.

(Multiple speakers.)

DR. DECKELBAUM: I'm going to ask a question to the Committee because actually at the last meeting, I was leaning toward the guideline saying, including whole grains. And I was out-discussed and beaten down and outvoted. So it came out especially.

Can I bring that to a vote again?

DR. GARZA: Well, I asked for that at the beginning, Richard, and I was told that the two individuals that had the most difficulty with this, which I think is Johanna and Suzanne, said that no, they had no problem with especially.

DR. MURPHY: That's true for me.

DR. DECKELBAUM: Okay. So, let's just leave it and move on.

DR. GARZA: So, we'll leave it as especially, and you'll cut down the advice for today. You'll change the box to give us a better indication of what servings are and sort of give some consumer

help on how they're going to choose these products, and then there are a number of text changes.

DR. DWYER: And what are we doing about quantitation?

DR. GARZA: What are we doing about — what do you suggest we do about quantitation?

DR. DWYER: I don't know. I'm not as comfortable —

DR. GARZA: I think we can't have it both ways, is my sense. We can't say especially, and then say but we can't tell you what we mean by especially, whether it's one, two, three or four. I mean, then we can say choose a variety of grains daily.

DR. STAMPFER: But we have several. Includes several servings of whole grains.

DR. GARZA: What do you do — what do I do as a consumer with several?

(Multiple speakers.)

DR. DECKELBAUM: I would prefer going with two to three because at least we have some science to back those two numbers up.

DR. GARZA: I mean, I'm not going to push it. I mean, if, in fact — because there's some of you that are much more familiar with consumer behavior than I am. If you think several are going to provide the type of advice that we need to give, then I think that's fine.

DR. DWYER: I'd be more comfortable about it, but I'm willing to —

DR. GARZA: Well, what do you feel comfortable with?

DR. DWYER: I feel more comfortable about it because it's an adjective. I think it's an adjective. It's not a false connotation of something that is derived from epidemiologic studies, which I feel is specious.

DR. GARZA: Okay.

DR. DWYER: And several is more reasonable.

DR. LICHTENSTEIN: I've never been in this position, but if I had to be in a position to provide — plan meals for school or for some kind of feeding facility, would I never use the dietary guidelines? Would they never be used for that? Because if they would be, I would want to know how many servings to include. That would be helpful.

DR. DECKELBAUM: How about at least two?

DR. GARZA: No, no. If people are satisfied with several, and you don't think we're being — there is any discrepancy between —

(Multiple speakers.)

DR. DECKELBAUM: I'm not happy with several. Does two equal several? If we looked up — two equals several?

DR. GARZA: Several just means it's more than one.

DR. GARZA: Let me take a vote here. We're going to be here till 7:30 tonight or 8:00. So let's take a vote and see how many of you would like quantitation versus several.

All those in favor of several, please raise your hand. Okay. All those in favor of quantitating it more specifically? One. We'll go with several.

And we're going to keep especially. Any objections to especially?

DR. GRUNDY: One question. You said the rationale for the special or for the whole guideline rests on the —

DR. GARZA: Those two major studies.

DR. GRUNDY: The rationale for which?

DR. GARZA: For especially.

DR. GRUNDY: Oh, for especially.

DR. GARZA: The seven were not as well-controlled as the two.

DR. GRUNDY: Okay.

DR. GARZA: Without those two, I think we'd be struggling with the seven.

Johanna?

DR. DWYER: I know the dietary guidelines about daily. Why do we need daily in there? Choose a variety of grains, especially whole grains. But why does it say daily?

DR. DECKELBAUM: One of the studies was done on a weekly intake and then you can average that per day. Another one of the studies was on a per-day basis. These are the large studies. And the other studies fall in between.

I think we're trying to get across the impression that this should be a usual daily habit as part of your daily lifestyle. And I think daily emphasizes it.

DR. DWYER: But why do it here when we don't do it anyplace else?

DR. GARZA: Let's take — this I think we can settle quickly, as well. All those in favor of daily, raise your hand. Three. All those opposed? All those who do not vote? Opposed to daily and just taking it out?

DR. KUMANYIKA: Well, some fruits and vegetables, too. I just don't think we've had enough time to ponder it, so I don't know.

DR. GARZA: So, you want to discuss it? All right.

DR. KUMANYIKA: Not now necessarily, but after we do fruits and vegetables —

DR. STAMPFER: As a quick point, I mean this is for people who like the pyramid. This is the bottom of the pyramid, the grains and fruits and vegetables. And I think an emphasis on daily for those things that we really want people to do more of is warranted.

DR. GARZA: Are you persuaded by that argument, Johanna?

DR. DWYER: No.

DR. GARZA: Okay.

DR. DWYER: I think it clutters it. That's what I'm concerned about.

DR. GARZA: All right. Any other arguments pro or against daily?

DR. DWYER: I think the dietary guidelines are daily so that I'm not trying to —

DR. GARZA: No. I just thought we could get over it quickly. Triumph of optimism over experience.

DR. KUMANYIKA: I have a comment. I think — I don't know what it was in the old book, although if I could fine one, I could tell you. But there's the five a day that's been out there for fruits and vegetables. Well, the new — the fruit and vegetable guideline says daily, which picks up on the idea of you have to do this every day.

So it's a part of that where people, kind of agreeing with what Meir said, where people are really not doing this on a regular enough basis. We're not aware of people eating meat daily. They seem to do that without prompting. So to try to push the idea of doing it — it doesn't seem like a terrible idea, although it is adding a word. If I had to vote, I'd probably end up on the leave it in side.

DR. DECKELBAUM: See, I don't think the science — you might say, "Well, what happens if you have all your whole grain servings of the week on Sunday after church?" You know, is

that — we don't know the effects of that.

DR. GARZA: Yes, I do, actually.

DR. WEINSIER: I'm just reviewing the titles of all the guidelines, and really only two that we're encouraging people to do more of relate to food. That's the grain and the fruits and vegetables. And I don't find anything in the introduction or in the pyramid section other than, you know, daily servings in the pyramid itself.

The bottom line is I agree with Meir. I think we do have to emphasize daily and not take the risk that people are going to interpret that fruits and vegetables — I eat them all the time.

When I see patients in clinic, if I ask the question openly, "Do you eat fruit? Yes. How often — have you had it this past week? Once." You know, this is common. So, I think it's too big a risk, and I think daily has to be in there unless it's clearly defined somewhere in here that we are referring to daily.

The other guidelines that relate to food go easy on choose foods with less salt. We don't need to say daily or give a timeframe.

DR. GARZA: Okay. Alice?

DR. LICHTENSTEIN: The first guideline mentions the pyramid, and the pyramid is for daily consumption.

DR. GARZA: Do you think consumers would be able to make the connection? Is that your argument? Okay.

DR. DECKELBAUM: Some of these guidelines are going to be presented without, you know, on their own in different kinds of meetings or groups. So I would think that — I don't have any problems with leaving daily in.

DR. GARZA: Well, are you ready to consider it again, or would you feel that you still need more discussion?

All right. Then all those in favor of keeping the word "daily" in the guideline, please raise your hand. Seven.

All those opposed? And, Alice, it stays like this because you don't care?

DR. LICHTENSTEIN: Yeah.

DR. GARZA: Then, let's go with daily then.

DR. TINKER: If you have a question, because we're also encouraging physical activity on most days of the week or daily. So to be consistent with activities and food behaviors that we're promoting, you want to put be physically activity daily if we're talking about eat fruits and vegetables daily and eat grains daily.

DR. DECKELBAUM: Good.

DR. KUMANYIKA: Let's put every day.

DR. TINKER: We've had that in once and we took it out for the reasons we're talking about with fruits and vegetables and grains, that it was implied eat daily. But I just suggest that we be consistent whichever direction we go.

DR. GARZA: Okay, let's — if somebody, maybe either Kathryn or Shanthy will help me to remember that on Thursday when we come back that we'll do the daily consistently across again and consider physical activity, rather than trying to do it in two minutes across all the guidelines. I don't think that would be very good. We'd have to think about it some more.

All right.

DR. DECKELBAUM: Can I go on to the next topic?

DR. GARZA: No, let's —

DR. KUMANYIKA: I just wanted to pick up something that Alice said earlier because I think we're losing sight of why some of these things are in the advice for today. You talked about dropping the next to the last bullet, I think, prepare added saturated fat and sugars. And I thought the reason for having that in there was because the pyramid can be criticized for being too general when it comes to the choice of products within a category.

And for some of these categories, we have to tell people that you can get your six servings from donuts or whatever. That's been one of the big criticisms, and I thought that's why that was there. I just didn't want it to go, you know, be whisked out without remembering that people need guidance within food categories, that there's some choices that are more lovely than others for certain purposes.

DR. GARZA: All right. Are you persuaded for — but remember, there are guidelines. We're asking people to watch their fat. And so, that in making those choices, you can't select — you can't take any single guideline and then try to cover all your bases because people are going to necessarily ignore the other nine. What we're indicating is, you know, you follow all 10.

With that in mind, would you still want to do that? Then would we want to say that for other —

DR. KUMANYIKA: Well, I think we talked about it last time that we use a kind of matrix approach of trying to highlight within the food ones what these other things were. I mean, the way it is in front of the notebook also makes that point that people need guidance about the form of food within a food category.

DR. GARZA: I think we need more explanatory text because I don't think it'll be obvious that you mean, "watch your donut intake." When I read that, I don't — that's not what it says to me. If I were a consumer, it'd be a veiled message.

DR. KUMANYIKA: Okay. Because I mean, the baked products, that was when the pyramid first came out. That was what people were screaming about and they made jokes about it.

DR. GARZA: I'm not arguing with that. I'm saying if that's the intent, we need to be clear on the advice for today.

DR. KUMANYIKA: Okay.

DR. LICHTENSTEIN: I would agree with that because that's now how I read it. And I would assume you put the choose before the prepare because most people don't prepare grain products, although they certainly do add. But it just needs a lot of word snipping.

DR. GARZA: Can you take that? Because I think it's a valid point because it doesn't — I mean, I certainly didn't interpret it that way.

DR. KUMANYIKA: Okay.

DR. GARZA: Other issues before we move on to other issues?

DR. DWYER: Are you going to say anything about these fiber-enriched products, or is that just not important to consumers in the United States?

DR. GARZA: You mean under the advice for today, you're suggesting —

DR. DWYER: Someplace, either that or in this —

DR. GARZA: We mentioned fiber in the adequacy guideline. But do you see this as a fiber guideline then? Is that the —

DR. DWYER: I think we have to mention it someplace, and it comes to mind here. But it can be pushed into the other guideline.

DR. GARZA: No, it's there now. I mean, I don't know — how — did you discuss this at all in your group, Richard?

DR. DECKELBAUM: No. The added fiber? No, we did not, but is it in the adequacy guideline?

DR. MURPHY: No.

DR. DECKELBAUM: I think it would be best —

DR. GARZA: Is it the last one then that talked about fiber supplements?

DR. MURPHY: Well, there's a sentence in here about fiber is best obtained from foods rather than from supplements. I mean, I guess you could say supplements or additions.

Is the idea to tell people not to use fiber-fortified foods?

DR. DWYER: No, it's to say what the Committee thinks about them.

DR. MURPHY: Well, I guess we didn't have an opinion.

DR. GARZA: Can you suggest some language to the group, Johanna, for what you think we should say?

DR. DWYER: No, because I can't — I'm not sure what — no, I can't right now.

DR. GARZA: Not necessarily right now, I mean, but send it in so that, in fact, they can put something in. I mean, I — okay.

Okay. Then, let's —

DR. DWYER: Yes. Let me tell you my problem. It's that the first guidelines in 1980 talked about fiber. And now we've gone away from fiber and we've come to something new, which is whole grains. I mean, they've always been there. But now it emphasizes whole grains, and fiber is dropped. And it's this huge clock — this circle where we keep going to new things, but there's

nothing said about the old. Maybe we need to go back to the first guidelines and see what it said about fiber.

DR. GARZA: I see fiber also in fruits and vegetables and in grains. It's not just a grain issue. I mean, it's multiple guidelines. And that's where I thought you were going to be addressing. That's what I thought. Well, we'll put it in adequacy.

DR. MURPHY: Well, this says —

DR. GARZA: Suzanne says that — you want to repeat that?

DR. DWYER: Well, it's enough for me to say don't get it from supplements. And that implies to me, don't rely on foods that have a lot of just fiber added to them. Get it from whole grains, fruits and vegetables. But I suspect you're making a point that I'm not grasping.

DR. DWYER: Yeah, I know. I pass. I'd like to come back to it.

DR. GARZA: Well, maybe what we will do is add the same sentence to the fruits and vegetable one.

DR. DECKELBAUM: Let's make it a little less slippery.

DR. LICHTENSTEIN: I may have a sentence. Fiber supplemented foods are not always equivalent to foods made of whole grain products. Something like that.

DR. GARZA: Do you — you may be able to incorporate that into the — one more try. Can we move on then to other issues? All right.

Richard, you're on.

DR. DECKELBAUM: Yeah. I think we're lucky because we've discussed a good part of this already. So this shouldn't take too long.

And in terms of the mechanisms, the potential mechanisms of the added benefit of whole grains, for example, over single nutrients, I will — I think we should actually add it to the Green Book, a discussion — a more detailed discussion on some of the potential mechanisms that are again unproven but do appear in literature in terms of antioxidants, vascular reactivity, changes in

clotting, resident starches, the effects of short chain fatty acids, and especially in post-menopausal women, the potential of estrogens to overlap with hormonal influences and come out with positive outcomes.

So, I think, with your permission, I'd like to add a paragraph into the Green Book on this.

I think we've discussed this already, whether the presentation in terms of qualitative — more quantitative terms. And I have been outvoted to include several in number.

And nutrient displacement, we've briefly mentioned, but we've covered that actually in our previous meeting and briefly today that, again, from Alice and other USDA staff analyses, we do not have any evidence for a list of micronutrients that were examined, that higher intake of whole grains up to I think three servings a day would lead to any displacement of other important micronutrients. In fact, I think the results showed a tendency for higher intake of important micronutrients such as iron went more to whole grain.

And bioavailability of the nutrients in whole grains and how it may affect bioavailability of other components in the diet had been considered also in the past. And again, we have no evidence at the present time, but I'm going to suggest this as an area that needs more research, that this should be studied a little more carefully.

I think clearly there is evidence as we've heard from Alice earlier that folic acid bioavailability in foods seem to be a little less than when it's present in fortified form or in vitamin tablets.

One of the issues that a number of people have raised is the cost. And I'd like to introduce that. Because if whole grains are more expensive, does that preclude its availability to certain parts of the population?

And here, let's see, I don't know if this is readable. That's a —

DR. MURPHY: We have it.

DR. DECKELBAUM: Oh, it's been handed out. Okay. So, there is — if you look at the different food categories where the whole grain part of that category is compared to the refined grain on your right-hand column, you'll notice that the average price is more than the refined grain. So, I guess that's somewhat of a concern.

And except for these two here near the bottom which are shredded wheat and — what was the other one? Cold cereals. That — so, it's going to cost more for, you know, to implement this diet today. And that is of some concern today.

But there's something very important to note here, that when you look at the dollar sales and the volume sales in terms of percent of that category, I think the highest we get up to is about 5.3 to 5.2 percent. So this is another example of how poor the intake of whole grains is in the United States where it really makes up a tiny share — a relatively tiny share of the grain intake.

So this sort of substantiates the science studies where we looked at the different quintiles. You need to get into the top quintiles to get two to three servings a day.

So this is a concern. But should this hold us back? And I would vote no because we happen to have a good example in Dr. Grundy's category. What happens with fat with oral intake?

If we look at mono-unsaturated oils, which is canola and olive oils, in a four-year period from 1989 to 1993, we can see that both in terms of volume sales and dollar sales, that there was a big jump, especially in volume sales in this

four-year period, 12 percent is doubling. Now, at the same time there was an increase in the volume sales, notice that the average price dropped substantially over 30, 35 percent.

So I think that in terms of the industry handling of this, if there's going to be a bigger demand, they'll be able to produce the whole grain products for us at a more reduced price, and that hopefully the data I showed you on the previous overhead in four or five years from now, the differential will be much smaller.

I think there's other examples that have happened in the United States. I believe that initially when low-fat milk came out, it used to be more expensive initially, and then that also changed, so that now there's no price differential, for example, between whole fat and the low-fat milks.

DR. GRUNDY: Can I ask a question about that? About the price, is that driven by economic factors or production factors or what? Why is it more expensive? Is there any reason that it should be?

DR. DECKELBAUM: I'm not an industrial economist, but I think there's a scale factor when

they have to produce these. And there's such a small volume of turnover, they have to — it's probably the manufacturing process I would predict is more expensive. But there are people in this room who are from industry, and could I invite one of them to comment?

DR. GARZA: I think we need to move on, Richard. This is an interesting discussion, but a big peripheral to the — I think the point has been made in terms of costs.

DR. DECKELBAUM: Good. So that's the issue page. Is there any comments? Residual comments?

DR. DWYER: Just a real quick one, and that is that there's several issues such as fiber and carbohydrate in terms of the starches and non-starch polysacharates, sometimes known as fiber, that were covered in the previous dietary guidelines, when you go back to 1980, that we're really not touching on very much.

And I think you've made a valiant effort to try to cover some of those things here, but perhaps after these guidelines — we need to revisit that and make sure that we're not leaving things out because we've gone to these very focused groups within carbohydrates. We really only talked about whole grains or grains and sugars.

DR. GARZA: So would you include that as a research need?

DR. DWYER: I think the group needs to talk about that and also calcium. That seems to be out there sort of floating around. But not now.

DR. DECKELBAUM: Okay. I think very quickly in terms of research areas that would be I think quite helpful in the field of grains and whole grains, I suggest again this has not been discussed by our working group, so it's open to wide discussion. The possibility of intervention studies. I think that's going to be more possible for coronary heart disease and cardiovascular endpoints than it will be for cancer.

But cancer, I think right now we really have case control studies, essentially those are what we have. And it would be valuable to have cohort studies relating whole grains to cancer.

There's a lot of work already ongoing on mechanisms whereby whole grains and different components of whole grains can have mechanistic positive effects to define the biology of the observational data. And as I mentioned earlier, I think we could do more work on the

relationship between folate and cancer and direct links between folate and cardiovascular disease to determine whether there's other effects independent, for example, of homocysteine.

And finally, as I mentioned, just for bioavailability studies, I think need to be carried out.

DR. GARZA: Okay. Alice?

DR. LICHTENSTEIN: Suggesting another one, I think there should be some tracking of the relative consumption of whole grain products and exactly what impact the change in the recommendation had, if it had the intended effect.

DR. GARZA: Okay. The other one was I'm surprised that you didn't mention some sort of more controlled trial. I mean, if that impact is as great as those two studies would suggest, that with just two to three grain servings, we get reductions in cardiovascular disease of the magnitude that you're describing.

If there were any chemical agents out there that achieve the same result, we'd be having a controlled trial, and NHBLI or others would be out there hammering away as to why we're not doing this.

DR. DECKELBAUM: I did suggest that for coronary heart. I suggested we should have —

DR. GARZA: Well, can you tell me why that hasn't happened?

DR. DECKELBAUM: Well, I haven't got any funds so far.

DR. GARZA: No, no. I mean, why do you think the cardiovascular community hasn't lobbied for that? I mean, is there something about the data that is not as strong, that, in fact, we haven't appreciated because the effect is so enormous?

DR. DECKELBAUM: One possibility — and Meir is going to probably answer this and maybe he's already funded to do it — but the studies are new. I think the Boston study came out in June. It was published in June. And the Iowa study was published in 1997.

DR. GARZA: You mean the data were available at least a year ago?

DR. DECKELBAUM: Yeah. But, Meir, why haven't you put on one for this?

DR. STAMPFER: Well, I think part of the reason is the data are new. But the other part of the reason is it's very hard to do randomized trials of food. Most of the randomized trials have been of pills. And we have a randomized trial of a folate pill or a combination vitamin pill. And there's are lots of trials of cholesterol-lowering pills. That it's very expensive to do randomized trials of food, very hard. Very difficult.

DR. GARZA: But, they've been, though, in the colon prevention trial, for example.

DR. STAMPFER: Well, that's a good example where — I think it was — I'm on the public record here, so I'm just going to guess at the cost. But I think it was something around $30 million. And the endpoint was not colon cancer. It was recurrence of polyps.

So, if you're talking about a trial with clinical endpoints, you know, real disease, very expensive. I think it's well worth it. You know, I strongly support such trials. Don't get me wrong.

DR. GARZA: Johanna?

DR. DWYER: Would you add a secondary analysis of the polyps trial because if, in fact, those effects are that large, then certainly in a four-year trial where they enrich the diet with what? That many servings of fruits and vegetables and whole grains, didn't they?

DR. TINKER: It's fiber, I think, not whole grains. But fruits and vegetables, low fat, high fruit and vegetable and fiber, but it wasn't specific to whole grains.

DR. GARZA: But they may have increased the intake of whole grains. Okay.

All right. Then, let's — are there other research issues? I always feel this always gets a shorter shrift in any of our discussions. Generally, people are exhausted by the time of discussion.

Let's take a —

DR. DWYER: I think we need to — we need to at least consider what the glycemic index number of these exist.

DR. DECKELBAUM: The record will not pick this up, but Meir is smiling.

DR. GARZA: All right. Then let's take 15 minutes. Let me tell you what our plan is so you can

plan the rest of your afternoon or evening.

We will then do the — we're going to save sugar for tomorrow, but we will do the other two guidelines — I think we need two more, alcohol and fruits and vegetables today. And we may squeeze in the discussion of the introduction this evening since we're going to move sugars tomorrow to make sure that, in fact, we're done by four o'clock tomorrow.

(Whereupon, a short recess was taken.)

DR. GARZA: Let's get started and go on to fruits and vegetables. As I said earlier, this is the most controversial and most difficult of all.

DR. LICHTENSTEIN: Okay. Given the way the discussions have gone this morning and this afternoon, I decided that I'm going to have to reorganize my talk, so I'm going to do most of this from up here.

I think the first thing that has already been addressed is the major change — okay. For those of you that didn't hear me, on the basis of the discussions on the prior guidelines, I've totally reorganized things. So, I'll do most of it just orally.

I think the major change starting with changes first

be — the major change has already been addressed by Richard. And that is that the two guidelines have — or the one guideline has been split to two guidelines, although for the most part, it was viewed as a positive change in that one of the comments was that perhaps more emphasis would be given to fruits and vegetables.

The other major changes center around the elimination of two boxes. One is the original box, 7 and 8, which dealt with foods that were high in croton and folate, and combining them, also adding information on Vitamin C and creating Box 12 so that there's just one box that addresses good sources of specific nutrients that are particularly high in the fruit and vegetable group.

And then in the previous booklet, there was a Box 9 which referred to serving size. But now, since the serving size issue has been addressed in the first guideline, that has been eliminated.

I think as far as the justification for why we're putting emphasis on fruits and vegetables, one thing that we need to be careful about in the text is not to overstate the point, because a lot of

the basis for the benefits of increased fruits and vegetables intake or at least meeting the current recommendations with respect to the pyramid or the five a day program have to do with observational data.

So that, I think when we go through as far as wordsmithing goes, things like stroke protective effect,

cardio-protective effect, we need to say is associated with a reduced risk.

My understanding is that we're going to deal with that throughout because there's a lot of that in the grains, also.

We do emphasize in this guideline, particularly variety. And I think that the primary reason for doing that, which is also why there is a Box 12, is that there is a variety of nutrients that are normally provided by different fruits and vegetables. And if you consume all your fruits and vegetables and you just pick two and you have multiple servings of those, you might not necessarily get all the nutrients that one would expect from the fruit and vegetable group.

There's also the recent data that was published that it's advantageous within the fruit and vegetable group to consume a wide variety. But I don't think that that alone is — justifies it, but I think there are other reasons on the basis of nutrient distribution.

Just to review the focus group data that one issue had come up with the titles, so I'm going to start at the beginning. And right now the title reads, "Choose a Variety of Fruits and Vegetables Daily." And then there was a suggestion to change it I guess on one of the conference calls that I did not participate in, which was "Eat Plenty of Different Fruits and Vegetables Daily."

And I think it was clear from the conference call that the current verbiage was preferable, choose a variety of fruits and vegetables. And we have daily in there now. And I guess we had that discussion for grains, so we don't need to re-discuss it, but it may all get readdressed.

But I guess, are there any comments on the title?

DR. GARZA: We either have unanimity or we're all exhausted. So, let's go with unanimity.

DR. DWYER: I don't like daily.

DR. GARZA: We're going to revisit daily tomorrow, for all the guidelines, rather than take them up one at a time.

DR. JOHNSON: I thought we had agreed on variety based on some of the work that Suzanne has shared with us in the papers we've looked at that show variety within the fruit and vegetable group was actually advantageous. So, I'm fine with variety.

DR. GARZA: Well, it's also that the nutrient content of fruits and vegetables differ in terms of some of the micronutrients, that if you want a variety to get Vitamin C, Vitamin A, et cetera.

DR. LICHTENSTEIN: Does anyone have any comments on the first paragraph?

DR. JOHNSON: I think if we're going to say — about the middle of the paragraph, we're talking about fruits and vegetables, we say they're low in saturated fat unless the fat is added during preparation. I guess I would add salt. And you could say unless fat or salt are added.

DR. LICHTENSTEIN: I would actually back that up. Do we feel we need the sentence?

DR. JOHNSON: Yeah. I think it goes back to the grain one when we were saying — you know, are we going to try and weave the fat, sodium, sugar issues in throughout? Or are we just going to take each —

DR. LICHTENSTEIN: Well, except the grain products are frequently prepared. There's donuts. There's cookies. And at point of purchase, you have grain products that have a wide range of amounts and types of fat.

DR. JOHNSON: But I would argue that there are people that add saturated fat and/or salt to vegetables in preparation.

DR. GARZA: Any strong feelings? Roland?

DR. WEINSIER: Yeah, at the bottom of the first paragraph, you refer to —

DR. LICHTENSTEIN: Well, what about that sentence?

DR. WEINSIER: Oh, I'm sorry.

DR. GARZA: Yeah, let's get this one. Is there a sense that we should add sodium and not just focus solely on saturated fats?

DR. LICHTENSTEIN: I think we should add salt, but I think that this may be too soon to introduce that aspect of it. I think somewhere later in the guideline might be more appropriate. So, you can focus on the qualities, then when we're later talking about how to choose within the fruit and vegetable category, we can talk about the different forms.

DR. GARZA: You would move that entire sentence?

DR. KUMANYIKA: I would add salt, but I would move that sentence to later in the guideline.

DR. GARZA: Okay.

DR. LICHTENSTEIN: Okay.

DR. GARZA: Is there a consensus with that? All right. We'll go with that.

Then, let me go to Roland and then Johanna. Roland?

DR. WEINSIER: Yeah, just real quick. I encourage you to be consistent and encourage us to be consistent in the numbers. The first paragraph we talk about two fruits, three vegetables, and then under Box 12, it goes to eat five servings of fruits and vegetables. And by the time you get to advice for today, it's two to four fruit and three to five. I mean, I understand what you're trying to say, but I think the consumers, it might be nice to just hit them with the same numbers throughout.

DR. LICHTENSTEIN: I agree.

DR. GARZA: You want to go with the lower levels or go with the ranges?

DR. WEINSIER: Well, I'm not sure we've set a precedent for talking about five servings of fruits and vegetables. So, unless the subgroup —

DR. GARZA: But for grains when we mentioned six, that's the lower range.

DR. WEINSIER: Yeah, I know that.

DR. LICHTENSTEIN: We said at least six.

DR. GARZA: Well, do we say at least, whatever the lower range is for fruits and vegetables?

DR. LICHTENSTEIN: But it's two boxes on the pyramid.

DR. WEINSIER: Yeah. And that's the point I was trying to make, that we shouldn't talk about eat at least five. But since there are two boxes, why don't we keep them separate throughout and then say, "Eat at least two of fruits and at least three of vegetables"?

DR. LICHTENSTEIN: Does that sound reasonable to everybody?

DR. GARZA: Okay. Johanna?

DR. DWYER: How are we going to refer to the delicate issue of regularity? Is it laxation regularity?

DR. GARZA: I think we have to say regularity. Most of the population —

DR. DWYER: Bowel function? What is it?

DR. GARZA: I think people, given anyone that is concerned about regularity, will have watched the evening news. And you can't miss it. Every commercial, I think, has to do with regularity.

DR. DWYER: But —

DR. GARZA: You should. It's all GI related, GI function related. I've been amazed. I've done my own personal survey. It's either antacids or irregularity.

DR. DWYER: Is that what the National Institutes of whatever it's called — gastroenterologic disease — which one is it?

DR. WEINSIER: NIDDK.

DR. DWYER: NIDDK. What do they call it?

DR. GARZA: Probably laxation.

DR. DECKELBAUM: I happen to be a gastroenterologist and I never can use the word, nor do I see it used at scientific meetings. But I agree that the media uses it.

DR. GARZA: The media uses irregularity, I think.

DR. DECKELBAUM: They use it regularly.

DR. GARZA: And focus groups — regularity, yeah. That's my sense. I mean, the consumers understand that, given the TV media. That's the words that they use.

DR. LICHTENSTEIN: It sounds like we should really lean towards what the consumer is exposed to as far as terminology.

DR. DECKELBAUM: How about regular laxation?

DR. GARZA: Okay. We've got —

DR. DWYER: I could talk about this for hours.

DR. GARZA: We know. That's what we're afraid of.

DR. DWYER: Then we need to add in all the things to be consistent and use the word regularity?

DR. KUMANYIKA: Yeah, I think consistency's going to be important.

DR. DWYER: Yeah, I think it's a — I just want to mention — get it on the record that this is a complex issues, because some of it has to do with the quality of the feces, and some of it has to do with frequency. It's not a simple thing to explain to people. And I'm not sure what this means.

Do you mean fecal bulk is increased?

DR. LICHTENSTEIN: This actually got added, and quite frankly, I'm not sure at what point it got added, which is why it's underlined.

DR. GARZA: I think people are concerned about the prevention of constipation. I mean, that's — so, it speaks to frequency, I think, Johanna, more than it does to consistency, at least as —

again, I'm basing that opinion on TV commercials. Because that's what consumers — I'm assuming all the consumer research. I mean, that's what — it doesn't sound quite as frivolous as it may come across.

DR. DECKELBAUM: From the clinical point of view, we need to detail what it's related to, diverticulosis and diverticulitis, hemorrhoids, anal fissures. So it's sort of bowel function and disease.

DR. LICHTENSTEIN: But does the average consumer know what bowel function is, or do they know what regularity —

DR. GARZA: Would bowel function based on —

DR. KUMANYIKA: Healthy bowel function.

DR. GARZA: Healthy bowel function?

DR. KUMANYIKA: They know bowel.

DR. DWYER: Well, I just think we need to define it in the Green Book, you know, scientifically, because this is an area of concern, but also an area of medicine.

DR. GARZA: No, bowel function is fine.

DR. TINKER: I'm sorry. It said proper bowel function in the last guidelines.

DR. DWYER: Let's go with healthy because what's proper?

DR. GARZA: In Boston, it may not be proper.

DR. DWYER: We have baked beans. That helps enormously.

DR. GARZA: Suzanne?

DR. MURPHY: Why was servings crossed out? Did I hear or miss — why aren't we saying servings?

DR. LICHTENSTEIN: The servings are going to be two or more or three or more, just consistent with what the recommendations are on the pyramid.

DR. MURPHY: So, why is it crossed out? It should not be crossed out.

DR. LICHTENSTEIN: It shouldn't be crossed out.

DR. MURPHY: Okay, thank you.

DR. LICHTENSTEIN: So, with the issue related on — to bowel functions, is that going to be dealt with in the fruits and vegetables, grains? Where's that going to be —

DR. GARZA: I think — people are suggesting that it promotes regularity, that it promotes healthy bowel functions.

DR. LICHTENSTEIN: Right.

DR. GARZA: And there may be a reason — instead of laxation which is I think what we say now in the other guideline, we'll say healthy bowel function, to be consistent.

DR. LICHTENSTEIN: Okay.

DR. GARZA: All right. Why eats lots of fruits and vegetables?

DR. JOHNSON: Unless I'm missing something, I don't think fruits and vegetables are a good source of Vitamin E, which is listed there. That's mostly in polyunsaturated fatty acids. So, I think we should drop that.

DR. GARZA: Roland?

DR. WEINSIER: For the title, I don't know if this may be the exception, at least in my mind it is that we've asked a question for these subtopics. And, I wonder if we should try to be consistent.

Secondly, instead of asking a question, I'd like these subcategories which give information, something to the effect, maybe "Fruits and vegetables are rich in nutrients." And then, you go on to find which ones. So, I was a little uncomfortable with —

DR. LICHTENSTEIN: I think it's parallel with the grain, why choose whole grains?

DR. WEINSIER: Yeah. But even so, I mean, my bias would be — the discussion is on the provision of a lot of nutrients and consider a title that might tell them what you're going to say and then say it, and then tell them what you said.

DR. GRUNDY: I would take out the question mark. Then, you could — instead of saying why.

DR. GARZA: The reason why the question is there is for consumer readability. That was my understanding.

DR. WEINSIER: I mean, my recommendation is largely, you know, to go ahead and say, "Fruits and vegetables are rich in nutrients."

DR. GARZA: What title are you suggesting, though, Roland?

DR. WEINSIER: Fruits and vegetables are rich in nutrients.

DR. GARZA: But, as a heading, not a question then?

DR. WEINSIER: Oh, yeah. I'm trying to turn it into a statement, "Fruits and vegetables are rich in nutrients."

DR. LICHTENSTEIN: But aren't dairy products rich in nutrients, and isn't the meat, fish, poultry group rich in nutrients?

DR. WEINSIER: I was just trying to pick up on what's the major point of the paragraph, and I thought that's what you were emphasizing.

DR. GARZA: You're suggesting that if why eat lots to say, "Fruits and vegetables are rich in nutrients" as a title?

DR. WEINSIER: Yeah.

DR. GARZA: You think that would be as inviting to consumers to read this as why eat lots? For text, I can see that your point is well taken, but if you're trying to entice somebody to read this —

DR. WEINSIER: Well, I'd have to leave it up to somebody else. That was my bias.

DR. GARZA: How do the rest of you feel? Because that's the way I read it, that it was trying to entice somebody to read it. And if you don't know the answer, then they would be enticed to read it.

DR. STAMPFER: The previous guidelines interspersed questions along with statements. I think it's nice to have a mix, especially when you're —

DR. GRUNDY: Well, what about lots? Is that a good word?

DR. KUMANYIKA: Something in the focus group about that.

DR. GARZA: I'm not sure.

DR. GRUNDY: I mean, a variety — I thought — that seems like a good term. If you have a variety of something, you eat more of them. And then, we want more and variety, so maybe —

DR. GARZA: I think this came — I'm reconstructing now, but because our fruit consumption was so low, that people wanted to increase. So, that was how we got the lots.

DR. GRUNDY: I think it should be more. Why eat more fruits and vegetables?

DR. GARZA: Yeah. Why eat more fruits and vegetables? Shiriki?

DR. KUMANYIKA: This is maybe one of the places where lots or plenty can work if we're not worried about excess calorie consumption from the source. In the focus group text, I believe it said that people thought saying plenty meant you could pig out. That was the term that was used.

In this last focus group?

DR. LICHTENSTEIN: Yes.

DR. KUMANYIKA: It's there in the last statement. And so, the question was did we want to have any text anywhere in the booklet that implied that there was an unlimited amount of consumption of something?

DR. DWYER: Oh, I see. You say plenty meant you could pick as many — oh, I see.

DR. KUMANYIKA: Meant you could pig out is what the consumers said.

(Multiple speakers.)

DR. GARZA: So, do people want to changes lots or move to plenty or go to a statement?

DR. DWYER: Use plenty.

DR. GARZA: Plenty? Is there an alternate opinion among the group going to plenty?

DR. KUMANYIKA: Plenty's in the text. I wasn't suggesting substituting. Plenty's in the text as an alternate.

DR. GARZA: So, you would go to plenty?

DR. LICHTENSTEIN: Lots is too slangy.

DR. GARZA: Plenty? Sold. All right.

The paragraph then. Any text changes in the paragraph? Johanna?

DR. DWYER: Just a minor thing. The last sentence

on — near the last — on the first page, it says: "Eating plenty of fruits and vegetables makes it easier to avoid getting too many calories from other foods."

Isn't it just that it makes it easier to avoid getting too many calories?

DR. GARZA: And drop from other foods?

DR. DWYER: Correct.

DR. GARZA: That's fine. Okay. Why don't we move on then to —

DR. DWYER: And the last sentence says: "Choose whole or cut-up fruits and vegetables rather

than juices most often." And then, it looks like it's trying to explain why. And you say, "juices contain little or no fiber." But isn't the real reason that juices are high in calorie and contain little fiber?

DR. LICHTENSTEIN: High, relative to what? Water, yes. Whole fat milk, no.

DR. DWYER: Well, you're comparing it to cut-up fruits and vegetables, which is the prior sentence. So it seems to me that it might be useful to also add the other things that are the reasons you tell people to drink — to eat whole apples.

DR. LICHTENSTEIN: I think we have to be careful with that because there was a study that — actually, from Richard's group that said that juices were associated with higher BMIs in children, but then USDA re-looked at that using the nationwide survey data, and said it's not associated with BMIs. So

there's — there's not consensus in the literature about whether or not juices are associated with body fat. That's at least in children.

So, I think we have to be careful about implying that juices lead to excess weight.

DR. GARZA: If that's the case, then do we eliminate the last two sentences? What would be the justification for —

DR. STAMPFER: Following on what Johanna was saying, a typical portion size or a typical portion that people eat of fruit is less calories than a typical — I mean — like you have an apple — a glass of apple juice, that's more juice than you'd get out of an apple.

DR. DECKELBAUM: More calories.

DR. STAMPFER: More calories, yeah.

DR. GARZA: Why don't we say that to say that, in fact, per serving size or something, if that's what we want to say.

DR. MURPHY: Is that true? Is that true, Carol, that a serving of orange juice is significantly more caloric than an orange?

MR. MURPHY: On our serving sizes, they're not different.

DR. JOHNSON: We could say, "Watch your serving sizes. Juices, they're calorically dense," or something like that.

DR. KUMANYIKA: That's better.

DR. GARZA: Then, that gives —

DR. JOHNSON: I don't think we want to discourage people from drinking juice.

DR. KUMANYIKA: I agree.

DR. DECKELBAUM: I'd just like to clarify one point. That study that you mentioned was by Barbara Dennison, who is from Columbia University. But it wasn't my group.

DR. GARZA: She was at Bassett Hospital when it was done.

DR. GRUNDY: One quick question about the juices. Now, orange juice, that's just pure oranges, right, that you mash up? So, if you have two cups or something, that's like two servings, right? I mean, isn't there different kind of juices? One would be the pure fruit juice. But it doesn't have anything added to it. Oh, so it has added — that's what I'm not quite sure. If the juices have the added sugar —

DR. GARZA: We're getting again hung up on a detail. I think that if we — if the message is going to be that you want to avoid a lot of calories, the statement is correct that juices are more calorically dense.

DR. DECKELBAUM: So, can't we say that?

DR. GARZA: That's what I'm saying. I thought that's what we agreed to. Now, taking that statement, is there any concern about saying that?

DR. MURPHY: Juices are more calorically dense than a fruit? The same fruit?

DR. GARZA: Well, it doesn't have the fiber. That's what — if that's not true either, then you can't say anything at all. Let's just drop — that was my first suggestion. Drop it.

DR. GRUNDY: Is it — is the juice the pure fruit juice, or is there other things where you add a lot of — is sugar added?

DR. GARZA: No, no. Juices, theoretically, other than cranberry juice, you can't drink it without added sugar.

DR. JOHNSON: I think the point is that because they don't have fiber, it's easier to consume a greater quantity, and therefore, get more calories. So the message should be to watch your portions or your serving sizes of juices.

DR. GRUNDY: But then wouldn't you get more fruits if you do that?

DR. JOHNSON: You would, but because fruits have more water and fiber, it's more difficult to eat more because you get full sooner. I mean, there is literature that Rick Matis has done that says it's easier to consumer more calories in the form of a beverage because you don't get the feeling of fullness.

DR. GRUNDY: That I can understand, but drinking orange juice, if you drink a lot of orange juice, you get the goodies in two or three oranges that would be equivalent to eating three oranges. Then you'd have three fruits.

DR. JOHNSON: If it's not strained or — well —

DR. GRUNDY: You don't get all the goodies. It'd be better to eat three oranges, I guess, than drink orange juice, but I'm not sure it'd be that much difference.

DR. GARZA: Shiriki?

DR. KUMANYIKA: If we're answering the question, why eat plenty of fruits and vegetables, it might be better to give the positive attributes of the whole fruit, saying that cut-up fruits and vegetables are filling. If that's what you're trying to convey. And then someplace later, talk about the calorie content. Because this is the reason for eating something, and then we end up by talking about what not to do, and that may not be the most effective way to handle the fruit juice issue.

That may be in the advice, or it says, "Which fruits and vegetables provide the most nutrients?" Maybe — that would be a place to address whole versus juices or something like that.

DR. GARZA: So, we would go to "Most fruits and vegetables are filling and low in calories and many are quick to prepare"? See, when I add are filling and we've got —

DR. DWYER: More filling —

DR. GARZA: Are filling. I'm just adding are filling. That's the only thing — words to the sentence if you go to them. Most fruits and vegetables are low in calories since they are filling and low in calories. Would that solve that — follow Shiriki's suggestion?

DR. KUMANYIKA: To try to give the positive reasons rather than —

DR. GARZA: And then avoid the last two sentences. And then move those to a box or something.

DR. LICHTENSTEIN: But also put in fiber. They're high in fiber, in that same sentence. Most fruits and vegetables are relatively high in fiber.

DR. GARZA: Good sources of fiber.

DR. LICHTENSTEIN: Good sources of fiber.

DR. GARZA: That's true. I just had a whisper saying, "Well, not necessarily." And that's —

DR. DWYER: Some are high in fiber.

DR. GARZA: Some are high in fiber. We can say — insert that as a phrase, "some are high in fiber."

DR. WEINSIER: Can you read the sentences as revised because I'm looking at the one above —

DR. GARZA: Most fruits and vegetables are low in calories; filling. Some are high in fiber and many are quick to prepare and easy to eat.

DR. WEINSIER: Only some are high in fiber?

DR. GARZA: Well, that's true. That's a true statement. Not all fruits and vegetables are high in fiber.

DR. WEINSIER: I know. But we start out with most, and that's inappropriate?

DR. GARZA: I don't know whether it's 51 percent.

MS. MCMURRY: I know that apples are not. Apples are not good sources of subtle fiber.

DR. GARZA: That's the reason why I was hedging, Roland, because I'm not certain I can say most.

DR. DECKELBAUM: Just this point about fullness and, you know, caloric density. The studies that you were referring to earlier when I was standing up, or Alice was, were they done with fruits and vegetables or with grains or with both?

DR. WEINSIER: They were generally mixed meals. They were essentially all mixed meals. Those two studies were mixed. I don't remember any that specifically separated the food.

DR. DECKELBAUM: So, we can use — both are sections of the Green Book, then.

DR. DWYER: If we could find a more recent study, not that I don't respect Dr. Gibson (phonetic), but she's in her late 90s now. And someone else must have done some work on this. People at NIH are —

DR. GARZA: Probably not as good as Elsie. She was a bit phenomenal.

Okay. So, we've got that paragraph. Can we then go to the next? Aim for variety?

DR. MURPHY: I guess I'm de facto chair for a moment here. Does anybody have any comments on the section? Let's finish this whole guideline before Bert comes back. You'll make me look really good.

DR. DWYER: Is this done the same way as yours were done? In other words, is it ranked by —

DR. MURPHY: I don't think we're on the box. I think we're going to come back to the box. So, we're on the text on page 39 at the moment.

DR. DECKELBAUM: Well, one point I'm just noticing. We just discussed it. It says, "All forms provide — and all vitamins and minerals and all provide fiber."

DR. MURPHY: It needs to be most.

DR. WEINSIER: Well, if it's most, then we have to revise the other one also, where it says some.

DR. MURPHY: I think it should be most.

DR. LICHTENSTEIN: Take a vote?

DR. MURPHY: Well, we need food composition, I guess.

DR. DECKELBAUM: There actually must be facts to back up most or some.

DR. LICHTENSTEIN: If you eat an apple with the skin, you're getting fiber from the skin.

DR. MURPHY: I think we're okay with most, myself.

DR. DWYER: So most, and then say most juices, or just eliminate that? Isn't it juices in banana that are the common ones that are low in fiber?

DR. LICHTENSTEIN: Well, that's the skin of the apple. Doesn't it have a lot of fiber?

MS. MCMURRY: We can check it, but it's some. It's

not — it doesn't qualify for 10 percent of the daily values you'd call a good source.

DR. MURPHY: Could I make a suggestion? This seems to me a very laborious sentence that "All forms provide vitamins and minerals and most whole fruits or cut-up fruits provide fiber."

Do we need to malign juices?

Roland?

DR. WEINSIER: Yeah. The paragraph — the second paragraph starting with, "Choose different ways," I don't know. I thought this was kind of unimaginative and didn't really excite me. In fact, I was thinking about eating frozen bananas, and I wasn't too excited. And people know you can eat fruit raw.

I don't know. I would say either delete it or come up with something that's a little more exciting.

DR. JOHNSON: I have a suggestion there. I agree with Roland on that. And, in fact, I think there's been some really nice work done with the five a day program by Tom Baronowski, where he's actually shown some ways that children are more likely to eat fruits and vegetables. For example, if they're served with a dip, or we might be able to look at some of his papers.

But I know they've done some actual studies that have shown how children, at least, are more apt to increase their consumption of fruits and vegetables. And maybe we could get some more creative suggestions there.

DR. MURPHY: Okay. So, Alice, you'll —

DR. LICHTENSTEIN: Yep. I'll follow up on that —

DR. GARZA: — follow up on that.

DR. MURPHY: Anything else on "aim for variety?"

DR. DWYER: Alice, what is it you want us to add to the "handle food safely guideline" or whatever it is? Eat food safe. Or do you want to handle the fruits and vegetables here? See, putting them in the food safety one is sort of awkward because it flows nice in here.

DR. LICHTENSTEIN: Well, I had actually assumed it was going to go into food safety because that's where they're sort of set up. The reader is set up to think along those lines. I think we'd have to — we could be done. You know, I think we may end up repeating a little bit, but —

DR. DWYER: Well, is there anything more you want us to say than what?

DR. LICHTENSTEIN: I think some comment should be made about these rinses that are on the market, whether it's advantageous for people to use these fruit and vegetable rinses or not. I mean, have most people seen them in the market? I'm not up on the food safety. I think that's Johanna's area.

DR. MURPHY: Well, let's maybe not get too into food safety here. That would be my recommendation, anyway. But we'll need to come back to the washes, I guess, eventually.

DR. LICHTENSTEIN: Well, one thing I'd like to suggest for this paragraph is it talks about buying fresh fruits and vegetables when they're in season, and you know, the issues of how much to eat when, but I've always been concerned that the emphasis seems to be on fresh fruits and vegetables.

And I think if we're going to talk specifically about fresh fruits and vegetables at this point, we should remind them to keep in mind that frozen and canned fruits and vegetables usually have the same nutrient content as their fresh counterparts or something like that. Because apparently what is confusing, we saw some information from the focus groups, thinking that fresh fruits and vegetables were the best, and the other ones weren't quite as equivalent.

And the concern was that one of the reasons they weren't getting enough fresh fruits and vegetables is that there were barriers to buying them, storing them, handling them in a timely fashion. So, a question for the group, do you think it's important to say that when fruits and vegetables are in season, it's okay to eats lots of them, or is that something that's just implied?

DR. DWYER: Do we need that?

DR. LICHTENSTEIN: That's what I —

DR. DWYER: Why don't we just drop "for example" and make it shorter?

DR. MURPHY: It's the last paragraph under "Aim for Variety."

DR. KUMANYIKA: The melon one?

DR. MURPHY: The second sentence.

DR. LICHTENSTEIN: Are we okay with that?

DR. DWYER: The reason is because, you know, I ran a consumer hotline for 10 years in Massachusetts. Nobody ever asked us if it was okay to eat corn or melon when it was in season. We were never asked. And we had like 14,000 calls a year.

DR. MURPHY: Then you'd omit the whole paragraph. You wouldn't have just the sentence, "the best time to buy them is when they're in season." That's sort of —

DR. DWYER: That's fine. But then after that —

DR. MURPHY: You'd keep that sentence?

DR. DWYER: Yeah.

DR. MURPHY: Okay.

DR. LICHTENSTEIN: Would you consider adding a sentence that "keep in mind that frozen and canned fruits and vegetables usually have the same nutrient content as fresh fruits and vegetables?" And sort of round it that way and emphasize that there are a lot of alternatives. We'll get into that later on. But it seems to be an important point.

DR. MURPHY: Sure. Shiriki?

DR. KUMANYIKA: Question, is the point of "the best time to buy them when they're in season," is that they're the cheapest?

DR. LICHTENSTEIN: Yep.

DR. KUMANYIKA: Well, why don't we say that they're lowest in price when they're in season? Because it sounds like the best time to buy is because they're fresher or they're different in some way, other than the price.

DR. DWYER: Well, that's probably true, too.

DR. KUMANYIKA: Is it true? I mean —

DR. LICHTENSTEIN: Frequently, yeah.

DR. KUMANYIKA: With all the things people do to preserve things that are not in season. I don't know. But if there is something else, then we have to take the chance of creating the perception that if it's not in season — heavens, I don't know when any seasons are anymore — but if it's not, then it's not desirable.

So, I just think if we're saying that, we should be clear why we're telling them that. And if the main thing is price, then say, "look for the ones that are in season because they're the cheapest"

or something.

DR. TINKER: Well, I read into it also that the reason is so that you can eat a lot of them and you might not get the variety at that point when there's something fresh, which comes later.

DR. KUMANYIKA: I don't know.

DR. MURPHY: Well, some of this seems to merge with the next section, also. Right?

DR. LICHTENSTEIN: Yeah, perhaps it can be moved in.

DR. MURPHY: Let's keep that in mind. I also had one question about the second little bullet in the middle paragraph, "Cooked with Little or No Saturated Fat." You've convinced me that they're low-calorie and therefore, I can eat lots of them. Why wouldn't I cook them with little or no fat?

DR. LICHTENSTEIN: I actually was going to comment on that, but then on the basis of Rachel's comments, we decided we were going to scrap that anyway. I had put in steamed or microwaved, actually, and would have eliminated that. But I think the point was well taken that these were not particularly exciting suggestions on how to increase or make them more appealing.

DR. MURPHY: But if we say something about saturated fat, we can make it — we're not going to say anything.

Moving on to the next section, "Find Ways To Include Plenty of Different Fruits and Vegetables in Your Meals and Snacks."

Comments on this section, which I guess goes on to page 40?

DR. JOHNSON: Why aren't you supposed to refrigerate tomatoes? It says not to refrigerate tomatoes.

MS. LYON: They lose flavor. They're not as flavorful once you refrigerate them.

DR. JOHNSON: But when they're ripe, don't they stay — don't they not rot sooner?

MS. LYON: I don't know. Some experts can answer it, but —

DR. JOHNSON: I always refrigerate my tomatoes.

DR. MURPHY: Okay. Anything else? Shiriki?

DR. KUMANYIKA: There's something — I don't know, maybe it's because it's late in the day. But there's something about these cautions, the way they're placed like "rinse your mouth out after" — it just doesn't have the right ring to it.

DR. JOHNSON: Where was that?

DR. MURPHY: That's at the top of page 40. You mean dried fruit to protect your teeth? I suspect I know who wrote that.

DR. DWYER: Yeah, I did.

DR. KUMANYIKA: I know why it's 80 or 90 percent. So I understand why it's there. I think it's good advice. I'm just talking about the positioning. If we could send the positive messages and then somehow separate the things to watch out for or other health tips about — there was just something about seeing that.

DR. DWYER: You still have your real teeth. All I have is plastic.

DR. KUMANYIKA: It just hit me as needing a little bit more explanation or something.

DR. GARZA: The concern here may be that in looking at the calories and sugar connection that this is a source of sugar. So the risks can't be or shouldn't be confused. You can't on the hand need to moderate your sugar intake because of calories and, on the other hand, have a source of calories that's sticky.

DR. KUMANYIKA: All I'm saying is that it might need a little header that says, "Fresh fruit and dental health" or something, and then point it out. The way you kind of roll into it, it just sounds —

DR. MURPHY: Would it be possible to say that in the sugar guideline, postponing one controversy, instead of right here when we're encourage people to eat these things?

DR. GRUNDY: I think that Shiriki makes a very good point about maybe having a separate comment on teeth care and consumption of fruits and sugar that goes with them.

DR. MURPHY: But could we put it in the sugar guideline?

DR. LICHTENSTEIN: Well, actually, if we'd use a box, it would be very easy to do that because there is a box in the sugar guideline. So, that may be the way to go.

DR. KUMANYIKA: It could go here, too. It's just that —

DR. DWYER: No, it's out of place. I agree.

DR. KUMANYIKA: Just didn't —

DR. LICHTENSTEIN: Okay.

DR. MURPHY: Okay. Shall we do Box 12 on page —

DR. LICHTENSTEIN: Before advice for day?

DR. MURPHY: Yes. Let's finish up all the content and then do advice for today.

So, there are any comment —

DR. LICHTENSTEIN: I think Kathryn can comment on how these were chosen. Right? Or, somebody can comment on what the criterion was?

MS. MCMURRY: Fruits and vegetables?

DR. LICHTENSTEIN: Fruits and vegetables.

DR. MURPHY: Confession time. If everyone points the finger, it's eventually going to come back, I afraid, to me. I ordered those. I rinsed out my mouth after I did it, however.

Carole did a lot of the work, but we collaborated on it and I think the final wording probably was mine. And it was based on the information from Carole Davis' group on sources of nutrients.

And I must say, I liked having only three bullets under each. But they are kind of broad groups. And so it's hard to say that they're in exact order of any kind.

DR. LICHTENSTEIN: Well, was there any criterion?

DR. MURPHY: Yes.

DR. LICHTENSTEIN: Okay.

DR. MURPHY: The foods in each of those groups provide at least 10 percent of the daily value for Vitamin C or for folate. Now, I'm going to forget what I've used for — we used the Vitamin A equivalent for the karotenoids. So at least if you convert the karotenoids to Vitamin A, they're at least 10 percent of the daily value for Vitamin A.

Shiriki?

DR. KUMANYIKA: Two questions about this box. One is whether potassium — there's enough evidence to add potassium here as a benefit of fruits and vegetables. The other is whether calling karotenoids, which term is only familiar to consumers from another aspect of the literature, not as a source of your — of adequacy for Vitamin A, I wonder if it should be called sources of Vitamin A (karotenoids) or P vitamin or something like that.

Because when I look at that, it looks like karotenoids and cancer prevention, which literature has taken some strange turns recently. And I'm really worried about it, especially having it first because that leads — it's misleading, I think.

DR. MURPHY: Sources of Vitamin A as karotenoids?

DR. KUMANYIKA: Sources of plant Vitamin A. I mean, it's not accurate, but how do you say it in a way that doesn't trigger the antioxidant?

DR. LICHTENSTEIN: Perhaps it also would be helpful to do that because it'd be consistent with what's on the label, say, if you'd like canned apricots. It's Vitamin A.

And then what about Vitamin A (karotenoids)?

DR. MURPHY: Johanna?

DR. DWYER: This is not on the box.

DR. TINKER: I have one more on the box.

DR. DWYER: Okay.

DR. TINKER: In the section on why eat plenty of fruits and vegetables, we list examples of nutrients from 6, C, A or karotenoids and folate. And yet B6 isn't in the box. It just hit me. I don't know why we chose the nutrients we chose for this box.

DR. LICHTENSTEIN: It actually was somewhat of a continuation of the prior guideline, although Vitamin C was added. But that's certainly something that we could consider.

DR. MURPHY: Are fruits and vegetables rich sources of B6? I always think of it as coming more from proteins.

DR. TINKER: I think B and B6 may be in the grains.

DR. MURPHY: Why don't we just say the three nutrients that we have in the box?

DR. LICHTENSTEIN: What about the potassium? Potassium came up and we had eliminated the potassium box from the salt guideline from the previous addition because it didn't seem to fit there.

What about moving that and adding that to Box 12?

DR. LICHTENSTEIN: Yeah. I mean, what would the general feeling be on that?

DR. WEINSIER: I think it's a good idea.

DR. MURPHY: And then we should potassium back here in this list of nutrients.

DR. LICHTENSTEIN: Yes.

DR. KUMANYIKA: Then, we could take the rationale out of the Green Book.

DR. MURPHY: Right. Remove it from the sodium guideline.

DR. LICHTENSTEIN: Now, does anyone have any feeling — will be able to use the same criterion of not less than 10 percent, or you know, on a serving basis? Is that going to have to be amended? If it is amended, is that going to be acceptable?

DR. MURPHY: How many fruits and vegetables are going to provide 10 percent of the DV for potassium?

MS. MCMURRY: 3,500 milligrams.

DR. LICHTENSTEIN: So, I don't know what criterion was used on the previous guideline.

DR. MURPHY: Yes, bananas and oranges — we can look. We can look.

Okay. We'll check into that. Johanna?

DR. MURPHY: Except advice — are you ready to go for advice for today? Is that where you want to be?

DR. WEINSIER: Yes, I'd like to comment on the box.

DR. MURPHY: Okay. Let's finish the box, and then we'll go back. Roland?

DR. WEINSIER: Three comments under — first, two under sources of folate, peanuts are listed. Do we want to suggest that people count peanuts as a vegetable or a fruit? I don't know how it's being considered here. I'm not saying it's not a rich source of folate. I'm just wondering whether you want to give this as an example where people would say, "I eat lots of nuts every day," and start counting those as a fruit and vegetable serving.

The second was the second bullet. Orange juice, we —

DR. MURPHY: Well, why don't discuss the —

DR. LICHTENSTEIN: Okay.

DR. MURPHY: I don't think nuts belong here. I'm not sure.

DR. LICHTENSTEIN: Okay. Next?

DR. WEINSIER: The second was orange juice. Should we just leave it orange? We kind of put down the juices, and why reinforce it here? Everything above is a whole fruit or vegetable. Why don't we just leave it as orange or oranges?

And then —

DR. LICHTENSTEIN: Wait. Does everyone agree?

DR. JOHNSON: I'm not sure. If you think about a fresh orange versus a serving of orange juice because it's more concentrated, is the orange juice more rich? I'm not sure that one orange would meet the criteria.

Do you know, Suzanne?

DR. MURPHY: Yes. I think that's why it was just orange juice.

DR. JOHNSON: Oh, okay. Trish says it does, though.

DR. MURPHY: It does? Okay. Okay. Thank you.

DR. WEINSIER: And then at the bottom it says, "Read nutrition facts labeled." But, I mean, everything is listed. You know, we don't talk about frozen or packaged or whatever, so I'm wondering — we're not going to get any labels on any of these items listed. Is that really helpful?

DR. LICHTENSTEIN: Well, you will get it for the frozen and canned varieties. You can get collard greens that are in frozen blocks and spinach, and you know, winter squash and broccoli and all those things.

DR. WEINSIER: So what is the fact label going to help us on these?

DR. LICHTENSTEIN: Compare relative amounts.

DR. WEINSIER: Yes, I know it, but I mean, we should try to picture which — this, we're talking about some TV dinners or — you know, are the facts labels? They're not going to be on the fresh. They are on the fresh?

DR. KUMANYIKA: They're in that section under fresh, but not on the food itself. But what

about the brand? Excuse me. The brand-specific. Is there something implying that? That different brands of fresh broccoli have —

DR. LICHTENSTEIN: Yes, I think it's — maybe the wording could be improved. I think it was sort of if you've got these frozen vegetables with these sauces, that at some point, the sauces sort of outweigh the vegetable. But that could probably be expressed better.

DR. KUMANYIKA: Well, maybe for processed foods or something like that?

DR. MURPHY: All right. Are we through with the box?

DR. LICHTENSTEIN: Just going back to the — are we going to — we agree that orange and orange can be included. Given the relative consumption of orange compared to orange juice and the contribution of orange juice to folate intake in the U.S., are we going to eliminate orange juice or say both orange and orange juice, or just the orange?

DR. TINKER: How about just oranges and orange juice?

DR. LICHTENSTEIN: Both, okay.

DR. MURPHY: All right, Johanna.

DR. DWYER: Maybe there's sufficient — you just mentioned under Vitamin C, but there are two ethnic-specific foods that I think are important to mention. One is plantain, green plantain. Maybe they're mentioned there, but I don't seem them. And the other is potatoes, which are the food of God's people, the Irish. And I don't mean French fries, necessarily. Boiled potatoes.

DR. MURPHY: I did look at potatoes, and they don't meet the 10 percent of the DV provided.

DR. DWYER: Oh, so that shouldn't be on there?

DR. MURPHY: And it should be?

DR. DWYER: Well, they're on there now, aren't they?

DR. MURPHY: I'm sorry. Well, then I'm — I'm sorry. And was it 10 percent or is that something we put in? Somewhere I have all this information.

DR. LICHTENSTEIN: Maybe we can check. We'll go back and re-check some of these foods.

DR. DWYER: I think it is important to mention them if they're going to fit there. I'm not talking about encouraging French fries. I'm talking about Irish potatoes.

DR. MURPHY: Well, someone checked, and potatoes are well over 10 percent of the daily value.

DR. DWYER: And plantain? Does anybody know? I have no idea about those.

DR. MURPHY: But we did look at frequency of consumption and sources. I mean, there are other fruits and vegetables that are more than 10 percent of the DV. These are the highest ones.

DR. LICHTENSTEIN: Canned pumpkin?

DR. MURPHY: Canned pumpkin is an enormously rich —

DR. LICHTENSTEIN: I understand that, but as far as consumption relative to something like winter squash?

DR. KUMANYIKA: Pies?

DR. LICHTENSTEIN: Huh?

DR. KUMANYIKA: Pies.

DR. LICHTENSTEIN: I actually had made a note about it.

DR. DWYER: Put low in saturated fat.

(Multiple speakers.)

DR. MURPHY: All right. Are we through with the box? Johanna, did you have a non-box comment?

DR. DWYER: That was it.

DR. MURPHY: That was your box comment? I'm sorry.

DR. DWYER: It was both. It seems to me we need to mention potatoes and plantain on the first page if that's possible because dried beans and peas are mentioned. I don't know of any ethnic group whose main — well, maybe. But, I don't know a staple — an ethnic group whose staple is dried peas, do you?

DR. MURPHY: So the question is, should potatoes be put in the list under "why eat lots of fruits and vegetables?" Are they especially rich in many nutrients?

I would — does anybody have a comment on potatoes? Meir?

DR. STAMPFER: One potato is enough. I mean, a lot of the potato consumption is french fries, and we already have a problem that people eat french fries and think they're getting their — up to their contribution to five a day. And I think if we promote that more, it's to our detriment. So, I think once is enough. We have it in the Vitamin C list, and I think we should leave it there, and I don't think we should add it.

DR. DWYER: My concern about that is for certain ethnic groups in the United States, these are a major source of energy. They're eaten — at least I grew up eating them at least once a day. And I wasn't eating french fries.

So I think it's a staple food for a lot of people. And it's not the same thing as your broccoli and so forth. It's a staple food.

This plantain issue is the same for other ethnic groups. And that's why I raise it. Because I'm not sure that that's given attention.

DR. MURPHY: All right. Well, I don't personally think it'll fall real well under sources of many nutrients. Okay? So I think the fact they come in as Vitamin C, and Kathryn tells me they're probably going to come in under potassium, as well. So they actually might be there twice.

Would that do it, Johanna? While Johanna's thinking, Shiriki has a comment.

DR. KUMANYIKA: I guess a question — I think I was talking to somebody maybe in the UK that said they actually had potatoes in a different part of their pyramid. And I know we talked about that once and were told that'd we be shut down if we mentioned it again.

But I'm wondering if it would be possible to footnote that potatoes also contribute to the

carbohydrate content? Something that says, yes, they do have a role as vegetables, but they're a different type of vegetable than some of these other ones so that they don't just carried along with the green leafy stuff and oranges.

They are different. I mean, when they're staples, they're staples for different reasons. They're not replacing greens and carrots. They're replacing bread.

DR. GARZA: I certainly appreciate Johanna's comment about the role of potatoes. I'm concerned, though, that we have such a huge consumption of these — of a potatoe that's fried. I mean, I forget. They make up half the vegetable servings?

MS. MCMURRY: One-third for children. I think it's age 2 to 19.

DR. GARZA: That's fried potatoes, right? And so, if we're going to do this, that we either put some statement in there that would say "try to avoid them" — maybe that's not the right word. But try to do something with text that says "we don't mean five potatoes because of the high fat content."

DR. DWYER: I agree. And I guess what I would suggest is that in "why eat plenty of fruits and vegetables" that someplace in there a statement being made saying some vegetables such as plantains and potatoes. And maybe there's some others I'm just not thinking of, are starchy. These are good choices, but can be high in calories. Avoid the fried versions or whatever. Something like that.

I'm not trying to —

DR. LICHTENSTEIN: Or some methods of preparation are high in fat.

DR. DWYER: Correct, yes. It's just that nobody has anything against baked potatoes, do they? You do. And how about boiled?

DR. STAMPFER: I showed the data earlier at this meeting in the nurse's health study. The women who were eating the highest quintile in potatoes had the twice the risk of heart disease. You eat a potato, it turns into glucose almost instantly.

DR. DWYER: I'm not sure that's true if you eat it with the skin, Dr. Stampfer.

DR. STAMPFER: Very quickly.

DR. LICHTENSTEIN: I'm in a more positive mode about potatoes. They were included as a good source of potassium. So, I don't know exactly what the criterion we used when the 1995 guidelines were made up. But they're a strong contender.

DR. MURPHY: My suggestion would be to show them as good sources of — it turns out two different nutrients, but not to necessarily highlight them any more than any of the others. I don't see that it changes our advice to consumers.

Do other people feel strongly that we need to say, "there are some vegetables that are sources of starch and therefore high in calories?"

DR. LICHTENSTEIN: We would then get into corn and then we've got the beans, the dried beans.

DR. DWYER: Boiled potatoes.

DR. MURPHY: I thought that was what you said you would recommend to insert, something about too many of them can provide calories or something.

DR. DWYER: That was the fried ones.

DR. MURPHY: The fried ones could provide calories. Okay.

DR. GRUNDY: Could we just have one little paragraph all about potatoes?

DR. MURPHY: I think Scott is serious.

DR. KUMANYIKA: Yes, I think he was.

DR. GRUNDY: Yes, I am.

DR. MURPHY: Okay.

DR. GRUNDY: And say that too much fat — you know, if they're cooked and eaten with a lot of

fat, baked potatoes with a lot of butter on them, and that's bad, or fried potatoes, a lot of fat, but they are a caloric source and they have some nutrients. I mean, you just have one small paragraph.

DR. MURPHY: Okay. Does everyone go along with what Scott proposed, which I think is essentially what Johanna's proposing, also?

DR. LICHTENSTEIN: Great. Maybe Scott and Johanna can draft something and then we'll work on it.

DR. JOHNSON: Maybe in this paragraph about potatoes, maybe we could say something, since it is such a high proportion of children's fruit and vegetable consumption about trying to encourage children to try a variety — you know, other varieties of vegetables other than fried potatoes or somehow we could get that in there.

DR. MURPHY: Okay.

DR. LICHTENSTEIN: Any feeling about where this would fit?

DR. GARZA: Aim for variety.

DR. LICHTENSTEIN: Aim for variety? And then limit your potato consumption to one serving a day?

DR. MURPHY: Yes. Maybe it could be under the "choose different ways to have parents serve fruits and vegetables." Would fit nicely under there.

DR. LICHTENSTEIN: Okay.

DR. MURPHY: All right. Can we go to advice for today? Shiriki?

DR. KUMANYIKA: I don't think we can say two to four. It sounds like the person — the individual should eat two to four servings. And that may not be what's intended there. This is the pyramid range.

DR. LICHTENSTEIN: I think we're going to change all this terminology as I think Roland pointed out at the beginning to be more consistent with at least two, at least three. Because I

think you're right. It's going to get very confusing.

DR. GARZA: Can you refer them to Box 2?

DR. MURPHY: It does. See Box 2 for servings.

Anything else on advice for today? Going, going, gone.

I'm turning it back to Bert.

DR. GARZA: Thank you. Alcohol. Let's move on.

DR. GRUNDY: Somehow I missed about the rationale that you had that meta-analysis?

DR. LICHTENSTEIN: Yes, I was going to come to that now in the next section.

DR. GRUNDY: I'm sorry.

(Multiple speakers.)

DR. LICHTENSTEIN: Scott, with reference to the rationale, and I think you made some very important points that I need to work on a better justification and be more specific with some of the references and not rely on meta-analysis, but deal more with the individual papers. I suspect what's going to happen, though, I'm going to go back further than '95 because most of the data were published prior to that time. But I think that's very important.

As far as the mechanism, that is as problematic as the grain situation because as you point out, they are rich in antioxidants and nutrients, but it's not clear that that's going to be — hold water as far as a mechanism for either cancer or cardiovascular disease. And I agree with that point.

So I will certainly present the individual studies in more detail.

DR. MURPHY: Richard?

DR. DECKELBAUM: Not trying to be too defensive about grains, but I must admit that fruits and vegetables even — the studies came out earlier, but they share the same questions that the grains do. Again, observational, association studies, with potential of multiple confounders.

So that when you get to — I think when we get to future research, I think this is an important field to really find out where — what the effects are and if they could be related to other factors, because the same people who eat lots of fruits and vegetables also eat more whole grains and they probably exercise more and smoke less. They're the same kind of people.

So the studies proceed the grain ones, but they're the overall same type of studies.

DR. LICHTENSTEIN: And I think we're also going to have to acknowledge that a certain amount of this — really, it's observational data with respect to dietary patterns. And that we can't rule out displacement. And ultimately, I think we're going to really have to start thinking about that because now we're sort of artificially separating things out into guidelines.

But when you look at the whole diet and collect the type of dietary data that you can get from large numbers of subjects, you really — ultimately, you've got to look for common threads in dietary patterns. And I think it's reasonable to acknowledge that that's what we're relying on. And hopefully, more of the issues will be resolved in the future.

DR. DECKELBAUM: I think that should be a major outcome of the least of our advice is that studies really are needed for this because they now affect two major guidelines, and they affect the whole bottom of the pyramid.

DR. LICHTENSTEIN: It sounds like it's ripe for a multi-sensor randomized clinical trial. Large.

DR. MURPHY: Are you going show an overhead and then let people react to it?

DR. LICHTENSTEIN: Yes.

DR. MURPHY: Is that the plan? Because I know Shiriki had a comment.

DR. KUMANYIKA: Well, I guess I wonder for fruits and vegetables and possibly grains, how much of the rationale is based on dietary adequacy? Because these things are still needed as sources of essential nutrients. And for that we have studies. We have studies that show we need those nutrients, very clear studies. You know, the balance studies historically. And we know that these are the sources that we're going to get them from.

So, even though we don't necessarily have trials for the chronic disease endpoints, that isn't the

only rationale for this guideline. And sometimes I think we forget that and think we have to justify fruits and vegetables on the basis of epidemiologic data, which we don't. We're not recommending excessive amounts.

DR. LICHTENSTEIN: I think that's actually a very helpful point, and I will incorporate that into the justification.

DR. MURPHY: Johanna?

DR. DWYER: Is it okay to talk about the justification?

DR. MURPHY: Yes. I'm not sure what Alice's plan is.

DR. LICHTENSTEIN: I think we probably should now talk about the future research.

DR. DWYER: Oh, all right.

DR. MURPHY: I guess these are comments on the rationale. So, Johanna?

DR. DWYER: Yes. It's on page 28 where it talks about increase variety. And it mentions the study by Slattery, et al, a large population-based study.

In the past six months, we've been hearing these snippets of information about the polyps trial. And has that come out yet, and was it positive? Wasn't that a fruits and vegetable rich —

DR. LICHTENSTEIN: But the endpoint was recurrence of polyps. And we're not —

DR. DWYER: Correct.

DR. LICHTENSTEIN: That's not a —

DR. DWYER: Then it would be important to include that. Now, is there any idea when it's going to be released because obviously, people here have read it in peer review — you know, some of the people seemed to have — do you have any idea?

DR. DWYER: The basic point is by December, it probably will be out. And I would just urge that we at least include it if it's —

DR. LICHTENSTEIN: It's unpublished data.

DR. DWYER: It'll be published probably by then.

DR. LICHTENSTEIN: By December?

DR. DWYER: Well, we can get the answer by tomorrow.

DR. LICHTENSTEIN: Okay, thank you.

DR. DWYER: Because a population-based case control study is not the same as a randomized trial. And if the data are cloudy, then that would strengthen the argument. If it isn't, then it may give us pause as to what the mechanisms are.

DR. MURPHY: Okay. Other comments on the justification? Shiriki?

DR. KUMANYIKA: I think I mentioned before that the DASH-1 study could be mentioned here.

DR. LICHTENSTEIN: Okay.

DR. KUMANYIKA: As far as the justification.

DR. LICHTENSTEIN: We will also work again on straightening out the wording as far as associations and getting all that straightened out.

DR. MURPHY: All right. So we're ready to go on to the future?

DR. LICHTENSTEIN: Well, besides, you know, the suggestion that we obviously — you know, we're going to continue to look at data on population-based studies, intervention studies, whatever's available, and I think we should that recommend it — I didn't write that down — that there be some support for intervention studies and continuing monitoring.

One thing I was thinking about was the impact of splitting the current guidelines since it seems like a good idea. There's justification with respect to barriers to consumption and that we do need to try to or we're hoping to promote increased consumption, those kinds of things.

But I think we're not going to know, and I think in the next committee, it's going to be helpful to

them if they have some idea as to whether this actually worked or whether this is not a particularly good approach because it created too much confusion.

I mean, certainly there was some positive comments from the focus groups because issues related to things like, is it that I have to consume grains or fruits and vegetables every day, or both? And it's quite clear now whether we keep daily in the guideline or not, that we mean they're two distinct entities.

But I think issues that should be followed are fruit and vegetable intake patterns, whether there are any educational campaigns that are spawned by splitting the two, whether there are advertising campaigns that can — that actually impact on intake — you know, promotional material for various places, whether those end up being creative — more of it's creative. Less, it means — or the material that from the five a day program gets wider dissemination or whether it doesn't. Whether it's too confusing to have two different programs, whether it's positive or negative.

Whether there is an increased awareness in the importance of consuming fruits and vegetables, whether that translates to actual behavior. I think we should learn a little bit more about the barriers to consumption. We've know for a long time that fruit and vegetable intake has not really met the recommendations for what we consider to be promoting optimal health. Well, this is one attempt to further address that. And is this the way to go?

Is it still — are there still going to be barriers because of cost? Because of availability? Because of those kind of things?

I think we can't just assume that by splitting fruits and vegetables from grains, that it's automatically going to improve the nutrient status of individuals or of the population. But we really need to look at it closely.

I had some other things on this list, but they were really more the general ones that I had brought up yesterday. But I think we also, as indicated, need more — you know, some type of intervention.

And then I think we also need to focus a little bit more on mechanisms with respect to individual components to see if there is justification to put more emphasis on certain fruits or vegetables or specific categories of species than others. And I think this is something that's an emerging field.

We at least now are aware of the thousands of compounds that are in fruits and vegetables. And we need to start narrowing down. At one point, it seemed like antioxidants was the answer. And while that still may be part of the answer, but it's certainly not the whole answer.

Issues related to — you know, now you can go into a store and you can buy fruit and vegetable concentrates. You can take a pill that's equivalent to five servings of fruits and vegetables. You know, I think those kinds of issues can be addressed. And I think it's important to how this gets communicated to the consumer.

DR. MURPHY: Okay. Any additions to Alice's list? Johanna?

DR. DWYER: I think that food composition data are absolutely essential. And the analytic word simply isn't there for a lot of the compounds that they're the greatest health interest in. And commodity groups, manufacturers and perhaps Government all need to be involved in this. There isn't enough money in the Federal Government to do all this work.

DR. LICHTENSTEIN: Do you want to be specific on the nutrients?

DR. DWYER: Well, I think the priority list of foods are the thousand foods that are most commonly — I think it's a thousand that the Beltsville Laboratory has focused upon. First, get the thousand most commonly eaten foods. And then there may be some things — very high sources of particular phytochemicals of interest.

I guess phytochemical-wise, it depends on — you know, who's studying what. I think Suzanne and I would be interested in the flavenoids. Others would be interested in other compounds. But basically, there's so many of these compounds that it's very, very important if we're going to go beyond this magic wand business of talking about phytochemicals and really getting down to the science to get the analyticals done.

I think there are also some other things that need to be done. And one is, again, I think the glycemic index needs to be looked at in these various foods. I take issue with some of the views that potatoes are potatoes.

There are a lot of different kinds of food preparation of these various fruits and vegetables, including the starchy ones. And I think it behooves us to take a look at the glycemic index. Where this can go? Maybe nowhere. But I think it's important to find out.

DR. LICHTENSTEIN: With respect to, again, to the phytochemicals, which are sort of right now this big amorphous group of compounds, if we're going to make concrete recommendations, it would be helpful — do you have any suggestions about where I could go to —

DR. DWYER: Yes, I have a suggestion. The critical review of Food Science and Nutrition. I think it was Pam Anderson who was the chair of the committee. But the ILSI people did, I think, nine or ten phyto — is that correct? Some of you probably could tell me.

It was just published. And it's Fergie Glyfield's (phonetic) journal. And it focuses on 10 compounds of great interest. One is, you know, the —

DR. LICHTENSTEIN: Well, I can check it.

DR. DWYER: Flavenoids in soy. But beyond that, I think there's a need for a broader array of things. And certainly Dr. Beecher's group at the USDA could probably give a list — a priority list of what they're working on.

DR. LICHTENSTEIN: Okay, thanks.

DR. MURPHY: Okay. Anything else? Anything else on the guideline?

DR. GARZA: Thank you. Meir is going up to take on alcohol.

There's one correction of information that Kathryn passed on to me. When we were discussing the fat guideline, we talked about the congruence between Federal definitions. And a low-fat food is any food that has — well, among the criteria, has 30 percent of its calories coming from fat. So, it isn't just the amount of fat. It's also on a calorie basis.

We need to think about that because that's — we don't have to be — we're not arguing for consistency across. So, we need to be aware that low is equated to 30 percent.

DR. LICHTENSTEIN: Let's just be careful there because when we refer to low-fat guides, we're talking about 30 percent less. We're not talking about individual foods. And that's always been a major sticking point.

DR. GARZA: I know. But it's hard to tell a consumer that when we about talk diet, we use moderate. And when we talk about fat, it means low and it's the same percentage.

You're on.

DR. STAMPFER: Okay. Somehow we always get to alcohol around this time of day. I was doing my lab session.

For the alcohol guideline, perhaps because the changes from the previous guideline are so modest, I think we're kind of maybe, I'm hoping, a step ahead in terms of how closely we've gone over the text. In previous meetings, we've already not only gone over the major issues, but I think had quite a bit of wordsmithing to get to the exact wording that we have before you.

So, just to review very briefly the proposed changes from the previous guidelines, I would consider them modest. We've proposed to change the first sentence, which used to be something about alcohol doesn't have a lot of nutrients or something like that. Alcoholic beverages supply calories, but few or no nutrients. That was considered kind of a bland start. And the focus was to start right off the bat by talking about the harm of excess alcohol because it's a major type of health issue in this country in some detail. Then sharpening the benefit side with a bit more detail and sharpening the who should not drink category.

So, really, there are no major changes. Oh, I guess one might consider a major change the deletion of the sentence, "Alcoholic beverages have been used to enhance the enjoyment of meals by many societies throughout human history." Undeniably a true statement that we've agreed to delete from this version.

So those are all changes that we made over the last several meetings. And the last conference call that we had went over some basically small wording changes in the section on Women Who May Become Pregnant and also in the Who Might Benefit with a Lower Risk of Coronary Disease Associated with Drinking in Moderation.

So, why don't we just go through like we've done before? Because I think — well, let's see what sort of comments come up.

DR. GARZA: Okay. Are we to begin then with the title, or the guideline, rather? Are there any concerns about the guideline itself? Then why not the first paragraph then?

How good is the data — I'm sorry, Johanna. How good is the data — are the data that higher levels of alcohol lead to dyslipodemius? Does that contribute to higher — is that sound pretty good?

DR. STAMPFER: Dyslipodemius? Well, we don't have that in there.

DR. GARZA: That's what I'm saying. That's why I'm asking. I mean, in terms of a potential harm, given all the attention we give to it in the fat guideline that, in fact, alcohol is — is it another major factor that contributes?

DR. STAMPFER: Well, with quite heavy drinking, you can get — you can raise triglycerides, although HDL goes up — continues to go up with more than two drinks a day. I wouldn't put it in the same category as these other ones.

DR. GARZA: Okay, good. I'm not arguing for it. I just want to make clear for the sake of completeness.

Johanna and then Shiriki, did you have your hands up?

DR. KUMANYIKA: Yes.

DR. GARZA: Johanna?

DR. DWYER: Yes. My question was the sentence that talked about too much alcohol may cause. I wondered, first of all, if it would be possible to mention social and psychological problems, because that's the manifestation most of us have seen with people who drink too much. And then perhaps put inflammation of the pancreas. And then psorosis and then damage to the brain and heart. Simply because, I think, that the pancreatic is a more acute effect which could take months or years or much longer than it does to get pancreatic inflammation. Or I stand corrected because I don't know that much about it.

The main thing is, though, to be sure to mention the social and psychological problems. We address violence and accidents above there, but it really doesn't get into problem drinking in terms of other types of problems.

DR. GARZA: Shiriki?

DR. KUMANYIKA: I was just wondering if it would be important to mention older adults and falls because the small dilution — older people, drinking people, giving them a drink to help appetite or something, and it actually increases risks of falls, I think. So, if there's data to support that, which I think there are in the literature, maybe we could add a mention as that as

a precaution.

DR. STAMPFER: I didn't find that, actually, because this came up before and I thought, "Yes, it must be there." If anybody has some science, we could add that.

DR. KUMANYIKA: I'll look in my files and see if I can find that.

DR. STAMPFER: Can we get back to Johanna's suggestion? Is there a general feeling to add social and psychological problems?

DR. KUMANYIKA: I agree.

DR. GARZA: There is a database for that, too.

DR. DECKELBAUM: I know that alcohol is also a risk factor for esophageal cancer. I don't know what the number of drinks is. But that's another prominent cancer that can be effected by alcohol.

DR. STAMPFER: Yes. Excess alcohol above the levels that we're considering moderate are associated with cancers at a variety of sites, which that was the intent of — in certain cancers. I didn't name them, but they're the oral cancers, the esophagus and in GI cancers, in general, are increased with — I didn't — I mean, we could name the specific sites if the Committee thought that was necessary. But I thought it was enough just to say certain cancers.

DR. DECKELBAUM: Well, it may strengthen the message about too high an alcohol intake being an important risk factor. You named a couple.

DR. GARZA: Any strong feelings either way? Alice?

DR. LICHTENSTEIN: I have a different comment.

DR. GARZA: Okay. I think it doesn't hurt.

DR. STAMPFER: So, maybe name the two leading

alcohol-related cancers? Okay.

DR. GARZA: On that first paragraph, Alice and then Johanna?

DR. LICHTENSTEIN: Excess alcohol consumption and driving is a leading cause of traffic accidents and traffic fatalities. And I guess I'm uncomfortable seeing accidents buried in the middle of that sentence. I don't know if it's the major cause, but it certainly is a significant cause. I would feel better if "drinking excess alcohol and driving" was actually in a separate sentence.

DR. JOHNSON: It's under advice for today.

DR. LICHTENSTEIN: Yes, I guess — I mean, the violence, suicide — that should — you know, there's data to support that. But I think it's dwarfed relative to the issues related to drinking and driving. And I think it should be given serious prominence.

DR. WEINSIER: It's also the fourth bullet under "Who Should Not Drink?"

DR. LICHTENSTEIN: Well, maybe it should be moved up and eliminated from some of those places.

DR. GARZA: I think it should be there twice. Your point is that it ought to be more prominent.

DR. LICHTENSTEIN: Right, and moved up as a risk, because I'm more concerned about that as a risk for alcohol consumption than some of these other issues. Or it just seems that there are more of a problem, a societal problem, in total numbers.

DR. GARZA: Then you would like to say that "taking more than one drink can raise the risk for automobile accidents, high blood pressure, stroke"? Is that the type of prominence you would like?

DR. LICHTENSTEIN: Yes. Either there or even just to say that "excess alcohol intake contributes to X percent of the traffic accidents and fatalities," if we have the data.

DR. GARZA: Well, but then we're going to have to have parallel construction for high blood pressures and everything else.

DR. LICHTENSTEIN: Yes, okay. That would get too complicated.

DR. GARZA: That would get too complicated. But I mean, we could deal with it in that way.

Any other suggestions for the first paragraph?

DR. GRUNDY: Well, I just don't know whether that deserves a box. I mean, maybe not, but I think the point being made here is that it is a major issue, a major problem, and we've got to highlight that out front that it's — we've got — that's the first consideration. And then the rest can come later.

Is that worthwhile doing?

DR. GARZA: A box for — that highlights the fatalities and the rest of it?

DR. GRUNDY: And the blood pressure, yes, so that people have — it's a little bit buried in the paragraph.

DR. LICHTENSTEIN: And birth defects is also a major — those seem to be the ones that are from a society perspective.

DR. GARZA: So, would you like to get these out and into a box?

DR. LICHTENSTEIN: Either that or in the first — be the focus of the first paragraph.

DR. GARZA: Well, that's — it is in the first paragraph.

DR. LICHTENSTEIN: It's buried.

DR. GRUNDY: Well, that's what I said. It's kind of buried in the text, and if it's listed A, B, C, and points, it might be —

DR. KUMANYIKA: You could list it out without putting it in a box.

DR. GARZA: You want to list bullets then? You want prominence?

DR. GRUNDY: You want something to highlight it?

DR. GARZA: So, that's just formatting, not changing words, just formatting?

DR. GRUNDY: Right.

DR. GARZA: Be more visible. Okay. Johanna?

DR. DWYER: Two things. I think part of it is when — we worked on this on the telephone. We put in things that are physiological and things that are not, or they're caused by physiological effects like accidents, violence, suicide, which is more behavioral, and then the social and psychological problems. Then there a whole bunch of toxic effects of alcohol that have effects on various organs and organ systems.

But back to Shiriki's comment and Meir's, we thought that there really wasn't very much evidence for the Falls. Maybe we could at least give a warning at the end of that first paragraph by saying, "Older people, whose blood volume decreases with age, need to be especially careful." In other words, all adults need to consume things only in moderation, but older people need to be especially careful because their blood volume is lower.

DR. GARZA: Okay. Is there agreement on that point that Johanna just made?

DR. STAMPFER: I'm just a little concerned if you say some people need to be more careful, that implies that other people need not be less careful.

DR. DWYER: Well, I don't know how to phrase it, but the point is there's a physiological reason why older people, if they drink the way they did when they were 25, will get into big trouble.

DR. STAMPFER: Well, if they drink the way we're defining moderation —

DR. GARZA: Shiriki, do you have a —

DR. KUMANYIKA: Well, I think the way to phrase it the way that the NIAAA, when I worked with them on some things, more like the dose of — the same dose of alcohol may have an even strong effect for an older person.

DR. GARZA: But remember, the point that I'm hearing Meir making, maybe, go to Box 22, we're not saying — the guideline is saying that no one should drink more than these limits. So unless you think that an elderly adult ought to drink less than what's on here, then that's the message, not — we're not saying, "Gee, you know, we don't really mean that

you" — it says that if adults choose to drink, they should consume them only in moderation. And moderation is defined.

And so the point that's he making is a good one by saying, but other people need to worry more about this, are we sending an implicit message that, well, maybe, you know, if you're not old, you can really go beyond this, but the elderly really need to pay attention. That only the elderly.

DR. DWYER: Well, I'm not sure I agree with you because it was placed after "if adults choose to drink alcoholic beverages, they should consume them only in moderation."

DR. GARZA: Well, that says only in moderation and moderation is defined as one drink.

DR. GRUNDY: Why couldn't that be listed as a bullet point under the adverse effects that older people are more susceptible to at least some adverse effects, rather than —

DR. GARZA: Well, but which adverse effects do you think they're more susceptible to, and do we have data to show that?

DR. GRUNDY: Well, I thought there were data. Are there not?

DR. KUMANYIKA: We have them in the Falls literature.

DR. GRUNDY: Yes, the Falls and things like that. I thought there was information that —

DR. GARZA: No, but —

DR. STAMPFER: I couldn't find anything that would fall under adverse effects at the levels of moderation.

DR. GRUNDY: That's what I'm suggesting, is you take it away from the moderation and put it up as an adverse effect of too much alcohol.

DR. KUMANYIKA: So with accidents, if there is evidence that excess alcohol intake increases accidents —

DR. GRUNDY: It's not just car accidents. That's right. It's a broader spectrum of accidents.

DR. DWYER: Snowmobiles.

DR. GRUNDY: Snowmobiles, right, exactly. Bicycles. Boats, airplane pilots.

DR. STAMPFER: The other issue for the elderly is of course elderly are higher risk for coronary disease. So, to the extent that they stick to moderation, they're more likely to benefit.

DR. GARZA: We're defining excess as anything beyond moderation.

DR. GRUNDY: That's what I thought, too.

DR. GARZA: That's what I'm saying. We're not recommending anybody drink beyond — so that you're saying that either some populations that have to worry, to which that excess applies more to others?

DR. GRUNDY: No. I guess what I'm saying is that moderation is not posing a problem in the elderly. It's the alcohol in excess that's posing the problem in the elderly. Now, maybe it's not what Johanna's saying, but —

DR. DWYER: I understand now what your concern is. I guess the issue is so many elderly are taking prescription drugs that I don't know if two drinks in an old man who's on barbiturates — what did Dorothy Kilgalan die of? She died of barbiturates, but was she having more than one drink?

DR. STAMPFER: I don't know. We have a bullet dealing — addressing the prescription — addressing medications.

DR. DWYER: But it doesn't link it to older people.

DR. MURPHY: Actually, it does, especially if you're an older adult.

DR. DWYER: Where does it say —

DR. STAMPFER: The very last box line.

DR. DWYER: You're right. Okay.

DR. STAMPFER: Actually, it didn't use to be there.

DR. GARZA: Then let's move on to the next paragraph on drinking in moderation may lower risk. And the question I have there — I need some help from those — from Scott, I guess. Are Federal guidelines for risk factors for men at 45? I mean, is the age 45 or 40 on the various diet and risk factors for heart disease? I thought it was 45.

DR. GRUNDY: At age 45 is called — age becomes a risk factor in itself.

DR. GARZA: That's right. And so that we're not consistent because we're saying here that it's at age 40. And so it's inconsistent with present policy.

DR. GRUNDY: I think I would say 45.

DR. GARZA: Yes. I'm pretty sure that that's what the NHLBI said is 45. I don't know if Nancy's here. It is 45.

Either we have data to say no, it's really 40 and it's wrong, or we have to stick to 45.

DR. TINKER: We changed that to be consistent with the physical activity.

DR. GARZA: I know, but we create another inconsistency in the process.

DR. STAMPFER: We could make them both 45.

DR. TINKER: Then we're counter to the Surgeon General report for the physical activities. I mean, do we stay true to the basic science for each of them and recognize that they'll be different in each guideline?

DR. STAMPFER: I think they're different because there's an element of arbitrariness. I mean, basically, the idea is that around 40, 45 among men, that's when risk of heart disease becomes a serious population consideration. And before that age, heart disease is less common. There's no exact age where —

DR. GARZA: I think we'll be able to defend 45 because it's consistent with all.

DR. GRUNDY: I agree.

DR. GARZA: Any other —

DR. MURPHY: Women are correct?

DR. STAMPFER: Women are correct. That's right.

DR. GARZA: That's my sense. It is over 50, right?

DR. GRUNDY: Fifty-five.

DR. GARZA: Fifty-five for women and 45 for men?

DR. STAMPFER: Okay. That's what we had originally.

DR. GARZA: All right. Any other changes?

All right. Then let's go to who should not drink and take them one bullet — I think the bullet has been misplaced there.

DR. STAMPFER: Yes. It's not meant to be a heading. That's a separate bullet.

DR. GARZA: I don't think anyone would argue with that, so let's go to the second one. That's pretty inclusive then.

The next bullet on women who are pregnant. And there was some discussion of this in the telephone conference regarding the effects of fetal alcohol syndrome. I mean, alcohol and fetal alcohol syndrome. So take a look at that language carefully.

I think Meir's been responsive to the conversation, as I recall.

DR. STAMPFER: Yes. The point was — well, the text speaks for itself.

DR. GARZA: Okay. The next bullet on individuals who plan to drive, operate machinery or take part. I don't know whether you feel that gives enough prominence to the driving or whether, in fact, you'd like to see it in a box or somewhere else.

Alice?

DR. LICHTENSTEIN: I thought we had actually broken it out of the first paragraph.

DR. GARZA: Well, I was going to say we've added it in the text in that first paragraph.

DR. LICHTENSTEIN: Right, yes.

DR. GARZA: But what I'm saying is, we had talked about a special box.

DR. LICHTENSTEIN: Oh, I see.

DR. GARZA: Do these bulleted items then cover your concerns, or do you still want to see a box that's specific?

DR. LICHTENSTEIN: No, I'm fine with it, just as long as it's its own separate entity.

DR. GARZA: Like this?

DR. LICHTENSTEIN: With the verbiage in the first paragraph that's specific related to driving and accidents and fatalities.

DR. GARZA: So what we said was the language, just to refresh everybody's memory — what was it? Taking more than one drink for women or two drinks for men can raise the risk for automobile accidents, high blood pressure, stroke accidents. Now, is that enough, or — because that's the first specific risk we're mentioning.

DR. LICHTENSTEIN: I personally don't think it's enough. I think —

DR. GARZA: What would be enough?

DR. LICHTENSTEIN: I think it needs its own sentence. However, if other people feel that it's enough, I certainly am willing to go with that, but given the problem in the United States, it seems to me that driving automobiles should not be combined with anything else.

DR. GARZA: You would say risk for automobile accidents, period. It also increases the risk for?

DR. LICHTENSTEIN: Yes.

DR. GARZA: Okay.

DR. WEINSIER: Yes, I support Alice. I think an ideal place for it would be to, at the bottom of that fourth bullet at the end of the paragraph, fourth bullet, to indicate if we've got a statistic, and the one that rings in my mind is that over 50 percent of fatal automobile accidents are due to alcohol or alcohol-related. Something to that effect I think would be a powerful statement to add at the end of that paragraph.

DR. GARZA: Where were you? Back in the first paragraph?

DR. WEINSIER: No, the fourth bullet.

DR. GARZA: In the fourth bullet?

DR. WEINSIER: Under who should not drink, just after "most people retain some alcohol, the blood dropped two to three hours after a single drink." Alcohol is related to over whatever. And if we don't have the statistic, then just what Alice said, something pointing that alcohol is a major contributor to automobile fatalities.

DR. LICHTENSTEIN: Accidents and fatalities. It's accidents, also.

DR. WEINSIER: Okay.

DR. GARZA: So does that mean that you'd like similar specificity to the percent of alcohol abuse? Women that — you know, are we singling out one problem and not paying significant attention to others?

DR. WEINSIER: Unless we have evidence the others are anywhere near that magnitude, but I think Alice is right. I mean, this is an exception.

DR. GARZA: Well, I'm asking. I don't know. I don't know the data that well.

(Multiple speakers.)

DR. GARZA: There are more babies born every year with alcohol syndrome than there are people killed. I just don't know the answer.

DR. LICHTENSTEIN: In car accidents?

DR. GARZA: In car accidents.

DR. DWYER: Many more in cars.

DR. GARZA: Due to alcohol. Is that true? I mean, I don't know.

DR. WEINSIER: Well, the figure that I'm accustomed to hearing is that over 50 percent of automobile-related fatalities are alcohol-related.

DR. LICHTENSTEIN: I don't know anything about the numbers at all. It just seems like major social issues —

DR. GARZA: I'm not arguing.

DR. LICHTENSTEIN: But I think that then fetal alcohol syndrome deserves its own sentence, also. I just am very concerned when you get a list of things in one sentence. That's where I'm concerned.

DR. GARZA: We're arguing two different things right now. I think we're through with the fact we're going to put driving in one sentence. What Roland is saying is that we need to add some statistics or something to the bullet. And I'm wondering if we're going to do that, then because — it's very unwise for committees to have their own personal interests highlighted.

All I'm trying to doing is if they're chariots to say Roland may have an interest in automobile accidents, if we're going to do that, then we need to make sure that, in fact, numerically we're correct and we're dealing with all these problems in a fair manner.

DR. STAMPFER: One problem with — well, I don't know if it's a problem. But if we put it under "Who should not drink," I mean, obviously, most of those automobile accidents are not from after drinking at the levels that we're permitting; they're from excess alcohol. But I guess we have that for the birth defects, too.

DR. GARZA: I think that we — there's nothing wrong with highlighting for people why it's such an issue in this country. We would probably need to do some homework to make sure that we've got the numbers on our other bullets to see if we can give them equal — and if we find that as

Roland and Alice feel, that in fact this so dwarfs it that we don't worry about it because it's clear that this dwarfs all the other problems.

And I suspect they're right. I just don't know the answer.

Okay. And the last one, taking prescriptions.

DR. STAMPFER: Just to refresh everyone's memory, this was a change from the '95 guidelines, which basically said — left off that phrase "that can interact with alcohol." So, the implication was that anyone taking any medication of any sort should never drink. And we had previously decided that that was too broad.

So, this was an attempt to focus it. We did try to come up with some kind of lists of drugs that fall under this category, but there are too many to list. It was too cumbersome. So, we fell back on the recommendation to refer them to their health professional.

DR. GARZA: Meir, is it possible to list the 10 most commonly used drugs? Rather than trying to be inclusive, I mean, what we've done in other boxes is list those that numerically are the most important. Would that be helpful here? Especially, for those drugs, for example, among the elderly, if that's the group we're most concerned about. Highlight a box that says that?

DR. STAMPFER: I don't know. We could try it.

DR. GARZA: That data should be available from the FDA.

DR. STAMPFER: Well, it was surprisingly unavailable when we tried to get that. Let's see. Joan, was that you or Kathy?

MS. MCMURRY: I'm sorry. Which information?

DR. GARZA: The list for drugs was so extensive that would it help if we listed the 10 most common drugs or something?

DR. STAMPFER: And it sort of relates to dose and individual. Some people have it. Some don't.

MS. MCMURRY: It was quite ambiguous and long.

MS. LYON: It may change over the course of five years, too.

DR. STAMPFER: I think we're better off leaving it as is, actually.

DR. GARZA: I'm not arguing. I'm just trying to make sure that we cover the concerns on the elderly that were voiced.

Alice and then Richard?

DR. LICHTENSTEIN: Is there any warning on the label that this drug should not be taken with alcohol? I don't know. If there is, then perhaps that would solve the problem by putting "check the medication label to see whether it's compatible with alcohol intake" or something like that.

Does anybody know?

DR. GARZA: Over-the-counter drugs will sometimes say that. Benadryl and some of those types, for example, will say.

DR. LICHTENSTEIN: And what about prescription?

DR. GARZA: But I don't know about the prescription drugs, I don't think — well, the insert's now coming more commonly.

DR. LICHTENSTEIN: No, no. I actually mean on the label.

DR. GARZA: Exactly.

MS. LYON: They put stickers on the side of the bottle that say —

DR. GARZA: Makes you drowsy.

DR. STAMPFER: They do that for everything.

DR. LICHTENSTEIN: Is that true, that there's nothing specific for alcohol, on a prescription drug, none of those stickers or —

MS. LYON: My pharmacy puts them. It says, "Don't consume" — you know, "Don't take alcohol while you're taking this."

DR. LICHTENSTEIN: Maybe could we just find out whether that's an arbitrary — it's regulated?

MS. MCMURRY: I'll find out.

DR. LICHTENSTEIN: Yes. And if it's regulated, then it may help to just say, "make sure you read the bottle to see if there's any warning."

DR. GARZA: Richard?

DR. DECKELBAUM: I think it's probably uneven if it's regulated because there are certainly some drugs where it's not on the label.

DR. STAMPFER: It's a little bit — I think we open ourselves up a little bit to some risk if we rely on people to read the labels.

DR. GARZA: I don't think anybody's arguing that we should not include the phrase that's there. It's whether there's additional.

DR. STAMPFER: Oh, to add. Okay.

DR. STAMPFER: I just think in terms of perception, these medication/alcohol interactions also occur in the young people. And when reading it here, it says, "especially if you are an older adult."

Does anyone agree that this gives the younger people leeway to not be concerned when they take medication?

DR. GARZA: But I hate to say this, but we're recommending this, that if you're going to drink, that it's only a benefit if you're over 45 or over 55. So that probably — you know, a young person wouldn't see themselves in that age category.

DR. DECKELBAUM: The thing is that we're addressing alcohol intake even if the benefits — if women have to wait till after the age of 55 to start drinking, it doesn't matter. But some of them

are going to have drinks before the age of 55. And if they're taking medications, I just think it makes — it sort of excuses the younger people who are trying to get healthier earlier from the danger of some of these interactions.

DR. GARZA: Johanna?

DR. DWYER: I think you raise a good point. Meir, I don't know enough about this work, but I've read some of Henry Wexler's papers and others on young people, especially young adults, where I believe the clustering of the motor vehicle accidents and deaths that we were just talking about occurs. Maybe we need to single out that group. It's really not children and adolescents. These people are legal drinkers.

DR. DECKELBAUM: Young adults.

DR. DWYER: Correct.

DR. DECKELBAUM: Twenties and thirties.

DR. DWYER: Well, it's really — his studies are late high school and college.

DR. STAMPFER: But what's the suggestion?

DR. DWYER: Single them out as another group who shouldn't drink or drink only with great caution. I guess it's probably hopeless to say.

DR. STAMPFER: Well, we have children and adolescents that shouldn't drink at all, and we also have a comment about risk of alcohol abuse increases with early age and initiation of drinking.

DR. DECKELBAUM: I would strike out especially if you were an older adult, even though I know we probably discussed it previously.

DR. GARZA: Now, remember a few minutes ago, we

wanted — we were sure because that clause was there. So, you can't have it both ways.

DR. LICHTENSTEIN: I would strongly argue to keep the older adults in there. There are a

higher proportion of them that are on medication, but also because of the physiological changes that occur that were already mentioned. I think it's really — and they're so much more susceptible to injury if they do fall. I think it's really critical that older individuals be targeted.

DR. GARZA: Okay. We have two opposing views. Can we have a show of hands? All those that want to see the warning to older individuals highlighted, please raise hand. All those that would like to see it deleted, raise your hand. Okay.

DR. GRUNDY: Well, why couldn't we have it another way and have both?

DR. GARZA: Well, what would you like to have, Scott?

DR. GRUNDY: They're two different issues really, I think.

DR. GARZA: So, how would you —

DR. GRUNDY: And maybe they could be — I think what you're saying is that alcohol — the emphasis has been on the moderation. But alcohol is a major nutrient in the diet and

it — or in the American public anyway, and that we have to highlight all the dangers that are associated with it. And I think what you've identified is a very important danger, and somehow it ought to be listed here, that young adults that are drinking are highly prone to accidents or something like that.

DR. DECKELBAUM: They are also susceptible to these drugs —

DR. GRUNDY: The drugs, too, but that — I know it's about the drugs, but it's a combination of things.

DR. GARZA: No. We don't say that you don't have to worry about it. I mean, there's individuals taking prescriptions over the counter. It includes everyone. So they're not excluded. So, how would we deal with that, I mean, in terms of — would you want two separate bullets? One that's targeted to young adults and one that's targeted to the elderly? And then saying the same message?

DR. DECKELBAUM: Well, I just been outvoted.

DR. GARZA: Well, no. Scott tried to rescue you.

DR. GRUNDY: I'm trying to rescue you by saying that it's a different issue in a way. I mean, maybe it's an interaction, but it's an exacerbating factor and a major problem of overdrinking in young adults and the accidents. Right? And so, it's — there's the generic problem and it's made worse when they take drugs in addition. But I don't know whether that deserves a separate — could be included in the bullets of adverse effects or not.

DR. GARZA: I'm thinking we could possibly deal with that in the first paragraph.

DR. GRUNDY: That's what I'm thinking, too.

DR. GARZA: But then, do we say this applies especially to young people? And then, does that give older people a license to drink?

I mean, that's why I think it's important that we read the whole context of the guideline. And the context of the guideline says, "Don't drink." I mean, that's the first sentence, is "alcohol beverages are harmful when consumed in excess."

And then we decide if you're going to drink at all, drink only in moderation. And then we define moderation for everyone. So, unless we have — I mean, I don't know how we would phrase it that the age group that is most potential for abuse are young people. And is that true? Or is that are perception? Therefore, we want to highlight young people? Is young 20 to 35 or —

DR. GRUNDY: Isn't that true that a high percentage of the accidents, the motor vehicle accidents and other accidents involving moving things, occurs in young people?

DR. GARZA: No. I think in general, yes. I don't know whether it's alcohol-related, though. At least insurance rates would certainly mean that young people have accidents more easily or frequently, but I don't know whether it's alcohol.

DR. GRUNDY: I don't know. I don't know the answer to that.

DR. MURPHY: I think we can get that easily if somebody can call NI — whatever it is, the National Institute of Alcohol Abuse because they've got all sorts of stuff.

DR. GARZA: So, if we find that that's true, then would we say something in that paragraph

after that sentence on driving? The highest rate occurs among young people or something?

DR. STAMPFER: I think that would be a risk. We're saying, you know, if you're middle-aged, you know, you can handle it. You're experienced driver, you know. Had a few drinks, it's okay.

I think every time you single out a group for special care, you're letting another group off the hook a little bit.

DR. DECKELBAUM: That's what I was saying earlier.

DR. STAMPFER: But I think for the elderly, you have some physiology behind it. With the young people, it's just the rates of accidents.

DR. GARZA: All right. Alice?

DR. LICHTENSTEIN: Well, I was just going to say, I think it's particularly important for the elderly because it's a change. They may have been able to handle things and then as their physiological changes, they no longer can. That's why it's important to keep that in.

DR. GARZA: Okay. Then I think we're on to research or the rationale.

DR. STAMPFER: We have advice for today.

DR. GARZA: Advice for today.

DR. STAMPFER: It's on the last.

DR. GARZA: Advice for today.

DR. STAMPFER: But we didn't do Box 22, but —

DR. GARZA: Oh, we've been through Box 22 a couple of times, but we could go through it again if you like.

I think it's all right, though, right?

DR. STAMPFER: It's unchanged.

DR. GARZA: It's not changed. That's why I think I skipped over it. There is a box. It's listed incorrectly. It's Box 16.

So, advice for today.

DR. DECKELBAUM: Is there no fiber issue here?

DR. STAMPFER: We tinkered with the wording a little bit for advice for today. That's why there's underlining there.

DR. DWYER: There's no place in here where we say

it's — this is a nutrient or a calorically dense beverage.

We never say it's a junk food.

DR. STAMPFER: Well, we give the calories, though, in the box.

DR. LICHTENSTEIN: And also with nutritious foods because alcohol contains calories that may substitute for those nutritious foods.

DR. DWYER: I don't think it stresses the adult junk food aspect of alcohol as much as it needs to.

DR. STAMPFER: Well, we have it there twice.

DR. DWYER: Where? I see a whole bunch of things listed.

DR. STAMPFER: Well, we have the caloric content of the three main types of beverages. And then we have the substitution issue.

DR. DWYER: Maybe I'm missing the substitution. Where is it?

DR. STAMPFER: Risk of malnutrition.

DR. DWYER: But that's — I don't think that's quite the point I'm trying to make sure we cover. And that is that even among people who are not heavy drinkers, a couple of drinks of alcohol is a

sizeable amount of high caloric density, low nutrient density food.

DR. GARZA: Would you like to add in Box 22, Johanna, a sentence at the end that says that "alcohol can also contribute significantly to your caloric intake?" I mean, is that — and then we've got the calories listed in the box. So that is drinking in moderation? That, even drinking in moderation adds significantly to your caloric intake?

DR. DWYER: Yes, that's fine. Alcohol can contribute significantly to your caloric intake. It adds seven calories.

DR. GARZA: Well, I know it's in the weight guideline. I was aware of that. But I think Johanna was arguing that, in fact, if you're going to be reading the alcohol guideline, that given it's — I don't see any concerns about — it still can be in both places.

DR. STAMPFER: So, is that a general consensus?

DR. DWYER: The other thing about it, Meir, maybe you found that there wasn't good support for this, but Charles Halsted and other people have done studies suggesting that satiety mechanisms are bypassed by alcohol. In other words, the hunger in satiety you would get from other foods is not quite the same when you're drinking; that it tends to add on. The calories tend to add on.

DR. STAMPFER: Well, I think there's some controversy about that, how much it adds on. Actually, I think there are gender differences. Actually, women tend to replace sugar. Men tend to add on.

But I guess I wasn't as persuaded as that being important enough to put in the guideline.

DR. GARZA: Suzanne?

DR. MURPHY: Well, I think a lot of people have reported negative associations with alcohol consumption and body mass index. And I think it's particularly in women. It's a little hard to make a case.

DR. GARZA: Okay. Advice for today then?

DR. TINKER: One more. In advice for today, I know in the last conference call, we added intake

with meals to slow alcohol absorption, but that's the first time it appears is in the advice for today. So, I don't know if we need to put it in the guideline, the text section as well, or whether it's okay to just have it appear spontaneously in the advice for today.

DR. STAMPFER: Seems okay to me.

DR. KUMANYIKA: Where would you put it?

DR. TINKER: That's what I've been looking at.

DR. STAMPFER: One of the issues with this guideline that sort of Scott kind of highlighted is the emphasis is on moderation, but in fact, most of the emphasis is on excess drinking. And there's hardly any that's actually related to moderation. There's just a couple sentences.

DR. TINKER: That's why it's hard to find a place to put it.

DR. GARZA: I don't know if we should be bothered by it. It's sort of an actionable thing that people can —

DR. STAMPFER: Yes, there was some — I think we discussed this previously — comments, public comments saying, with food rather than meals. But I think the sense was that when — meals provide more calories enough to really sustain a slower absorption, whereas if you have it with food, it could be your canape while you're —

DR. TINKER: Well, that I agree with. It just occurs for the first time in the advice for today. I'd been thinking of advice for today as kind of the summary of the key points of what's in the text and the boxes of the guidelines. But I just made that up on my own.

DR. GARZA: Would you like to have a discussion of the physiology of absorption?

DR. TINKER: No. It could just be as simple as it is in the advice for today, but not have it come up the first time in the advice for today.

DR. GARZA: Where would you change it?

DR. KUMANYIKA: What about Box 22?

DR. TINKER: It could be in Box 22 where we talk about what is drinking in moderation?

DR. GARZA: So, drinking in moderation is drinking with your meals?

DR. JOHNSON: Or I think you could put it right after the sentence about men over 45 and women over 55 because that's where we're kind of saying this is the benefit of drinking in moderation. Then we could say, you know, drink with meals to slow the absorption.

DR. GARZA: Shiriki, and then we'll go to Meir.

DR. KUMANYIKA: I was a little worried. I thought about putting it in Box 22. And then I wonder what is this point because if the point is to reduce the chance of inebriation, then putting it in Box 22 may make people think, "Okay, if I drink this with meals, I can get two of them." So, I mean, what is the point? I don't think it changes the HDL issue or it doesn't change the risk. It changes your likelihood of having behavioral effects.

DR. DWYER: But those are the lethal things.

DR. KUMANYIKA: Well, not for that level of moderation. That's what I'm saying. It seems to me it would almost encourage people to drink more if you talk about drinking five ounces of wine and then take with meals to slow the absorption. I don't know. I like it where it is.

DR. STAMPFER: For what's it worth, in the '95 guidelines, it also came up for the first time in advice for today.

DR. GARZA: Roland?

DR. WEINSIER: Yes. I think a perfect fit would be add on part of the last sentence of the first paragraph because that's where you're saying if you choose to drink alcoholic beverages, they should consume them only in moderation and take with meals to slow alcohol absorption. So, if one didn't choose earlier, that would probably fit okay.

DR. GARZA: Okay. Does that seem like the reasonable solution for everyone?

DR. KUMANYIKA: Yep.

DR. GARZA: Okay. Any other comments on advice for today? And if not, let's go on to research

in the future.

DR. STAMPFER: There's a few references I sought to put together for the rationale.

DR. GARZA: I'm sorry. Are you going to the rationale? I got ahead of myself.

DR. STAMPFER: But since the changes were small and not substantive, the rationale section is pretty short.

In fact, I'll welcome any comments or suggestions.

DR. JOHNSON: It still starts out in the first paragraph that it's going to be a second-tier guideline that receives less emphasis than the —

DR. STAMPFER: Oh, yeah. Sorry about that. Right. I've got to change that. Perhaps keep that in mind for whatever the final decision is.

DR. GARZA: There was an earlier version of the rationale that appeared to have much more documentation than the current one. Was that cut back, or am I not remembering that correctly?

DR. STAMPFER: No, I think this is a different version. There is one that has more, somewhat more. I'll have to check with Kathryn to figure it out.

MS. MCMURRY: You might be remembering an earlier discussion that Meir prepared.

DR. GARZA: That's right. Because this one really has a very limited discussion, even of the putative protective effects and the ages. It's again more who should not drink,

but —

DR. STAMPFER: Well, I guess I didn't put that in because we're not changing it from the previous. I thought the focus was on changes from the previous. And the previous guideline had all that in there.

DR. GARZA: But we didn't have the ages.

DR. STAMPFER: It didn't have the ages. That's the only thing. And I can beef that up. But

basically, it's based on the lower rates —

DR. GARZA: If you think that's all that's needed because this guideline will be scrutinized by almost everyone. So, we make sure the rationale is —

DR. KUMANYIKA: Well, this comes back to something that Scott mentioned about the salt guideline, and I looked back at the rationale. If you have two or three revisions of the guidelines with no major changes, then the actual rationale for the guideline is buried back in the Brown Book or the Red Book or whatever it was in 1985 to 1990.

So, I'm wondering at some of the evidence that I thought was in there for salt is not actually in there anymore because we didn't change — it didn't change. Maybe we could talk tomorrow about putting a certain amount of basic supporting evidence in every rationale, not just we didn't change this and carry it on from before because —

DR. GARZA: You mean a synopsis of —

DR. STAMPFER: I mean, we could just refer readers to the previous one. Why not?

DR. KUMANYIKA: Or the one before that.

DR. STAMPFER: It's available.

DR. GARZA: That's what scholars do. Right? Scott?

DR. GRUNDY: I want to follow up on what Shiriki said and not depend on the previous ones. I think each one has to stand on its own, even though it may be summarized from the previous one.

The evidence up to a certain point of — up to the last time, I think, ought to be at least summarized so that someone can take this Green Book and get the essence out of it and not have to go to the previous one because I think there's some concern about if you refer always back to the last one, the foundation may erode.

DR. GARZA: So, you're suggesting that we have a summary and then also cite in those three so that if people want to go back and look at the detail —

DR. GRUNDY: They can, but it ought to be summarized.

DR. GARZA: Okay. Meir and then Suzanne?

DR. STAMPFER: I disagree with that because when we first came into this, our charge was to justify changes. And we were specifically, and we keep getting reminded that we can't go back. But we have a higher bar to pass for changes than for the original. And if we were recreating the guidelines from scratch, you know, I think they'd be different from where they are right now.

And I think it's misleading to give the rationale as though we've done that. We haven't. We're given what came to us, and we can only make changes with strong evidence even though weaker evidence was allowed in the past.

DR. GARZA: The other point to remember is that the Green Book is not intended for consumers, so that there will be other scholars who, in fact, will be using it, or individuals that are not lay individuals. Lay people may get it, but they're never the intended audience for the Green Book. So that in fact it may not be such a harsh task to ask that type of individual to go back and look at those earlier rationale.

DR. STAMPFER: Suzanne was next.

DR. MURPHY: I'm invisible. I'm in your blind spot.

I was going to add another reason for maybe not taking on the new tasks so late in this particular game because the way I might summarize all the back stuff would be different than the way other people would. And we're going to have to have a whole other round of review of documents, which I think is pretty late to start doing that.

DR. GARZA: Well, awfully convincing, I think.

DR. LICHTENSTEIN: I'm wondering if we can make a strong recommendation that the previous additions be put on the Web to increase the availability in those Web sites, if it's possible to have that done, actually be printed in the new Green Book so that it'll make it easier for people to actually access it.

DR. GARZA: I think recommendations are easy. It's the fulfillment — it would make sense.

DR. LICHTENSTEIN: It's a way of getting around things.

DR. GARZA: It's standard. It's not a major issue. I mean, you can scan them in.

DR. LICHTENSTEIN: You know, I don't think it's that easy to get back issues of things all the time.

DR. GARZA: Okay.

DR. GRUNDY: I want to just put my vote in to disagree with that because I think that this committee is charged with reevaluating the whole situation and not just saying, "What has changed since last time?" And I think people are interested in how we view the state of the problem right now. And even if it's a couple of paragraphs, at least we confirm that the previous recommendations were valid in the light of what has happened since that time. I think that ought to be in there.

DR. GARZA: I think the concern, Scott, that some people have is that there may be some disagreement with the weakness of the evidence in terms of the previous guidelines. And then, to ask if — specific people then to defend what they weren't involved in is going to be difficult. But yet they didn't have the evidence that said they changed it, either.

Is that your concern, Meir?

DR. STAMPFER: Yes.

DR. GRUNDY: You mean, that we can acquiesce in previous mistakes? Is that what you're saying?

DR. GARZA: I would suggest that if, in fact, one can reasonably summarize the rationale for what you did, then

that — and it includes then text that was not changed, I don't see any reason for not including that. You may have the choice to do it either way.

DR. DECKELBAUM: But if you take the example of fiber, you know, previous editions were strongly based on, you know, let's say one major factor was the cancer prevention effects of fiber. And also, I think it was raised in an earlier edition, the association of fat and cancer.

And the data that's coming out now suggests otherwise. So that, you know — and we're using other rationales to justify, let's say, grains or perhaps fruits and vegetables. And I think what Scott says is appropriate, is to include the — you know, the new database and how the old database, even though it may have been consistent with what we're saying, was built on different rationales.

DR. GARZA: That's what I'm saying. That you should use that. You should take it under your own personal advisement that in order to build your case, it's necessary to do what Scott is suggesting, then by all means, you should. If it's not, and as we review the rationales, you feel that that's missing, and want to recommend that it be done, give specific guidelines. And as you review the rationale, then bring those forward.

But it's easier to say that, I think, then to say, "Well, go back and do it, regardless of whether you think it's essential or not or necessary."

DR. DWYER: Let's make Carole Suitor do it.

DR. GARZA: Okay. Now, tomorrow — research.

DR. STAMPFER: I'll be brief. I tried to think of the single most important research need that I could to keep the discussion focused. And I think what I could come up with as the single most important research need, and I'll welcome other suggestions, is that we're faced here with a food or a dietary item that in moderation is — it's associated with really markedly strong reductions in risk of cardiovascular disease and total mortality, more than many of the other foods that we're talking about.

And we're in the uncomfortable situation of emphasizing the negative aspects because of our society's problem with excess alcohol.

So I think my number one research suggestion would be to find out how we can — well, if and how we can promote moderate alcohol consumption among adults, especially

middle-aged and older adults who are most likely to enjoy the benefits, if this can be done in a way that would not increase alcoholism in those groups or spill over to cause younger age groups to drink more and create problems.

So, that was my number one research problem.

DR. GARZA: Are there any other comments?

DR. GRUNDY: All I can about that is wow. All I can about that is wow. To get more people drinking. Is that what you said?

DR. STAMPFER: Pardon me?

DR. GRUNDY: Say again what you said in your research. Well, drinking in moderation, I guess I took that a different way.

DR. STAMPFER: Well, yeah. I think the research need is to figure out how we can get the benefits of modern alcohol consumption without having — without promoting excess alcohol use, in a nutshell. And in particular, that is how can we promote moderate alcohol consumption, especially in middle-aged and older adults who are most likely to benefit and likely to benefit very dramatically. Can we do this in a way that won't increase alcohol problems?

DR. GARZA: Given the physiological effects of ethanol and its dependence. I mean, do you mean some finding some pharmacological way to avoid —

DR. STAMPFER: Well, we know that alcohol dependence problems are more — they're more common with early initiation of alcohol. And we really don't know what happens to people who first start drinking much as middle-age or older people. Are they at risk of alcohol abuse? I don't think we know that.

DR. GARZA: I thought that we had asked the director of the Institute — the Alcohol Institute, that question specifically, and he had said yes. There's no — that the risk for abuse is not age-dependent.

DR. STAMPFER: Well, we can check the transcript to see what he said, but the article that came out of his institute shows that it's very strongly age-dependent. And the earlier you start drinking, the more likely there are to be alcohol problems. That particular study ended around the 20s, initiation around the 20s. And there were no data that I'm aware of for initiation at older ages.

And if older people could be encouraged to drink moderately without risk of alcohol abuse, that might be good. It's a research question. I'm not suggesting it.

DR. GARZA: Johanna?

DR. DWYER: I think that's an interesting topic. It's just difficult to study because many of the people who are in their 40s and start drinking are people who were — perhaps had religious reasons or some other reason not to do it. And when they start doing it, it's because they've thrown a whole bunch of things aside and gone hog wild.

DR. GARZA: I think just to be careful so that it won't be taken as Scott originally thought —

DR. GRUNDY: I think the words "encourage" and "promote," things like that concern me. I think we have to be careful with the language. If you want to say find out how people drink, could be convinced to drink only moderately or something like that, that would be good.

I think if you're going to suggest that people who don't drink learn to drink moderately, then I think you're playing with fire. I mean, I think you have to be careful how you say that. That's all.

DR. GARZA: I think so. It's just a matter of making sure the focus is on the — the question is focused appropriately.

Okay. Now, before everybody gets too relaxed, we have one guideline to do tomorrow. And we have to go over the introduction. And we also then have to go back and look at variety. The adequacy guideline, there were a number of issues that we left open.

I don't think that we need to revisit any of the others, but I want to make sure that that's true. I mean, is everyone satisfied that you've reviewed the material, or are there issues that are left hanging that we need to cover that relate specifically to either guidelines or the rationale at tomorrow's meeting?

DR. JOHNSON: Any of the other guidelines?

DR. GARZA: For any of the others. I'm aware that we need to come back to two. There was one that I asked Kathryn to remind me of, was on the daily. Several of the guidelines. We need to review the adequacy and go through at least four or five issues that we said we'd come back to.

DR. JOHNSON: Yes. I had asked for us to review the kids' food guide pyramid.

DR. GARZA: That's right. And we've got the — that was part of one of the four or five things in

the adequacy guideline.

DR. DWYER: And what about these overarching issues like — some of the guidelines, in my view, are being asked to carry too much of a burden. And it seems me there are overarching issues that we've sort of seguaed around, on fiber, on calcium and on carbohydrate, starch.

DR. GARZA: We can have those discussions, but I need for somebody then to say they will lead each one and have them science-based, because if we're going to have a discussion on fiber, I mean, I don't know what we're going to say unless somebody can tell me, and I'll raise the issues in calcium. Because otherwise, I don't know how — remember, all the transcripts are read, and we want to make sure that people have a chance to think about them.

Aside from being — I mean, we can raise it to be aware of them as we read them, but is there more?

DR. DWYER: Yes. I have one specific question. Do we have anything on the books from earlier than '95 when there still was a guideline that said carbohydrate and fiber? What the Green Book said?

DR. GARZA: I thought we had all been sent all of the rationale, so they should be in your office. We were sent all of them.

(Multiple speakers.)

DR. DWYER: Well, is there one around that we can look at?

DR. GARZA: Tonight?

DR. DWYER: Tomorrow.

DR. KUMANYIKA: Is it covered in this thing on the evolution of the guidelines that we have in our notebook?

MS. MCMURRY: That's really abbreviated.

DR. GARZA: That's really very abbreviated. I mean, if you're going to look at it, I mean, I'm just concerned that our discussion, if we're going to have one, that it not be focused.

DR. DWYER: I'll tell you my concern. The problem is we've got part of carbohydrate in one guideline on mono and disaccharides. And then we have part of it in grains. Fiber is cut — cuts across two guidelines. And starches are really not dealt with anywhere.

And it seems to me that we have to talk about that in research. There's several other areas that we may have just let go.

DR. GARZA: For research purposes or for guidance?

DR. DWYER: And also for guidance.

DR. GARZA: Well, if for the guidance one, I think what we may want to do is maybe schedule a telephone call so that someone then can lead it and we can structure it in some way. But if we have a discussion tomorrow on starch, I'm not sure where it would lead us.

DR. JOHNSON: I agree with the calcium, and I'd be willing to help with that.

DR. GARZA: Now, let's assume that we raise calcium.

DR. JOHNSON: No, I mean if we do a phone call.

DR. GARZA: Oh, if we do a phone call.

DR. JOHNSON: Because there's been a movement that there should be a guideline for calcium. I think we need at least to address how we're getting that. I think it's too late for another guideline, but I think we need to think about how it's integrated.

DR. GARZA: Okay, thank you for that reassurance, because we did have that discussion at the very beginning. And as I recall, the discussion is that we wanted to get away from nutrient-specific guidelines. We felt that we had too many, that they've given us trouble from the very start, and that they're difficult to deal with when they're nutrient-specific.

DR. DWYER: Well, they could be, but we're older and wiser now. And some of these things cut across the various —

DR. GARZA: Johanna, I'm not arguing about having the discussion. I want to make sure that the purpose for it is clear, and that it's primarily for research or to help us some dot some i's or

cross some t's as we look at all of the guidelines and the rationale. That's fine.

If you think the outcome is, do we mean the guideline, then I need to structure that discussion very differently.

So which is it, just the former? Okay.

But we'll try to do that between now and — I think we can get through tomorrow then if we do the introduction. Take a look at how we grouped the ABC's. That has an implicit tiering. I think we have to think of the fact that once you have an A and B and a C, that some things from A are important; B, less so; and C are the least, because they sort of reflect grades.

As I thought about how will a consumer think about

this — there are other things you need to think about — so you look at those tiers, think about them, the grouping, what they represent. And we'll do that after the moderate sugar guideline.

And we'll do introduction. Then we'll come back to these other issues. And I think we'll be able to finish by the scheduled time if we don't have to reopen any other issues. If not, we need to do introduction tonight.

(Multiple speakers.)

DR. DECKELBAUM: I would just ask in terms of the grains guideline, in view of the issues I raised and the type of research that we're using to justify the guideline, that I'm still concerned about the meaning and perception of several.

DR. GARZA: We settled it. I mean, unless —

DR. DECKELBAUM: No, because I think I would appreciate if someone from staff, people who have access to dictionaries can look it up because I'm concerned about that perception. And also, I'm a bit puzzled by the people who — I mean, the big vote. Most of the majority are voting for especially whole grains. And these are the, by and large, the same individuals who are raising concerns about the type of research and whether we have too strong of an emphasis given these issues.

And I'm not — so I'm not putting it to bed. I am raising it again, because I'm concerned about it.

DR. GARZA: And I appreciate that. But one of the things that groups like this can get into is coming back continuously to revisit issues. And if, in fact, I get eight of you coming back and saying, "Gee, we have to revisit it," then I'll be happy to revisit it. But if there's only two people — if there's only two people that want to revisit it —

(Multiple speakers.)

DR. GARZA: Well, there's three then. You know, that still leaves seven people. Because then we're going to revisit every single item where, in fact, there's two or three people that don't agree with the others. And so it's difficult.

So I would urge you to do your lobbying, recruit others to your purpose. And we can revisit it either tomorrow or on the telephone. But without that, it really makes the process a very difficult one. And you know how I feel about this one.

The only thing that we need to make sure that we do is for tomorrow, think about a schedule where each of you can summarize your research recommendations, because in fact those need to be looked at in prose. We've not done that.

DR. DECKELBAUM: Do those go with each at the end of —

DR. GARZA: Of each rationale.

DR. KUMANYIKA: So we should do that by when?

DR. GARZA: No. Just think of the schedule of when we're going to be making those — you know, when you can — due to the fact that we've got to complete this, then I would hope that you would be able to give us this by October 10 or something or 15.

DR. TINKER: Would that include a sentence about why each one of them is important?

DR. GARZA: Yes. I mean, it's not just a matter of just a paragraph with documentation. We just can't say, "Gee, we came up with this list of 10 things," and not explain why. There should be a rationale behind each of them. It doesn't have to be very extensive, but at least, you know, why is this an issue?

DR. LICHTENSTEIN: What kind of documentation? Just prose?

DR. GARZA: Yes. If the reference is that — if there are two conflicting references, then give two conflicting references.

DR. DWYER: If we do that, then is that the end?

DR. GARZA: That's the end.

DR. KUMANYIKA: We're not meeting again?

DR. GARZA: We're not meeting again. Now, having said that, what I'd like you to do is still keep those December dates just in case. But I mean, I don't see that we've got issues that would require everybody to come back to Washington and spend three days. And we would develop something each day. That's very true.

But because we've not finished, I don't want you to give up those December dates and then come back and say, "Well, gee, you know, you told us that we weren't going to meet again. And so I gave those up." That was the whole object of getting you to save them back in June.

DR. DECKELBAUM: Does this mean not have a closing party?

DR. MURPHY: Well, we could.

DR. GARZA: By conference call or something to that effect.

And at the risk of making everyone sort of irritated, the only possible rationale I can see for a November/December meeting is if when we get the research pieces, if we want to come together and talk about them and spend at least one day or at most two days. Because in my experience, Scott has heard me get on the soapbox, that's the issue that always gets shortchanged in any committee process.

And if we were willing to say we put the guidelines and the rationales to bed, we can't raise I want to revisit a guideline. But I think we want to look more carefully at our research recommendations, give the department at least — we've all been thinking about these issues more than the five minutes that each of us was able to spend today and yesterday on research. Because that's where your expertise lies.

And I think it's ironic that we get people like this together and we get so focused on the task of

the guidelines and the rationale that we don't do the — what we probably are best equipped to do, is to say, "Well, what sort of — are the research issues that made your work most difficult," because they weren't resolved.

I mean, we'll save the dates, but outside of that, maybe that would be the time for the party.

Okay. So, we'll do the introduction. We'll do sugars, introduction and the daily and the — there was another one.

DR. DECKELBAUM: Which one?

DR. GARZA: Well, the pyramid. But that's part of the adequacy guideline.

DR. DWYER: Are we going to have a class picture?

DR. GARZA: I'm sorry?

DR. DWYER: Are we going to have a class picture? I'm serious.

DR. GARZA: We should. I didn't bring my camera.

DR. DECKELBAUM: I was asked to do a couple of lactose sentences.

DR. GARZA: Oh, that's right. That's right. I think Shiriki said she would help you with those, on the lactose.

DR. KUMANYIKA: I was going to work on that section.

DR. GARZA: Okay. So, is that a work plan that's acceptable to everyone? All right.

Thank you. You've been great.

(Whereupon, the meeting concluded.)

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Washington, DC
Place of Hearing

September 8, 1999
Date of Hearing

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