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FOOD ADVISORY COMMITTEE MEETING

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

FOOD ADVISORY COMMITTEE MEETING

Wednesday, June 17, 1998

7:45 a.m.

Sheraton Reston Hotel
11810 Sunrise Valley Drive
Reston, Virginia

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

PARTICIPANTS

Edward N. Brandt, M.D., Ph.D., Chairman
Lynn Larsen, Ph.D., Executive Secretary

MEMBERS

Rhona Applebaum, Ph.D.
E. Wayne Askew, Ph.D.
Stephen H. Benedict, Ph.D.
Henry W. Blackburn, M.D.
Bruce M. Chassy, Ph.D.
Katherine L. Clancy, Ph.D.
Fergus M. Clydesdale, Ph.D.
Owen R. Fennema, Ph.D.
Naomi K. Fukagawa, M.D.
Susan K. Harlander, Ph.D.
Morris E. Potter, D.V.M.
Donna R. Richardson, J.D., R.N.
Mary Y. Wang, Ph.D.

TEMPORARY VOTING MEMBERS

William S. Blaner, Ph.D.
Tim Byers, M.D., M.P.H.
Manning Feinleib, M.D.
Van S. Hubbard, M.D.
Steven H. Lamm, M.D., D.T.P.H.
Barbara A. Underwood, Ph.D.

C O N T E N T S

P R O C E E D I N G S

Labeling

DR. BRANDT: It is 7:45, time to begin. This morning, our topic is going to be labeling, following which we will have all the presentations on the labeling issue and then discussion on that topic.

Then we will open up and we are going to go around and poll everyone about your views on the three questions. We do not vote. Each of you is here because you are at least allegedly an expert on something. Therefore, that is what the FDA needs. Remember, the FDA has all the options they need, including ignoring us, should they choose to do so, which is fine.

Or they can accept everything we say or nothing we say or someplace in between. Just to give you the sort of ground rules under which we are operating.

I want to begin by thanking the graduating members of the committee, Dr. Harlander, Dr. Blackburn, Dr. Benedict, Dr. Clydesdale, Dr. Applebaum, Dr. Clancy and Dr. Wang, our perpetual tourist who goes around taking pictures. We appreciate everything. I have enjoyed working with you. Recognizing that feeling may not be mutual, I have enjoyed it.

I also want to thank the temporary members who have been brought in to assist us in our deliberations on

this issue, Dr. Underwood, Dr. Lamm, Dr. Feinleib, Dr. Byers and Dr. Blaner. Thank you all for being here to help us out.

That said, Ms. Campbell, are you here? We sure need you right now.

FDA Presentation

MS. CAMPBELL: Good morning. You are going to talk about labeling today. You have been asked to consider newly available data and information regarding olestra and, in light of this data, the current label for olestra-containing products should be changed.

However, it is important that you understand how FDA has to deal with labeling and that you consider this question within the legal framework of the FD&C Act and the governing authority that permits FDA to require specific label statements on food products.

The Act requires, of course, that a food be safe and wholesome and that its labeling be truthful and not misleading. Specifically, the Act states that a food is misbranded if its label is false or misleading in any particular. It then lists several kinds of information that must be on the labels of all foods, nutrition labeling being the most recent edition.

A food is misbranded if its label fails to have all of this required information. FDA also has authority

under the Act to require specific label statements on specific foods when there is a safety issue. When the agency evaluates the safety of a food ingredient, either as a food additive or in affirming the food is GRAS, if it determines that a specific label statement is needed for safe use of the food, the food additive or GRAS regulation can specify the statement needed.

The PKU statement on foods containing aspartame is one example of labeling necessary for the safe use of the food. But the Act also provides authority for the agency to require specific label statements when needed for reasons other than to insure safe use of the food.

The statutory authority to require these specific label statements comes from the general provision that a food is misbranded if its labeling is misleading in any particular. We all understand that this prohibits statements that are misleading.

But the Act goes farther in clarifying what is meant by "misleading." It say that, "In determining whether labeling is misleading, we must take into account not only representations made about the food but, also, the extent to which the labeling fails to reveal facts material in light of such representations or material with respect to consequences which may result for customary or usual use of food."

In other words, labeling may be misleading not only because of what it says but because of what it does not say. The omission of a material fact from labeling may misbrand a product. However, there is no statutory definition of material fact nor has FDA defined it in its regulations.

But we have used this standard in several instances and, each time, on a case-by-case basis. There were two criteria. I said one was when there is a representation on the label that would be misleading without additional information and the other is when there are consequences of use of the food.

With respect to the consequences of use criterion, the agency has required special labeling in cases where information was necessary to insure that consumers are alerted to adverse consequences that are associated with consumption of a particular product.

One example is the special statement for protein products intended for use in weight reduction. That has been in the regulations for a number of years. It states, in part, that very low-calorie protein diets may cause serious illness or death. The need for that statement was not because the product was inherently unsafe but because of certain misuse patterns that had become common.

Labeling is also misleading if it omits

information that is material in light of representations made about a product. Over the years, FDA has required special labeling to clarify statements on the label or to put them in proper context.

For example, in the original nutrition labeling that was established in the mid-70's, that was the voluntary nutrition labeling. One of the basic principles was that if there was nutrition information on the label of a food, that nutrition statement would be misleading unless the entire nutrition profile was present.

That was the basis on which we required nutrition labeling at that time. And we still hold that principle, that a claim triggers nutrition labeling, a claim is misleading in the absence of nutrition labeling.

Also, in the NLEA regulations that we did a few years ago, we defined terms like "reduced" and "light," and we found that those terms, without accompanying explanatory information, could be misleading. And so the accompanying explanatory information, "reduced fat is 25 percent fat," that accompanying information was material fact.

Now, that is the general principle, some of the ways that we have used the material fact part of the statute. Now, let's talk about it relationship to olestra. At the time FDA approved the use of olestra in savory snacks, it concluded that this use was safe.

However, the agency recognized that the consumption of olestra may be associated with GI effects such as abdominal cramps and loose stools but concluded, as you have discussed for the last couple of days, based on the available scientific evidence, that these effects did not represent adverse health effects.

The agency, however, went on to conclude that consumers should be provided with information to enable them the association olestra with the GI symptoms that it can cause. This information was also considered necessary to preclude unnecessary concerns and inappropriate medical treatment.

Therefore, we required a label statement informing consumers of the possible consequences of use associated with the consumption of olestra. Also, as I have already said, labeling is misleading if it omits information that is material in light of representations made about a product.

The final rule on olestra requires the addition of four vitamins, A, D, E and K, to compensate for olestra's vitamin absorptionability. These vitamins have to be declared on the label because of the statutory requirement to list all ingredients.

FDA concluded that consumers might interpret the listing of these vitamins in the ingredient statement as evidence that the snacks had been fortified for nutrition

benefit. Therefore, we decided that the label for olestra-containing products should disclose the reason that the vitamins had been added to the snack food.

Thus, you have the two-part label statement that is required on olestra, one that addresses the GI effects and the other that addresses the reason for the addition of the vitamins.

Now, this material fact standard in the law is widely usable and it is flexible, but there are limits. FDA cannot require a label statement unless the need for it meets the statutory criteria of, as I said before, being necessary to clarify existing label statements or necessary because of consequences that may result from the customary or usual use of the food.

As you consider new data and information on olestra, please keep in mind this standard of material fact that we have to use in deciding what specific labeling belongs on the specific foods.

That's my presentation.

DR. BRANDT: Any other comments from the FDA about this issue?

Questions

DR. BRANDT: Does anybody on the committee have a question about the labeling issue?

DR. APPLEBAUM: Ms. Campbell, I have a question,

if you could just provide a little more clarification, it would be helpful. When you were referring to consequences, facts material to the food as it relates to consequences, you mentioned once, but you didn't mention it again, associated with customary and usual use.

Can you just clarify that a little bit more as it relates to customary and usual use?

MS. CAMPBELL: In what respect? The statue says customary or usual use.

DR. APPLEBAUM: Okay. So does that mean that the statute does not consider the hypothetical?

MS. CAMPBELL: We did with the protein products that we talked about, the very low-calorie protein products. We labeled that product with respect to a misuse of the product. It was not the labeled use but it had become a common use insofar as it had begun to occur. We had documentation. We had adverse impacts from that.

I am not aware that we have dealt with a hypothetical under material fact.

DR. APPLEBAUM: But in regard to the protein issue, you had data to support the requirement as it relates--

MS. CAMPBELL: We had data to support that there was adverse effect from this particular use even though it was not a labeled use.

DR. APPLEBAUM: But you had evidence in terms of the potential for--or actual data that this product could be abused and, therefore--

MS. CAMPBELL: We did. We had data.

DR. LAMM: Am I correct in hearing that the question before us relates only to the factual information in the label and that issues of placement of the label, and so on, are not before us?

MS. CAMPBELL: Yes. The question we are asking you has to do with the nature of the information that should be on the label based on the scientific information you have been asked to evaluate.

DR. POTTER: Do you consider a 90th percentile user to be using the product in the usual and customary manner?

MS. CAMPBELL: I don't know the answer to that. I know how we use 90th percentile users in safety determinations. This is not, however, a safety determination.

DR. FENNEMA: That was the essence of my question. I was going to ask about the 99th percentile. Where does "usual and customary" end in this framework is the same question, I guess, that is being asked.

MS. CAMPBELL: I am not sure that we have enough experience with making decisions based on that factor in the

material fact decisions to be able to say that we have a general pattern. We have made these decisions on a case-by-case basis and there have been few enough of them that I don't think we have established a general pattern and not often enough has there been a question about the maximum user.

DR. JACOBSON: I have three points.

DR. BRANDT: Wait a second. You are going to get a time a little bit later so let's not make them now. This is purely for information to the committee about the law, about the FDA's requirements. That is all we are talking about.

DR. JACOBSON: That's right. I wanted to address three things regarding that.

DR. BRANDT: Okay.

DR. JACOBSON: One is that Betty Campbell was asked whether the FDA is asking for information solely on the wording of the label. The charge doesn't say that. It says, "Should the label be changed in any way?" The label is now specified with a box around it with a certain type size with a position. It is required to be printed on either the front of the package or any other side of the package.

I think it is appropriate that those various matters be included in the discussion.

The other two points that Betty Campbell didn't note were two other aspects of olestra labeling that the FDA specified in the Federal Register notice. First, the FDA said that this indigestible fat should not be considered a fat in the nutrition label. So it says, "zero fat."

Second thing is that, in terms of front label claims, products containing this indigestible fat can be labeled "fat free" or "low fat," as the case may be. I am going into that a little myself, but those are other aspects of the olestra regulation.

DR. BRANDT: You will have an opportunity. I have time for you. That's fine. Thank you very much. We appreciate your being with us this morning.

MR. LEVITT: I would like to just respond to Dr. Jacobson's question there. I think the honest answer, in terms of when we framed the question, we were thinking in terms of the wording used. However, in sitting and thinking about it, we certainly would welcome any additional comments the committee has on things like box warning, placement of label, that kind of thing.

That wasn't our initial focus but, while you are here, if you have comments on that, that is certainly germane.

DR. JACOBSON: Thank you.

DR. BRANDT: Dr. Rulis, do you have anything to

say? No? Okay.

DR. TREIBWASSER: Question. Would the FDA or the committee be willing to define the boundaries relevant to Dr. Jacobson's subsequent comment about the other aspects of the overall olestra petition. It is not our understanding that aspects of the labeling of the product outside of the specific information label are going to be the subject of this discussion this morning and I would like some clarification of that.

MR. LEVITT: I'm sorry. Maybe I wasn't listening carefully enough. The point I was trying to address was the label statement as Dr. Brandt described it, the two or three sentences that are in there. Again, if you want to discuss the box around it, placement of the label, of that statement, then that is what we are here to discuss.

DR. TREIBWASSER: What about the "fat free" claim?

DR. BRANDT: We are not going to be discussing that. That is not the issue that is before us today.

DR. TREIBWASSER: Thank you.

DR. BRANDT: This committee has never been shy about offering its advice to the FDA irrespective of whether it has been asked for it. So all of you can feel free. The FDA has the option of ignoring anything you say because you are a hired gun brought in here to give them advice. So that is not an issue.

The issue of whether or not is fat-free, low-fat or somewhere in between is not an issue that we are concerned with today but if you want to say something about it, you are free to do that, as if I could stop you anyway.

So that is where we are. We will now turn to--Dr. Treibwasser, is it okay for me to combine P&G and Frito-Lay together or do you want to keep them separate.

DR. TREIBWASSER: I would prefer you give Frito-Lay their separate ten minutes.

DR. BRANDT: Thank you very much. We will do that. I don't know who is in charge at Proctor and Gamble, so you now have 45 minutes to make your presentation with respect to the label. Please begin.

Proctor and Gamble Presentation

DR. ALLGOOD: Thank you, Dr. Brandt.

[Slide.]

I am Greg Allgood from Proctor and Gamble. Thank you for the opportunity to present our information on the interim label.

[Slide.]

Here is the interim label. It reads, "This product contains olestra. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E and K have been added." This is now on very bag of olestra

snacks.

At the time of olestra's approval, FDA asked for additional comment and information on the label. Specifically, the FDA requested comments on the need for the label, the adequacy of its content, the word choice and its configuration. They said that they would revisit this interim label once this additional data and comments had been received.

Proctor and Gamble agreed to conduct additional research to address these issues. We have conducted the research and we have submitted it to the agency and today we will include these results in our presentation.

[Slide.]

Here is an outline of our presentation. After briefly going over FDA's requirement for labels, we will address these three specific questions. Is the interim label consistent with the new clinical data which we have looked at over the last couple of days? Is the interim label consistent with previous labeling precedents? And is the interim label understood by consumers? Here is where we will show you some new data about consumer research.

I will address these first two questions and then I will turn it over to Lisa Papa from Proctor and Gamble who will address the last question.

Let's briefly look at FDA's requirement for

requiring labels. This is just a brief summary of what we heard from Ms. Campbell. She said, "Labels, in order to not be misleading, must reveal material facts, and these should be with respect to the customary or usual conditions of consumption."

This makes a lot of sense because almost any product could cause symptoms under exaggerated consumption conditions. For example, if you eat too much fruit, you may get digestive effects but that doesn't mean that fruit needs a label for digestive effects.

[Slide.]

Now, at the time of olestra's approval, FDA based the requirement for the interim label on the 56-day nutrition studies, those studies which we are not allowed to talk about this week but we have. Those studies were conducted with mandatory consumption of olestra at every single mean for 168 consecutive meals.

What hasn't been mentioned here, olestra is used to prepare a variety of foods in this study. It wasn't just salted snacks, because they had to eat them at breakfast, lunch and dinner. What these studies were designed to determine was the potential for olestra to cause digestive or nutritional effects under these exaggerated conditions, and the studies showed that olestra is safe, even under these conditions.

Now, these studies were never intended to provide an understanding of olestra's potential to cause digestive effects under typical snacking conditions or, to use FDA's standard for labels, these studies were not conducted under the customary or usual conditions of consumption.

So that was the situation at the time of approval. FDA had studies which showed that olestra could cause digestive effects under exaggerated conditions and FDA did not have substantial data with olestra consumed in salty snacks. They said that they would revisit the label once this additional data had been received. We are now at that point today because a substantial amount of research has been conducted with olestra used in salty snacks.

[Slide.]

We will look at that research and see if the interim label is consistent with this new data.

[Slide.]

These are the three studies that we have talked about over the last couple of days. We will go back to these studies very briefly and look at the design and the key results. Overall, these studies showed that when people eat olestra snacks compared to full-fat snacks, there is no meaningful effects on digestion.

[Slide.]

Let's look at the acute consumption. This was a

study conducted by Dr. Lawrence Cheskin of Johns Hopkins University. This was the study where people could eat as much as they wanted of the large bag of potato chips while they were watching a movie. This study showed that when people ate olestra chips compared to full-fat chips, there was no difference in the nature of digestive effects, the severity of the effects or the frequency of effects.

[Slide.]

The results are shown here. This slide, I would remind you, is the percent of subjects reporting symptoms. Placebo is shown in white, olestra in green and then the specific symptoms on the X axis. There was no difference in any GI symptom and, importantly for our discussion now, there was no difference in the symptoms of either loose stool or abdominal cramping, the two symptoms listed on the label.

Now, as Dr. Cheskin mentioned yesterday in the public comment period, there was a numerical lower level of effects for any GI on the olestra group--not statistical, but lower. So, based on this, we could look at the power of this study based on the actual data.

What this showed is that, based on the confidence intervals, there was a 1 in 1000 chance of missing a difference that was larger than 5 percent. So this study was very powerful to see if olestra causes any digestive

effects at a single sitting.

[Slide.]

The next study that provided critical data was an upside-down slide of the rechallange study. This study was designed to determine if people who called the 800 line usually after eating the snacks one time and eating an ounce or two of snacks were somehow intolerant to olestra.

This study retested 98 of these people and found that they were not intolerant to eating olestra and it was likely that we were measuring the background rate of digestive effects in the population.

[Slide.]

Look at the specific results. The study showed that there was no difference in any GI symptom and no difference in loose stool or abdominal cramping. So this study showed that people who were calling the 800 line were not intolerant to eating olestra snacks

[Slide.]

Now, the last study which we will discuss this morning is the six-week consumption study. This study we have spent considerable time discussing because it is a very powerful study. It had 33,000 eating days of people eating olestra snacks. This study was conducted by Dr. Robert Sandler of the University of North Carolina at Chapel Hill.

Households were provided with eight bags of free

product every week to encourage consumption and the study showed, and FDA agreed, that the study resulted in no meaningful effects on digestion.

[Slide.]

Let's look at the study again. We will begin by looking at consumption compared to what we looked at yesterday from the active surveillance program. You have not seen this comparison before.

[Slide.]

We are looking at the 90th percentile from the real-world intake, what people were eating in the active surveillance program compared to what was estimated prior to approval and the compared to the six-week study. This is the 90th percentile and the active surveillance program showed that people are eating at the 90th percentile about 2 grams per day.

This is among people who were actually eating the product and that was only about 15 percent of the people in the month of the survey. It does not include the people who were not eating it or would dilute it further. The MRCA, which is sort of the gold standard for estimating intake prior to approval showed a 90th percentile of 8 grams per day.

It is higher. That is because this is a conservative assumption which assumes that only olestra

snacks will be available, essentially that we would have 100 percent market share. That may be true for some people. They may only choose olestra snacks so that is why we made that assumption.

And then we see that the six-week study was successful when we provided people eight large bags or cans of a product a week, it did encourage them to eat a lot of product. That was about six times what we saw in the real world.

[Slide.]

What symptoms did we see when people had this much to eat? This is percent of subjects, again, and there was no difference in any GI, no difference in loose stool and no difference in abdominal cramping.

There are a number of other ways to look at this data. Let me show you some of those.

[Slide.]

This is symptom days and it is for all subjects. You will recall that we showed a statistically significant increase in more frequent bowel movements. The difference was about one symptom day over the 42 days of the study and it had no significant impact.

The difference in more frequent bowel movements also resulted in an increase in any GI event, again of about one symptom day over the course of the study.

[Slide.]

FDA showed a different way of looking at this data and we discussed that some yesterday, our duelling statisticians.

[Slide.]

What they showed, just for reference, to take you back to that, this was at the median consumption, which was 27 ounces. They showed an increase not only in more frequent bowel movements but also in loose stools and, at the median level of consumption, this was about a quarter of a symptom day over the 42 days of the study.

For perspective, a quarter of a symptom day is two extra symptom days over one year. Clearly, this is not a very large effect. But is what is really important is what is the impact of this symptom.

[Slide.]

We looked at this by a number of different measures. One was through the direct questionnaire and we show that there was no difference in the way people rated their symptoms as far as their impact on their daily lives. We also looked at some objective measures. We kept track of the medication use and there was no difference including use of anti-diarrheals.

We also looked at doctor visits and drops from the study and there was no difference. Finally, perhaps, the

most subtle way to look at this, we looked at whether people continued to eat the product because that is really a neat way to look at this.

Let me show you the slide again.

[Slide.]

This shows people who did not report symptoms compared to people who did report symptoms and how much they ate both by the total amount eaten in the study as well as the number of eating days. You can see, both at the median and at the 90th percentile, that there are no meaningful differences.

When people have symptoms, they continue to eat the product. One of the simplest things that people could have done in this study, if they were concerned about their effects, was simply not eat the product. And we didn't see evidence of that.

[Slide.]

So, in summary, these three studies which were specifically designed to understand what happens when people eat olestra snacks, showed that olestra does not have meaningful effects on digestive effects. And importantly, for our label discussion, all three of these studies showed no increase in abdominal cramping. And FDA agreed with that assessment.

[Slide.]

In conclusion, the interim label is not consistent with these new clinical data which were designed to determine what happens when people eat snacks.

[Slide.]

Now, let's look at the next question. Is the interim label consistent with labeling precedence. Here, we will look at three examples of foods for which FDA has made a decision regarding information labels for digestive effects.

We will look at sorbitol, psyllium and bran fiber. You will recall that we used sorbitol as a positive control in the stool composition study which we discussed on Monday. We will go back to that study to compare olestra and sorbitol.

Then we will look at psyllium. Recently, FDA has made a decision regarding the need for a label regarding digestive effects for psyllium food. We will look at that logic and compare it to olestra.

Finally, we will look at bran fiber. Bran fiber, as you know, is a laxative and does not require an information label for digestive effects. So we will compare bran fiber and olestra.

[Slide.]

Sorbitol is our first example. First, let me make it clear that sorbitol is one example of the poorly absorbed

sugar alcohols which all require similar information labels regarding digestive effects. In addition to sorbitol, there is a mannitol and xylitol. And polydextrose also requires a similar information label regarding digestive effects.

These foods only required the information label regarding digestive effects if expected consumption reaches a certain level. There is a threshold. For sorbitol, this label is 50 grams and that level was based on a clinical study where 50 percent of the people reported diarrhea-like symptoms after a single eating occasion.

[Slide.]

Now let's look at the digestive effects which occur after eating sorbitol foods compared to olestra. This, again, is from the stool composition study. We will look at two critical parameters measuring diarrhea; total stool output and stool water output. And we will look at the average change from baseline.

Our assessment was that olestra did not cause meaningful changes in these parameters and FDA agreed with that assessment, as you heard the other day. Sorbitol resulted in quite large increases in both total stool output and stool water output. And, I would like to remind you that the dose of sorbitol that we used in this study was below the level which has a label.

[Slide.]

Now let's look at our next example, and that is psyllium. This is a really neat example because FDA, in February of this year, approved a health claim for psyllium foods. Psyllium is used in the bulk laxative metamucil and it is also used in foods, like breakfast cereals. It was in relation to psyllium's use in foods that FDA approved a health claim.

This was because of psyllium's ability to lower serum cholesterol and, thereby, lower the risk of heart disease when it is used as part of a diet low in cholesterol and saturated fat.

Importantly for our discussion, in February, when FDA made this rule, they made the decision regarding whether psyllium foods needed an information label. They decided that it did not. And they have laid out their logic for that decision.

What we will do is look at that logic and then compare it to olestra

[Slide.]

The FDA said that psyllium foods did not need an information label because psyllium does not cause diarrhea. It does not cause meaningful water loss. In fact, the FDA said there is no reason to expect that eating psyllium foods would cause any effect on the bowel than to promote normal bowel function by stool softening, increasing stool volume

or increasing bowel movements.

And they said that if there were any consumers who were intolerant, they could avoid future eatings because psyllium is identified in the ingredient list which is part of the nutrition label. In other words, to say this product contains psyllium would be redundant.

This provides an excellent, very recent, precedent for olestra so let's compare the digestive effects which occur after eating psyllium to olestra.

[Slide.]

Neither olestra or psyllium will cause diarrhea, and the stool composition study established that for olestra. Both olestra and psyllium will increase stool volume. Now, olestra will do this by its simple presence. It is not absorbed so, about, for every gram you eat, there will be an extra gram in the stool.

Psyllium will increase stool volume both by its presence and because of its water-holding capacity. When psyllium becomes hydrated, it forms a gel-like matrix in the bowel so it will increase stool volume by about 4 grams for every gram that it eaten.

You can see that the digestive effects which occur after eating olestra foods and psyllium foods are similar although psyllium's effects will be a bit more pronounced. And yet we see that psyllium does not require an information

label.

[Slide.]

Our last example is bran fiber. Bran fiber does not require an information label regarding digestive effects even though one of the reasons people presumably buy bran-fiber products like bran cereal is for their beneficial laxative effects. Now, like psyllium, bran will cause a more pronounced stool-bulking effect than olestra. It is about five times greater effect.

Let me now go back and compare our three examples of sorbitol, psyllium and bran fiber directly to olestra in a summary slide.

[Slide.]

For the purposes of this slide, I have combined bran fiber and psyllium as dietary fiber since their effects will roughly be the same. All three--olestra, fiber and sorbitol--will increase stool output. Olestra will do this by its presence, so about 1 gram for every gram that is eaten.

Dietary fiber, like psyllium and bran fiber and also fruits and vegetables, will increase stool bulk by about five grams for every gram that is eaten. Sorbitol will cause a more pronounced effect because of its osmotic effect so about 9 grams for every gram that is eaten.

Olestra will not cause meaningful increases in

stool water while both psyllium and sorbitol will, although sorbitol's effects will be more pronounced. Only sorbitol, because of this, will cause diarrhea as defined by significant water or electrolyte loss of a lot of those other objective parameters that we measured.

Despite this comparison, we see that the olestra product is the one that has the information label.

[Slide.]

In summary, the interim label is not consistent with labeling precedents. This can result in some consumer confusion. Now, that leads us into the next part of our talk and I will turn the podium over to Lisa Papa from Proctor and Gamble. Lisa is the person who is responsible for conducting the consumer research to see if the interim label is understood by consumers.

Lisa?

MS. PAPA: Thank you, Dr. Allgood. Good morning and thank you for the opportunity to present our consumer research on the interim label.

[Slide.]

I will be addressing the third question in our series, is the interim label understood by consumers.

[Slide.]

Now, at the time of olestra's approval, Proctor and Gamble proposed and committed to conduct consumer

research on the interim information label.

We surveyed over 2,000 adults and teens in over 40 cities across the U.S. using nationally representative survey methods. We asked consumers to read the interim information label and then respond to a series of questions. Let's look at the general reaction from consumers.

[Slide.]

As you can see here, after reading the interim label, 61 percent believed that the snacks are unsafe. The same percentage, after reading the label, believed that the government is telling them that the product is unsafe. And a majority believe that this is a warning label and not just for information.

[Slide.]

As you can see here, consumer's interpretation is not consistent with FDA's conclusion. In the Federal Register, it states that, "FDA concludes that all safety issues have been addressed adequately and that the use of olestra in savory snacks will be safe.

[Slide.]

Now we will turn to the GI portion of the interim label. What I have shown you here is the consumer interpretation of the interim label and I am comparing that to the results of the new clinical studies that were specifically designed to look at olestra in savory snacks

under the customary and usual conditions.

50 percent of consumers believe that they, personally, would experience abdominal cramping after consuming olestra products. This is not consistent with the results that we saw in the clinical studies. We saw no increase in abdominal cramping.

[Slide.]

44 percent of consumers believed they would experience--again, this is after reading the interim label--they, personally, would experience moderate or severe symptoms. Again, we did not see an increase, and this is not consistent with the clinical findings. As you can see, the label is misleading to consumers.

[Slide.]

Now let's look at how it is possible that consumers could misattribute symptoms to olestra that are very unlikely to be due to the olestra. To make this point, I have gone back to our 800-line callers where we saw a majority of people are calling us reporting abdominal cramping.

If you remember from Monday, those calls were generally after someone had eaten one or two servings in a single sitting, so a very typical snacking amount. It is not consistent with what we have seen in the clinical studies that, again, were designed to understand what would

happen in a snacking condition.

We saw in these clinical studies that olestra snacking, there was no increase in abdominal cramping. But it is easy to understand how there is lots of consumer confusion based on the interim label.

[Slide.]

To take it ever further, I have shown you here one example where a consumer's interpretation goes well beyond the words that are just written on the label. After reading the labeling, one out of four consumers said they would attribute any blood stools they might experience to the olestra snacks.

Now, this is concerning because this interpretation by consumers may lead to delayed treatment. This is something that olestra does not cause so, clearly, this is incorrect. And we do not believe this is what FDA intended with the label.

[Slide.]

We also wanted to understand why consumers' interpretation would go so much farther beyond the actual words on the label. When we interviewed consumers, we asked them about labels in general and they told us that the way they evaluate labels is generally based on context or their frame of reference.

For olestra specifically, their frame of reference

is other foods. Now, consumers know that there are other foods that cause GI symptoms and those products do not have a label. So the interpretation is that olestra must be worse.

Consumers also say things like if this is like my other experiences, then why does it have this label. We also note that consumers' interpretation is influenced by the way the label has been portrayed in the media.

[Slide.]

Let's watch a short video clip.

[Video clip.]

As you can see, the media has essentially done a good job of reflecting consumers' interpretation of the label but, obviously, this was not what FDA intended.

Now, I am going to shift gears and move into the vitamin portion of the interim label.

[Slide.]

Specifically, these last two sentences; "Olestra inhibits the absorption of some vitamins and other nutrients, vitamins A, D, E and K have been added." What are these sentences supposed to convey.

[Slide.]

The FDA again stated their intent in the Federal Register. The agency believes the consumers who see the added vitamins listed on the ingredient listing could be

misled and believe that the food is fortified with the vitamins. Let me briefly explain this again. Because we add any vitamins to the product to prevent any reduction, those vitamins must be in the ingredient listing and part of the nutrition label.

Because they are on the ingredient listing, some consumers might be confused that these snacks, these olestra snacks, are a good source of vitamins. So one of the intended purposes that the FDA had was to prevent this potential consumer misunderstanding

Let's see if this was clear to consumers.

[Slide.]

Our research shows that 43 percent believe that they would experience a change in their fat-soluble vitamins. Another 39 percent believe that other nutrients that olestra does not affect, things like calcium, folate, vitamin C, iron, potassium, et cetera, things that olestra does not affect, would be affected.

So, clearly, this is incorrect and this is obviously not FDA's intent.

[Slide.]

There is a potential solution to this conundrum of consumers thinking that the products would be a good source of vitamins. I have shown it here. Specifically what you see is an ingredient statement for olestra potato chips.

Each of the fat-soluble vitamins has an asterisk indicating that it is not a nutritionally significant source.

Now, the nice thing about this type of labeling is that it is actually consistent with NLEA or the Nutrition Labeling Education Act. So it already complies with that and it is something that consumers are used to seeing. This is something that is used, for example, to indicate the fat ingredients on fat-modified foods, things like skim milk.

So, again, consumers have seen this. It is something that they are familiar with.

[Slide.]

Our research shows that the interim label is not understood because it leads consumers to view the label as a warning label, to view the product as unsafe, to misattribute symptoms to the product, to expect depletion in vitamins and minerals and to speculate about the meaning of other nutrients.

[Slide.]

Net: the interim label is not understood by consumers. Recall, at the time of approval, given the data that FDA had in hand, it was a reasonable decision for them ask for additional data looking at olestra in salty snacks under the customary and usual conditions. We have gone out. We have collected that data, run rigorous studies and looked at consumers' interpretation of the label as well.

[Slide.]

And we have found that the interim label is not consistent with the new clinical data. Specifically, all three studies designed to look at olestra under savory snacking conditions showed no meaningful impact on consumers' daily lives and no effect on abdominal cramping.

The interim label is not consistent with labeling precedence and it is clear that this compounds consumers' confusion around the olestra label. The interim label is not understood by consumers. We have completed the consumer research that we committed to conduct at the time of olestra's approval and that research shows that interim label is misleading to consumers.

[Slide.]

In summary, this new information and data provide a sound basis for FDA to reevaluate the interim label.

Thank you.

DR. TREIBWASSER: That completes our presentation.

Questions

DR. BRANDT: This is open for the committee. Questions?

DR. HARLANDER: I am wondering if you have tested the vitamin statement with consumers with the asterisk and not a significant source. And my second question is would you be willing to provide a copy of the questionnaire that

was used in your consumer testing.

MS. PAPA: Let me answer both of those. The first one, have we tested the asterisk, we actually tested a label that had that as part of it and also had that as part of it and also had some other GI wording. So we have not tested that in a single variable way.

On the questionnaire, we would be happy to share that.

DR. BRANDT: Do you have a copy of it here that you can give to Dr. Harlander?

MS. PAPA: Yes; be happy to.

DR. BRANDT: Thank you. Other questions?

DR. CLANCY: I wanted to ask, Dr. Allgood, if you could separate out from that one slide that you had; you combined moderate and severe, and those are so different that I think that is incorrect to combine them. Could you give me the numbers for moderate and severe separately--

DR. ALLGOOD: From?

DR. CLANCY: From the research of consumers about expecting what their symptoms might be from reading the label?

DR. ALLGOOD: That was actually from the consumer research.

DR. CLANCY: Fine. Would you break that down, please?

MS. PAPA: Yes; I will break that out for you. It will just take me a minute.

DR. BRANDT: Let's go on while you are looking for that.

MS. RICHARDSON: A lot of the testimony that we have read and heard from consumers indicates that they had not read the label before they ate the olestra chips, that they read the label afterwards. I was wondering, in the questions that went to the callers, the 70 percent of the callers who indicated that they had abdominal cramping since the inference is that it was because of autosuggestion, were they asked had they read the label before they ate the chips?

DR. ALLGOOD: It is not part of what we ask as part of our questionnaire when people call us so we don't know the answer to that.

MS. RICHARDSON: So you are just assuming that they were suggested to have abdominal cramping because they read the label beforehand.

DR. TREIBWASSER: It is probably more likely that the suggestion of abdominal cramping came via all the media coverage but it is also confounded by the fact that the label also states that.

DR. BRANDT: Did you find the data, Ms. Papa?

MS. PAPA: Yes. When we asked consumers how

severe do you think these symptoms would be, 37 percent reported moderate and 7 percent reported severe.

DR. CLANCY: Thank you.

DR. BRANDT: Does that answer it, Dr. Clancy:

DR. CLANCY: Yes.

DR. CLYDESDALE: You just mentioned a few minutes ago that you had some other wording for the GI symptoms. Could you share that with us, or not?

MS. PAPA: Yes. Actually, we have looked at several different wordings. In fact, in the research that we did in early 1996 and submitted during the comment period to the FDA, I think there were three other labels, alternative labels, that were looked at.

The key conclusion from that, though, was that each of those--there was no significant difference. So each of those labels was also misleading to consumers. And now that we have this new clinical data and, again, looking back in hindsight, we can see that, for example, abdominal cramping is not consistent with the clinical facts and that is different than what was tested previously.

DR. BRANDT: Any other questions?

DR. BYERS: It seems to be pretty clear from your presentation what your recommendations would be and that would be that there would be no label indicating GI effects and that you would just simply use this asterisk approach

for the vitamin-restored vitamins; is that correct?

DR. ALLGOOD: Our position is that it is FDA's decision on the label but we want to work with them to help them fix the label. Clearly, we think the label needs to be fixed.

DR. BYERS: I understand that. I was asking your opinion as to how that should be done. Do you have a recommendation?

DR. ALLGOOD: No.

DR. BYERS: Then there is one aspect of what you have presented in terms of consumer confusion for which you at least implied no cure. That is, you said that consumers were confused about what nutrients might mean. Do you have a suggestion to consider with regard to that?

MS. PAPA: No; we do not.

DR. HARLANDER: Is it fair to ask FDA a question at this point? Can we ask FDA a question right now?

DR. BRANDT: Yes.

DR. HARLANDER: Can I ask anybody if there is any precedence for a label that would say digestive effects with exaggerated usage?

DR. BRANDT: FDA want to take that one? Somebody? Anybody? They are now having a sideline conference. It is like the quarterback calling time and the running-to-the-coach issue.

DR. CHASSY: I guess this is for Dr. Allgood. You made a comparison between the labeling of olestra and the labeling of two fiber products that people might take as laxatives or which would have a known laxative effect. It seems to me that that comparison is only valid if people expect the effect or if there are not digestive effects of significance for a 90th percentile user of olestra.

How would you come down on that? Are you arguing that the 90th percentile user will not experience laxative-like effects? You follow that when they take fiber products, they expect a certain effect, that they may be taking them for that reason.

So I am getting at what is customary and expected.

DR. ALLGOOD: For the bran-fiber products and the psyllium bulk laxative, I would agree with that. They are clearly taken for laxative benefit. Our clinical studies have shown that at the 90th percentile of consumption, and particularly what is going to happen in the real world, that people are not experiencing particularly abdominal cramping but no meaningful changes in digestive symptoms.

For psyllium foods, however, I would not say that that is necessarily the same case. When psyllium foods' approval came, that would certainly encourage the manufacturer of lots of different foods which are made with psyllium for that health claim.

FDA took that into full consideration when they gave the health claim approval and made the decision that the information label is not needed. But what is most important, I think, is that consumers in their comparison of different products are confused because they look at the olestra interim label and see that, in their minds, it is worse than what other products contain, which they know to cause digestive effects.

DR. BRANDT: FDA, do you have a response to Dr. Harlander?

MS. CAMPBELL: Yes. I am Betty Campbell. Your question had to do with whether or other label statements take into account high use of a product with respect to its effects or its consequences. Off the top of our heads, I don't think we have direct language on the label that says if you use a lot of this product, there may be consequences.

However, the label statements with respect to the sugar alcohols are triggered a higher use level. At that lower use level, there is no statement. So the concept of higher use needing a label statement is inherent in the decisions we made for the labeling of the sugar alcohols.

DR. BRANDT: Happy with that?

DR. HARLANDER: Yes.

DR. APPLEBAUM: I just want the clarification. If you have a serving of mints that contain sorbitol and it

doesn't hit the 50-gram level, it doesn't have to carry the warning? I can't remember from the regulations.

MS. CAMPBELL: I think, if I remember correctly, that it is a daily intake of 50 grams. So it would depend. If it is a single-serving-a-day type of food, then it would take the full amount in one serving. But if it is a multiple-serving-a-day type of food, then a lower amount than the 50 grams per serving would trigger the label statement. I believe it is on 50 grams a day.

DR. ALLGOOD: For example, when we went and bought the Smarties for the sorbitol still water study, the Smarties that we bought did not have an information labeling on it.

DR. APPLEBAUM: I have one more question because I am looking at the label statement is currently required. I am focussing on vitamin K, based on what we heard yesterday from the Fred Hutchinson group--and I know it is still rather early on in the study, but in hearing today from FDA in regards to what constitutes material fact and misleading information, where it has olestra inhibits the absorption of some vitamins and other nutrients, vitamins A, D, E and K have been added.

Looking at that, K is added because there is the potential for olestra to impact its absorption. But yet, yesterday, we heard that, with increasing olestra, you do

have increasing levels of vitamin K. So I just want to get some clarification in terms of these two sentences, in terms of whether or not, with K included, that constitutes a misleading statement.

Could we get, perhaps, P&G's point of view as well as FDA's point of view?

DR. TREIBWASSER: I am not quite sure I understand your question.

DR. APPLEBAUM: My question is, yesterday we heard, from the data that were presented, that olestra did not impact, or there were increases, if you will--there was a positive relationship between olestra intake and vitamin K, serum vitamin K levels.

Reading these two statements, at least I am led to believe that there is an impact on vitamin K absorption so, therefore, that is why it is added. Based on yesterday's information, in terms of there not being any impact on absorption per se--in fact, it is a positive. It could be a positive.

Again, it is preliminary or early data, let me call it that. This appears to be misleading. I just want to hear your views on that as well as FDA's, based on the data that was presented yesterday from Fred Hutchinson.

DR. TREIBWASSER: Two points. First of all, I think the data from the Fred Hutchinson are very

preliminary. I think we have to be very careful that we do not overinterpret the vitamin K data from the Fred Hutchinson.

Second of all, even of those levels that they measured are, indeed, true, they are still nutritionally insignificant. That was only a 15 percent elevation in plasma K.

DR. CLANCY: I wanted to ask for a clarification on psyllium. You mentioned specifically that the psyllium proposal to FDA came because of its proven cholesterol-lowering effects. You are not comparing olestra to psyllium in that way; right?

DR. ALLGOOD: No; I am not. Not at all.

DR. CLANCY: I wanted to make sure you were not doing that. Okay.

DR. ALLGOOD: No.

DR. BRANDT: One last question.

DR. FEINLEIB: I would like to clarify Dr. Applebaum's question. The data we saw yesterday was using olestra products in which the vitamins had been added to the product whereas the label appears to refer to pure olestra having an effect and then separately to the fact that the vitamins are added.

Is it still true that olestra alone will inhibit absorption of some vitamins and nutrients?

DR. ALLGOOD: That's true. Olestra has the potential to have a small effect on fat-soluble vitamins but consumers don't buy olestra. They buy olestra snacks.

DR. FEINLEIB: So, as currently marketed, this is extra information that has no direct impact on the information for the consumer.

DR. TREIBWASSER: Correct.

DR. BRANDT: Dr. Drotman from Frito-Lay. You have fifteen minutes, sir.

Frito-Lay Presentation

DR. DROTMAN: Thank you. I am Robert Drotman from Frito-Lay.

[Slide.]

This morning, I would like to review a consumer perception study that we have done on the olestra information label.

[Slide.]

In this study, we tested several different labels. I want to make it real clear before I begin that I am not recommending the use of any of these labels. These were only for test purposes. We tested four different labels. Label 1, and I am not going to read it again, is the label, the current label, on olestra packages which is required by FDA.

Label 2 is a very shortened statement. We want to

see how this affects the consumer. It just simply tells the consumer that this product contains olestra and that olestra may cause GI effects.

Label statement 3 also remarks about the GI effects but the main difference in this label is if you look at the second line, it says that, if symptoms persist, you should contact a physician.

The fourth label has a direct statement of safety. The first line states that, "This product contains olestra which has been found safe for consumption by the FDA." It then goes on to tell that, "Sensitive individuals may experience temporary GI effects." That one is toned down quite a bit.

Throughout my talk, if you want to--everybody should have a copy of my talk. You can leave that one page of the labels tested open if you want to because I am going to be referring back to these labels.

DR. BRANDT: It was on the top of your pile this morning.

[Slide.]

DR. DROTMAN: A little bit about the study. This study was conducted in February through March of 1996. Because of that, we believe we probably had some fairly naive consumers.

[Slide.]

A little about the methodology. This was a central-location test. It consisted of adults, or people 18 and over who had used savory snacks at least one in the past month. We used at least 228 respondents per label and each respondent only was able to evaluate one label.

There is a comparison by respondents. It was done by questionnaire. It was self-administered. Phase 1 and Phase 2 were done separately. The labels were shown as a box in the lower right-hand corner of a drawing of the package. The only thing this package had on it was that it was a nutrition facts label, the ingredient statement and then the information label or the different iterations of the information label.

[Slide.]

One question that we asked, I want to call your attention to; "Based on this label, do you believe products containing olestra are safe?" The important issue here--I do want to point out that we used a little bit different--I just noticed from Proctor and Gamble's talk, we did not just force consumers to saying it was safe or unsafe.

We also wanted to give them a chance to say they were uncertain about the safety or uncertain about the information. As you can see, the majority of people wound up in the uncertain category in every case. In every label tested, they were uncertain about the safety.

In this case, all labels tested negatively impacted the respondent's perception of the safety of olestra.

[Slide.]

Doing that, we realized all we got was the impact of the label. What consumers also hear is about this new food additive that the FDA has approved. So what we decided to do was do a before-and-after study. Before, no label was reviewed and a simple description of olestra was given to the consumer and was something like this; "Olestra is a new cooking oil approved by the FDA. It does not contain any calories and passes through the body unchanged."

That was all they received. And then they were asked, "Do you believe olestra to be safe, this material to be safe?" And afterwards, they were shown a label and then asked the question, based on this label, "Do you believe products containing olestra are safe?"

When we used that current FDA-required, FDA-mandated label, we made that statement before, it still left a lot of people uncertain. Again, the majority of people are uncertain regarding the safety of the material. Once we showed them the label, it significantly moved. You looked at the "uncertain" category again, it significantly moved a number of people to believing the material was unsafe.

Out of 162 people, 36 moved to the "unsafe"

category. 49 people felt it was safe before they saw the label and only heard the simple statement. After they read the label, which is on the right-hand side, 16 of them were now uncertain and three of them actually felt it was unsafe.

The label, then, in this test significantly moved respondents towards believing olestra was unsafe but left most people uncertain, still.

[Slide.]

The next label we tested in this before-and-after test was label 4 which, as you all remember, has the direct statement of safety embedded within the label. It is up there where it says, "This product contains olestra which has been found safe for consumption by the FDA."

Before, again, the largest number of people were uncertain about the safety of olestra even after being read that simple olestra description. When they were shown a label that had a direct statement of safety, in the uncertainly category, about 28 people out of 169 moved to believing it was safe and then, surprisingly, a number of people actually moved to believing it was unsafe.

Of the people who felt it was safe beforehand, nine now remained uncertain but no one felt it was unsafe. Finally, in the unsafe, one person actually moved to believing the olestra was safe.

So a safety statement significantly moved people

to believing olestra is safe but it still left most people uncertain regarding its safety.

[Slide.]

I just want to go over two other questions very quickly with you that we asked during the test to make my point. One question was, "Based on this label, do you believe that vitamins and nutrients, other than A, D, E and K are affected by olestra?"

Once we asked that question, we were expecting not to get as even a split as we did because of what the label says. By the way, in this one, this is the current label only and I have combined the current label answer from phase 1 and phase 2 since it is basically the same.

It says, "This label did not convey a clear understanding of whether other nutrients were affected by olestra."

[Slide.]

One other question I would like to share with you is we asked the question, "Based on this label, how do products containing olestra affect the level of vitamins A, D, E and K in your body?" And, again, this is just the current label. While we were expecting, of course, an answer of no effect, the majority of people felt that olestra decreases the vitamins in your body even with the statement the A, D, E and K have been added to olestra.

Our conclusions from, at least the data I have shown you today out of the study, is that consumers did not conclude that olestra was safe to eat under any of the conditions or any of the labels we tested.

Secondly, in general, information on the label is not really well understood by consumer.

[Slide.]

What is Frito-Lay's position on the label at this point? We believe that the scientific evaluations of the new data will take place, of course, at the Food Advisory Committee Meeting and you all will provide that input to the FDA. At that point, we will determine if any of the science justifies a label on the package.

If it doesn't, if not, the label should be removed. If it does justify a label, then what we would like to see happen is that the label is drafted and tested with consumers or with respondents to insure that they are clear and understood by the consumer.

Thank you very much.

DR. BRANDT: Thank you, Dr. Drotman.

Questions of Clarification

Are there questions of Dr. Drotman by any member of the committee?

DR. HARLANDER: Again, would it be possible to receive a copy of the questionnaire that you used with

consumers?

DR. DROTMAN: Yes.

DR. HARLANDER: Did you ever test any product about excessive usage? These are the labels that you tested.

DR. DROTMAN: Yes.

DR. HARLANDER: Did you test any others?

DR. DROTMAN: No.

DR. BRANDT: Do you have a copy of that questionnaire which you can provide to her right now?

DR. DROTMAN: I think I have it upstairs in my room. I will run upstairs and see if I have that. I think I do.

DR. BRANDT: Don't run up there right now. Wait until you finish the questions.

DR. FEINLEIB: I gather that, there was no separate information according to whether they previously used olestra products or not.

DR. DROTMAN: No. This was tested about a month of two after the approval. There were no products on the market.

DR. FEINLEIB: So it was before.

DR. DROTMAN: That is why I said the consumers basically can be regarded as somewhat naive. They had never seen a package of olestra chips, had never eaten any.

DR. CLANCY: Dr. Drotman, if that is the case, it is really hard to try and understand--I am going back to, I think it was Dr. Chassy who said not too long ago that there is an expectation on certain kinds of foods that consumers have, quite appropriately, about what they are buying them for, about what the effects are going to be of, for example, a bran food or something like that.

Since you did this research so early, it is very hard, I think, to interpret any of the responses to the labels because it appears that there really is going to be a use factor here, not only a use factor but an educational factor.

Can you project--I suspect you can, but would you like to project what you think the responses might be to some of these questions now after more use, more information, more education, more experience, et cetera, might be to some of these labels?

DR. DROTMAN: There are two issues here. Number one is, on a new product, when a consumer picks up the bag, he doesn't have any experience with the product. So this would represent that new consumer. But you are correct. Since the time, a lot more people know about olestra, a lot more people understand it.

I think it certainly would be much different today if we did this study again.

DR. TREIBWASSER: I would like to comment that the data that we showed on safety perception and warning perception was conducted just this year in 1998, so it does reflect in-use perception or perception that has been informed by all of the information that has been in the media since the products began to be marketed.

DR. CLANCY: Remind me again. Were those only done in your test markets?

DR. TREIBWASSER: It was a national sample.

DR. CLANCY: Okay. So it is not from use, per side effects, in a lot of places. It is just from media exposure.

DR. TREIBWASSER: From awareness.

DR. BRANDT: However, that was after you had gone national with respect to the product. You can consider the United States kind of the whole market. That's everybody.

DR. BENEDICT: What about the comments that were made sometime in the last couple of days that no one ever actually sees the label, unless you put it in front of them and ask them for a comment?

DR. DROTMAN: This, again, was a drawing of a bag which had the label and it specifically asked them to look at--this test was done by computer. It just said, "Punch 1 or 2." And the first thing that comes up is a bag, a drawing of a bag with a label on it that says, "This is what

you have to focus on."

So we didn't test how many consumers read labels or not.

DR. BENEDICT: In your suggestion that the label should be removed if the committee determines there is no scientific support for certain things, do you harbor any small feeling, either of the two companies, that you might need that label eventually for some protective, some personal protective, effect of the company, itself?

DR. ALLGOOD: My feeling is that any label must really reveal factual information because if people are avoiding a product because they think, as our research showed, that this is a government-mandated health warning, then that is not good. That is not serving the public for them to think that the label is doing that.

So the answer to your question is no. We want any label to be justified by the facts.

DR. TREIBWASSER: I would just add, though, that if we had any reason to believe that the company wanted the label on there for any liability reasons that we could voluntarily put such a label on the product as long as FDA did not agree that it was somehow misleading.

MS. RICHARDSON: I guess I am a little confused about the surveys with both companies. You indicated that the participants in the surveys appeared to be confused

about the safety of the product. With that in mind, were you surprised at the amount of product that was purchased?

Early on, during the hearings, we heard how many consumers had purchased this product and, apparently, it was not a one-time purchase.

DR. DROTMAN: First of all, from our study, we didn't say that the consumers were confused. We said they were uncertain. There is a little bit of difference there, I believe. The second thing is I guess most people just go ahead and try things. I was a little bit surprised by the purchase intent but, if you go back and look--I don't want to get into this today because we didn't do it on this particular label--when you really come down to it, people do not read labels a lot.

If you look at the data on labels, there are studies that have been done on that.

MS. PAPA: I also wanted to point out that, to us, one of the important things--on our consumer research, we felt that this showed that this was inaccurate and misleading people. I don't think consumers want to be misled. So I think that is really the issue here that we are trying to point out.

DR. BLANER: It is very surprising to me--your label 4 which explicitly states that the FDA believes this is safe that so many people were uncertain to its safety or

actually felt it was unsafe. One could imagine several reasons for that. One possibility might be that just having a strange substance such as olestra is unattractive to people.

Another people is media that the product may have received or there may be other possibilities. Could you share some of your insights into that?

DR. DROTMAN: One thing I didn't show was some of the direct statements we go. We also gave them a chance to write in comments to us. As our feeling is right now, and I don't have any hard data to show you this, is that labels in general, like this, make people suspicious no matter what you put on the label.

On the statement of safety, some people who read that, we got some comments like, "If this is safe, why is this label necessary?" stuff like that. So that is the only answer I can give you at this point.

MS. PAPA: I would like to build on that a little bit because we also have interviewed lots and lots of consumers on this. The point is that if you ask consumers about labels, some of the labels that first come to mind for consumers are things like cigarettes, the warning label on cigarettes, the warning label on alcohol that is warning pregnant women that there may be severe consequences.

So, because of labels that are warning people

about potential serious hazardous effects, it is very difficult to set up a distinction that is very clear in the consumers mind that makes something--that is just information very different from this other information that they are used to that is about harm and about true hazard.

DR. FUKAGAWA: This is, perhaps, more of a comment but I am sure you may want to respond, and that is that, in many ways, I think it is very important for the public to have choice. Part of being able to make an educated choice or decision about one's own personal health or family-food choices and everything is being educated and having information.

So, therefore, I think, in a sense, it is somewhat reassuring that, I think, the majority of people who read the labels felt that they were still uncertain about the "safety" or possible effects of a new food additive or a new food that is sort of meeting, or at least partially replacing, one of the macronutrients in our diet and are raising questions and may lead them to seek further information, in which case, I think the industry could then truly help the public by providing that education.

I think one of the big problems we do have, which I see both as a physician and a practitioner, a scientist, and as a mother, is that too often people want to shift responsibility to a body that they will then be able to

blame at a later time if something does go wrong.

But, in the meantime, they will say, "Oh, yes; well, I could pig out on this or that," or, "I will continue to smoke despite what is on the label and whether I know it is bad." So, therefore, I think even though it is important that, from your perspective, from selling your product, that it may be raising some questions in the consumers' minds, I think it is still serving an important role in terms of raising people's level of alertness of things that they should consider, especially with respect to nutrition because nutrition is an area that people are very confused about.

At one time, you hear you shouldn't eat butter. And then, the next time, butter is okay and margarine is this--but, yet, the basic components are all sort of similar. So, therefore, I think--I don't know where I am actually going except to comment on the fact that, in many ways, I wouldn't want to not see a label.

I think the fact that people are maintaining or seem confused and uncertain only means that we need to do more for education so people can make reasonable choices for themselves rather than placing it in the hands of a government body to decide for them whether or not it is good or bad.

Thank you.

DR. BRANDT: Do you want to respond, either one of you?

DR. ALLGOOD: Yes. I would like to respond. I think that I agree with your comments very much that there is an important need for education about this product. A lot of us at Proctor and Gamble have spent their lives on the road in the last couple of years doing just that. I have personally talked with thousands of dieticians about this product.

I think that the way to provide accurate information is through health professionals where consumers can have a dialogue about the product. I disagree that the information--I respect your opinion but I disagree that an information label is the right place to do that.

But I thoroughly agree with you that there is a big need for education on the product and we are going to continue to work very, very hard to do that.

DR. FUKAGAWA: But the label is a place where you can initiate that dialogue because not everyone will go to a nutritionist and say, "Tell me about olestra." You have to look at it, where do most people get their information? T.v., newspaper ads, perhaps, if they read the newspaper, and labels on boxes.

Despite the fact that they may not look at it

initially, if they think it tastes great or they have suddenly lost ten pounds, they may look and say, "Wow." Oooh; I shouldn't have used that. Oh oh. Anyway, you know what I am saying.

DR. BRANDT: Mr. Levitt, do you have something to contribute to all this?

MR. LEVITT: I only had a question to ask, if I am permitted.

DR. BRANDT: Not now. Dr. Clydesdale first and then you.

DR. CLYDESDALE: I wondered if you had any information on health professionals' interpretation of the label, physicians and other health professionals?

DR. ALLGOOD: I'm sorry; could you repeat the question.

DR. CLYDESDALE: I wondered if you had information on physicians and other health professionals on their interpretation of the label.

MS. PAPA: Yes. Actually, we do. We did survey physicians as part of our physician education program. We did a follow-up survey with physicians. I can't recall the numbers off the top of my head, but there were some concerns also expressed by physicians around consumers' potential in terms of misinterpreting the label.

DR. ALLGOOD: Just to clarify, so we are not

misleading. Our physician surveys, we have had a poor rate of response, as you typically get. So that is one of the reasons we didn't present that data. But it does show--one of the interesting things that it showed was that after reading the label, the physicians who responded, a significant proportion of them said they had some level of concern, either slight or very concerned, that people's interpretation of the label would mean that they would delay medical treatment.

Of course, that can have some serious ramifications. In fact, when we ran one of our test markets in Cedar Rapids, there was an E. coli outbreak. Some of the gastroenterologists in that community, which was our test market, expressed some concern that people might read the interim label and delay medical treatment when they really had, in fact, an E. coli outbreak.

So some physicians, based on our limited sample, are expressing concern about the interim label.

DR. BRANDT: It reminds me. I have done a lot of surveys with physicians. Two things come to mind. First, you get a low rate of response and, second, you have to hire a pharmacist to read their handwriting.

MR. LEVITT: I just wanted to follow up on an earlier question and see if we can get a maybe more direct answer, and that is what impact do you think this label has

on sales or what impact would you think not having this label would have on sales. It is the same question in the inverse.

DR. BRANDT: I am going to let you answer that question but I think that is contrary to your instructions to this committee, Mr.Levitt, to talk about sales.

But if you want to answer it, that's fine.

DR. TREIBWASSER: I am not sure I want to answer the question. I think this discussion is about what does the scientific data support that ought to be on the label, what do the data say, what does it mean, what do people, what do consumers, perceive about the label?

If we want to discuss the impact on sales perhaps we can do that separately. I am not sure it is a piece of information that this committee needs to worry about.

DR. BRANDT: As a matter of fact, I don't think this committee needs to worry itself about Frito-Lay sales or Proctor and Gamble sales. That is not our issue.

MR. LEVITT: If I might clarify. I did not word my question well, but I was trying to get at the question of people's uncertainty, does it affect their purchase of it or does it affect them thinking about it after they purchase?

DR. TREIBWASSER: I think as you saw from the video clip, there is no question that people who perceive this as a warning label avoid buying the product.

MS. COPP: Actually, I wanted to follow up on an earlier question so, perhaps, you should go with Dr. Clancy and then I will ask my question.

DR. CLANCY: I wanted to ask Ms. Papa the follow-up question to the other one. Have you surveyed dieticians about their response to the label, not what they think consumers are going to do because I am much more with Dr. Fukagawa on that. I think that consumers really do have to have the ability to make their own decisions and not have it always filtered through professionals, even though I am one such.

What do dieticians tell you about their response to the label--not what they think consumers are going to say about it but their own response to the label. Are they uncertain or are they completely confused?

MS. PAPA: When we said physician research, that was actually health professionals and that included physicians, some pharmacists and also dieticians. What we specifically were asking them about was interpretation of the label. So what Mr. Allgood said for physicians, that included the dieticians in that.

DR. APPLEBAUM: But you didn't ask them to respond in their own role as consumers. You asked them to respond about what they--as if they weren't consumers would say. No? You did ask them specifically?

DR. ALLGOOD: Right. We were asking their impressions of the label. I can tell you that, especially, working with a lot of dieticians over the last year, there is a lot of confusion over the label. I don't think I have, in fact, met a single dietician that understood the last two sentences, what they really meant.

DR. BENEDICT: I was just struck by a statement, a series of statements, and that is I can, on the one hand, perceive why a label might prevent people from visiting the physician in a timely fashion. Certainly, that makes sense.

On the other hand, two years from now, it might not make a difference. But right now, at this time, when perceptions by the public have sort of begun to pervade by not stabilize, it would seem to me that, in the absence of a label--this is just a hypothesis that I would like for you to explore. It is not my own opinion.

It would seem to me that, in the absence of a label but in the presence of a public perception that there might be a problem, that, in the absence of something that says this is safe, meaning, "think about some other source of your difficulty," people might, in fact, attribute their difficulty to olestra and delay their appearance at their physician's office.

I am wondering if you could respond to this with respect to the near term, not necessarily after opinions and

education have stabilized our population.

DR. ALLGOOD: What we have seen that happens from olestra in any of these studies, the digestive effects which might occur after eating olestra are not severe effects. The people who had severe effects that we heard about, those effects are not due to eating olestra.

So when people need medical treatment, they need medical treatment.

DR. BENEDICT: No, no. Forgive me. I think you are misunderstanding the question. What I am saying it is possible that the public will perceive, regardless of what the truth may be, that their difficulties are due to olestra and delay going.

As you have said, in the presence or the absence of a label, these are two different things. Do you guys in the back there have a different perspective?

DR. DROTMAN: That is one of the reasons we tested the third label to see--especially if we are looking at the comments from the consumers to see a label that said, "If you have serious symptoms, or symptoms persist, please go see a physician."

I think your contention is absolutely correct, though, that people might too easily blame something on olestra that has nothing to do with olestra and delay going to a physician and get themselves in trouble, like

appendicitis or something like that.

I think that is a good point.

DR. ZORICH: I would like to add that when people do call us, if it is something--and it is a very fine line to take with a consumer because you don't want to tell them you are not listening to them. But when they do call us and they are having effects that we believe they need medical care, we encourage them strongly not to simply be fixed in their opinion but to see appropriate medical care.

DR. BENEDICT: But they all, of course, won't call.

DR. HARLANDER: I am thinking about your comment and I am wondering--you know, a number of years ago, the Kellogs Company put a lot of information about the impact of fiber in diet and health on their package. I realize that people that eat breakfast cereal probably sit with the package in front of them--at least I do when I eat breakfast cereal in the morning--and I read it.

Maybe you don't with a potato chip bag, but in light of the need to educate consumers about this, I am wondering if that has ever been tested. You kind of test it because you say that it is a new cooking oil--at least one of your things talked about that and there was still quite a bit of uncertainty about that--but at least it might encourage an educational goal about macronutrient

substitutes and what people might expect.

In fact, people, then, might expect a laxative effect so that when they eat olestra, they are doing it for that purpose in the same way that you consume bran or psyllium or some of these other products.

Have you ever tested or thought about, either of the companies that market these products, in doing something like that?

DR. TREIBWASSER: I don't believe P&G has tested anything like that.

DR. BRANDT: Has Frito-Lay?

DR. DROTMAN: No. What you saw is what we have tested.

DR. BRANDT: Since I got in a lot of trouble the other day for saying nasty things about lawyers, I have to let Ms. Copp finish this session, except for a joke I am going to tell.

MS. COPP: Catherine Copp from the Chief Counsel's Office at FDA. This is a question that I would like to direct to both companies. I am wondering whether any of your survey data or any other consumer survey data that you are aware of can tease out the lack of consumer enthusiasm, if I can use that term, for these label statements because we are talking about a new substance or a "food additive," a chemical that has been added to food.

That is the question. Dr. Treibwasser is looking at me.

DR. DROTMAN: We probably can't tease out on a statistical basis. We did get some comments from some people--I think I actually have them upstairs. These is just the written-in so there is no real--these are anecdotal. But some people did say, "I don't like statements on this on my food packages. It makes them unappetizing and I don't want to buy them." That is the sort of thing we got.

I can't remember if we got a lot of them or a few of them but we did get statements like that on the free-form portion of the questionnaire.

DR. TREIBWASSER: I am not sure we have anything that is very salient to that point.

DR. BRANDT: Dr. Harlander brought up one of the more painful memories of my term as Assistant Secretary for Health, having served as the referee between the Cancer Institute, the epidemiologists about fiber. It was an interesting time that I would like to forget.

The story I was going to tell when I saw all the FDA people rally around to try to respond to this question just reminded me, I was watching Monday night football one time back when Dandy Don Meredith was on and Frank Gifford. This is a real story--true, that is; not just real but true.

The quarterback called time out and went running over to the coach. And Frank Gifford said, "You know, when I was playing, Don, Y. Tiddle used to do that." He said, "What do you guys talk about when you run over there?"

And Dandy Don, in his own inimitable way, said, "Well, I don't know what Y.A. and his coach talked about. When I run over with a problem to Coach Landry, I explain the problem, he looks at me and says, "It is up to you, son."

We are going to take a break, now, for fifteen minute.

[Break.]

DR. BRANDT: The committee will reassemble please. We are now going to hear from Dr. Michael Jacobson representing the Center for Science in the Public Interest for 20 minutes.

Dr. Jacobson, the floor is yours.

CSPI

DR. JACOBSON: Thank you very much once again for allowing us this opportunity to present our views.

Labeling is not an appropriate means of protecting people from risks associated with olestra. The GI symptoms are unpleasant and sometimes downright severe. The carotinoid losses are imperceptible and their likely effects many years off. Also a label does nothing to protect people

who don't see it.

CSPI has received reports of adverse GI reactions from many people who never saw the label because they ate the chips from a bowl at a friend's house. Some of those people told us that if they had known the chips contained olestra, they wouldn't have eaten them.

I don't think I have to reiterate that our preference would be that olestra not be on the market for the two problems, GI effects and carotinoid losses. But, in the context of this labeling discussion, I would like to present our views.

Proctor and Gamble maintains that olestra does not cause meaningful gastrointestinal symptoms and suggests, therefore, that a label notice is not necessary. Proctor and Gamble cites studies that it contends demonstrate complete safety but it fails to acknowledge that its several recent studies involve very few people.

For instance, the six-week study involved roughly a thousand people who ate olestra which means the 90th percentile group is only about 100, 150 people. To extrapolate from that kind of study to 100 million or 200 million consumers of olestra products provides no grounds for reassurance whatsoever, and it certainly provides no grounds for stating that olestra does not cause this effect or that effect.

The number of people was too small. It is impossible to identify rare effects from that kind of a study. The other studies, the movie-theater study, involved only about 500 people who ate generally quite modest amounts of olestra. It simply provides no--there is no safety factor in that kind of a study.

Furthermore, other studies conducted previous to the approval of olestra have found that olestra can cause symptoms that are sometimes severe. In figuring out what the wording of the label should be, it is important that we not have amnesia prior to January 30, 1996, but have to put the recent studies in the context of the previous studies.

In addition to those studies, thousands of people have suffered symptoms that they attributed to olestra and, in some cases, their physicians concluded that those symptoms were, indeed, due to olestra. There is no way that you can do a double-blind study on every single person who calls in.

The second rechallange study, the rechallange done after approval of olestra, involved only 100 people were not prescreened to look for sensitivity as was the previous rechallange study called the fecal-parameter study.

If olestra is allowed to remain in our food supply, consumers need a prominent, candidly worded notice in both labeling and advertising to apprise them of the

problems that this chemical can cause. We are basing our recommendations on comments submitted to us and the FDA by Dr. Sidney Lirtzman, a labeling expert at and the dean of the Zicklin School of Business at the City University of New York and by Professor Michael Wogalter, a labeling expert a North Carolina State University. Both of those professors have consulted for federal agencies or served as expert witnesses on labeling issues.

I would first like to discuss the visibility of the current notice. Three companies use olestra in their products. All three companies print the notice on the bottoms of the backs or sides of packages as inconspicuously as possible. As Dr. Lirtzman said, "The way the FDA-required statement is used virtually insures that it will not be noticed or read by most consumers."

I mentioned earlier, we did a random telephone survey that we conducted in Indianapolis and we asked people whether they saw the notice. We asked olestra eaters how many of them saw the notice. Only 32 percent of those olestra eaters, and there were about 200 people, said they had seen the labeling with some of those seeing it only after they ate the product.

We also asked people who call our toll-free line whether or not they saw the label notice and whether or not they saw it before or after they purchased or ate the

product. Only 44 percent of a sample of 716 people said that they had read the label notice before purchasing or before eating the chips, 44 percent.

Many people have told us such things as, "I didn't think I had to search around on a bag of potato chips for a warning notice." And, "Current information on labels is not sufficient. It needs to be as large as the product name." And, "No one will look for a warning label on chips." Those people are exactly right. Consumers expect food to be safe.

They don't expect that a warning label, or call it an informational notice or whatever you want to call it--they don't expect that to be on a food especially one as commonly consumed as potato chips.

The FDA should require the notice to be printed on the front of the package. If the whole notice is not on the front, a statement should be printed on the front guiding people to a longer statement elsewhere on the package. I don't recall if I said it already, but the FDA gave companies permission to print the label notice either on the front of the package or on the back of the package, which seems like a waste of ink to me. Clearly, they are going to print it on the back of the package.

Secondly, the notice should be printed about one-third of the way from the top of the front of the label. Otherwise, the notice may be hidden by the shape of one of

those big bulging potato chip packages or by the lip on store display cases that hide the fronts of the labels, the bottoms of the labels.

Thirdly, the notice should include an attention-getting signal word such as "caution." The current wording of the notice is inadequate. First, it fails to indicate the potential severity of symptoms. Many consumers who experience severe symptoms that they attributed to olestra said they saw the notice but felt that loose stools wouldn't be any problem.

They said that they would not have eaten the product had they known that the symptoms could be severe. As one woman told us, "The pain felt like childbirth. P&G should put 'severe' on the warning label."

A candid notice about GI symptoms is particularly important considering the companies are mounting massive advertising campaigns that proclaim that olestra is "safe for everybody" and that olestra snacks are "a little healthier" than regular snacks.

Second, the label only discloses cramps and loose stools. Because diarrhea was a symptom identified in several of P&G's preapproval studies, the new six-week study and in hundreds of vivid adverse-reaction reports, labels should state the possibility of diarrhea. Labels should also indicate gas as a possible symptom.

Other concerns include discolored stools and oil in toilet. Many people have told us that they were very concerned about whether they were experiencing some kind of severe unknown sickness because their stools were coming out yellow or orange or greenish. And also they were concerned about the presence of oil in the toilet. Where in the world could that come from? Without label information about such concerns, it is much more difficult for communities to identify their cause.

Third, and this is one I agree partially with Proctor and Gamble and Frito-Lay, the language on nutrient losses must be clarified.

[Slide.]

These are the two sentences that are currently on the label. "Olestra inhibits the absorption of some vitamins and other nutrients, vitamins A, D, E and K have been added." But the label is silent about the nutrients not added back. The fat-soluble carotinoids are the most prominent such nutrients but it is possible that other, even unknown, nutrients are also affected.

We urge that the label include the statement, "Olestra keeps your body from absorbing vitamins and other important nutrients. Vitamins A, D, E and K have been added to reduce this problem but carotinoids and other nutrients have not been replaced. Carotinoid losses due to frequent

consumption of olestra products may increase the risk of cancer and other chronic diseases."

That is based on Dr. Colditz testimony from yesterday and also by the general consensus of the scientific community that carotinoids likely protect against cancer and other chronic diseases.

Finally, the label should advise people with severe symptoms to call or visit their doctor. Indeed, many people have told P&G or CSPI that they experienced such severe symptoms that they did go to the doctor. Severe symptoms that are caused by olestra may require medical care. If the symptoms are due to something else, it is also critical that a physician determine whether a patient is suffering a gall-bladder attack, appendicitis infection or other problem.

I would like to turn to the current utility of the label for passive surveillance. The olestra label could, but now does not, promote the reporting of symptoms and lead to a better understanding of their nature and prevalence. When the FDA approved olestra, the agency suggested, but did not require, that companies include a toll-free telephone number in the required label notice, itself.

Not one of the three companies has accepted the FDA's suggestion. Instead, the notice has been placed elsewhere on the label, oftentimes on the fat-free Pringles,

quite inconspicuously. I think it is gold print on shiny red paper. The phone number is a general consumer-service number, not one designated specifically for reporting adverse reactions.

Apparently, the FDA thought that providing a telephone number would help consumers obtain information about olestra but that it was not, necessarily, intended to facilitate the reporting of symptoms. But, considering the large number of people apparently experiencing and reporting symptoms, the FDA must insure that a phone number is provided expressly for that purpose.

As Dr. Wogalter noted, to provide for the safe use of olestra, the FDA should require manufacturers first to maintain a phone line devoted specifically to health concerns and, secondly, to include a toll-free number in the label notice, itself.

I would like to wrap up my discussion of the label notice by showing you the kind of notice that we think would be necessary to inform consumers and prevent misleading labeling. We say this based, again, on the totality of evidence, not on just three recent studies.

We also are building into it the recognition that we need a safety factor, that when you are going from small studies, inevitably small studies, to the 100 or 200 or 250 million people who will be consuming a product such as

this, we might run into especially sensitive people, idiosyncratic reactions, or much larger consumption by some people, by many people, than would be seen in these very limited so-called clinical studies or other controlled studies.

[Slide.]

"Caution; this product contains olestra," the signal word that labeling experts know helps draw people's attention to the label notice. If you think that is too strong, simply the word "notice," or "important notice," can also draw people's attention to the label.

"The Food and Drug Administration has found that olestra may cause diarrhea, loose stools, gas abdominal cramps and other digestive symptoms." A couple of those symptoms, like cramps, clearly was not seen in the overall results from the six-week study, but it clearly was seen in the previous eight-week studies at a statistically significant level. Also, many people have reported anecdotally that they experience cramps shortly after eating the olestra chips, and they blame the symptom on the consumption of the olestra.

The first term, "diarrhea;" that was clearly seen in the fecal-parameter study submitted to the FDA after the advisory committee met in November, 1995. That was a small study. It involved about sixteen people who had been

screened for an apparent sensitivity to olestra.

There was a statistically significant increase in severe diarrhea and four people had stool weights above the cutoff for diarrheal stool, the gas that is seen, loose stools that is obviously seen. Symptoms, occasionally, may be severe, seen in the eight-week studies and in the fecal-parameter studies. "If symptoms are severe or persistent, contact a doctor."

We have talked about the next paragraph concerning nutrients. "If you take Coumadin, consult your physician before eating olestra." People who are on Coumadin have never been tested with regard to vitamin K status following consumption of olestra. "Children should not eat olestra-containing foods." The tests on children are very, very paltry and certainly there are no studies on children under two.

[Slide.]

If that is too big to put on the front of the label, there can be a pointer on the front of the label suggesting that people read the label on the back. "See back panel for more information."

Now, I would like to turn to a totally different aspect of olestra labeling. I am talking about how olestra is referred to in the nutrient labeling and in nutrient-content claims. When the FDA approved olestra, the agency

granted a special exemption from nutrition labeling and nutrient content claim requirements.

First, the FDA allows the nutrient facts label to state that a serving of olestra chips contains no fat when, in fact, it contains about 8 to 9 grams of fat. Although the fat is not digestible, it is still fat. Second, chips fried in olestra may be labeled "fat free," even though they are full of fat. It is indigestible, but it is still fat. On that, I think everybody agrees.

Allowing olestra chips to be called fat-free deceives consumers and is unfair to makers of truly fat-free chips.

[Slide.]

This is two packages of potato chips both labeled fat-free, but the product on the left has no fat. The product on the right is full of fat. If you can see, this is how much olestra is in a five-ounce package of Wow chips. So, if somebody eats those fat-free Wow chips, this is what they are consuming. To call it fat-free I think is highly deceptive.

There are two other labeling practices that show how out of kilter the olestra labeling exemption is. FDA's Veterinary Medicine Division regulates animal feed and they require, in products for animals that contain olestra, to disclose the full fat content and then indicate either how

much is digestible or how much is indigestible.

The FDA should require consistent labeling of reduced-calorie fats including olestra.

[Slide.]

This is what we are recommending for the nutrition label. It was say, "10 grams of fat, 1 gram of available fat," in whatever product this is. And then a footnote saying, "This product contains 9 grams of olestra which is not digested by the body."

Second, claims like "fat-free" are not truthful and should not be permitted on olestra-containing products.

[Slide.]

Instead, the FDA could permit a truthful statement such as "no calories from fat," and, to prevent people from concluding that there is no fat in the product, it should state, in smaller print, perhaps, "contains 8 grams per serving of the indigestible fat substitute, olestra," to explain to people how a food that contains fat doesn't provide calories.

That finishes my statement. Thank you.

Questions

DR. BRANDT: We are now open for questions of Dr. Jacobson. Dr. Applebaum, who I was accused of ignoring last time, I am going to start with you.

DR. APPLEBAUM: Thank you, Mr. Chairman. This is

for FDA. So can I still ask it?

DR. BRANDT: That's quite all right. You can ask FDA as long as they don't want to talk about sales.

DR. APPLEBAUM: I just have a question for FDA in regards to criteria used in determining when a separate label is warranted above and beyond the ingredient panel. I guess my question refers to, specifically, sulfites. In terms of opinion reached by FDA that the ingredient panel, in and of itself, was sufficient to inform the consumer of the presence of sulfites.

MS. CAMPBELL: The principle that is being referred to here has to do with hypersensitivity reactions to foods where a food is generally safe but there is a subpopulation of people who have adverse reactions. In many cases, those are allergies. In other cases, they are intolerance or other kinds of hypersensitivity.

For sulfites, our general principle is if a person needs to avoid the substance, the particular food item, that can be done as long as the person can be told by the label that the substance is presence. It has been our policy for a long time that the ingredient declaration provides that information.

The ingredient declaration provides information on everything that is in the food whether or not it causes a hypersensitivity reaction. All of those substances that do

cause adverse reactions are covered in the ingredient list. A person who needs to avoid can avoid by reading the ingredient list.

A number of years ago, we decided that sulfiting agents--we recognize that they cause hypersensitivity reactions. Where the ingredient list did not include the sulfiting agent that was present in the food, it was due to an exemption, we removed the exemption so we were still consistent with the principle that an avoider can obtain enough information from the ingredient list to avoid the food where there is a hypersensitivity reaction.

Is that the clarification you need?

DR. APPLEBAUM: Yes.

DR. POTTER: Betty, if it were shown that the pathogenesis of the acute-onset gastrointestinal signs were limited to a specific identifiable population, would your sulfite example then suggest that listing olestra in the ingredient statement would be enough information for avoiders to avoid products containing olestra?

MS. CAMPBELL: We could certainly evaluate whether that was the case. For allergens and other similar substances that cause adverse reactions, we are talking about a limited population and we are talking about these substances are perfectly safe for other people, that other people don't have a reaction to them at all.

DR. LAMM: Dr. Jacobson, I heard yesterday the presentation both of Dr. Colditz and Dr. Ommen. It would seem to me, based on that, that your recommended label might say that the reduced carotinoids may increase or decrease the risk of cancer of cardiovascular disease. Would you accept that modification?

DR. JACOBSON: No; I wouldn't. The issue with olestra is lowering carotinoid levels and lowering levels of numerous carotinoids. The only evidence of risk comes from an unusual scientific study where huge amounts of beta carotene, one carotinoid, are added to people's diets. That is very different from what olestra causes. It is not something that normally occurs, certainly with olestra.

I think that we need to turn to the various expert committees that have reviewed the situation and, where there is a general consensus that carotinoids likely reduce the risk of certain chronic diseases and that people should consume more foods with those carotinoids.

DR. HARLANDER: I want to make sure I understand. You are suggesting that the label be changed to include the word "diarrhea," based on the results of sixteen people who self-reported diarrhea. But everything that I have heard has discounted that what we are really dealing with is clinical diarrhea in any of these cases.

Did I understand that right? You want to base

this label change on the results of sixteen people? Did I understand that correctly?

DR. JACOBSON: There are virtually no tests looking at clinical diarrhea, when you look at water loss and electrolyte loss. The fecal-parameter study is the one study that was designed to detect if olestra can cause any kind of the diarrhea or severe diarrhea. And that one looked at stool weight and water content. I don't think it looked at electrolyte losses.

The FDA acknowledges that that study, a small study, showed a significant increase in diarrhea and severe diarrhea and that the increased weight of the stool could not be made up for by the extra weight of olestra. Some of the people in that study had huge increases in stool weight, up to almost a tripling of the normal stool weight, well over the cutoff point for diarrheal stool.

Remember how that study was done. It tried to identify people who were sensitive to olestra and, apparently, it did that. The more recent study, comparing olestra to sorbitol, did not involve sensitive subjects. Those were just random people. I think there were 22 people or 44 people who ate a given amount of olestra.

That study was not designed to detect whether olestra can sometimes cause diarrhea. It was designed to detect whether olestra typically increases stool weight,

presumably by an osmotic effect. It did not find that. There was only a little bit of increased weight of stool.

So the fecal-parameter study clearly showed olestra can cause diarrhea. Then you can throw out all the anecdotal reports, if you want, but I think with a background of the controlled studies demonstrating that olestra sometimes causes diarrhea, I think you throw them out at your peril.

If you throw out all the anecdotal reports, why even bother collecting them.

DR. FENNEMA: I am having some difficulty, Dr. Jacobson, with your definition of fats. In all the books I have read on the subject, I understand that fat is a triacylglycerol. So olestra is not a fat. It is a lipid. That is fair enough. But it is not a fat.

DR. JACOBSON: Well, Proctor and Gamble calls it a fat. Proctor and Gamble calls it a cooking oil. Frito-Lay calls it a cooking oil. FDA's definition of fat is something that, when hydrolyzed, releases fatty acids and that when you are putting nutrition labeling on, you should convert those fatty acids back to the triglyceride equivalent.

FDA's Center for Veterinary Medicine considers olestra a fat. It is an indigestible fat. That is what people have said for years. To list it as "no fat" on the

nutrition label and "fat-free" on the front of the label hides from people the fact that they are consuming this glob. They are ingesting this. Otherwise, there is no evidence of this on the package.

DR. FENNEMA: This committee has been assigned the obligation to deal with scientific issues, and what you are describing is unscientific.

DR. JACOBSON: It is up to you decide. That is for each person for decide.

DR. FEINLEIB: Dr. Jacobson, yesterday we heard from two pediatricians, Dr. Clish and Czinn, about the usefulness, or potential usefulness, of these olestra products for treating obese adolescents. How does that square with your--

DR. BRANDT: Let's be careful. We are not to discuss benefits.

DR. FEINLEIB: How does this square with the labeling recommendation you just made that it should be an explicit warning that it should not be used by children.

DR. BRANDT: Oh; okay.

DR. JACOBSON: The testing on children is paltry. The FDA concluded several years ago that children have gastrointestinal symptoms that are essentially identical to adults and that, therefore, the FDA would not give much weight, if any weight, to the studies on children but would

apply the studies on adults to children.

Other pediatricians, who are not consultants to Proctor and Gamble, have expressed concern to the FDA about consumption of olestra by children because it depletes nutrients like carotinoids and that it may cause gastrointestinal symptoms.

I think even Proctor and Gamble's, or Frito-Lay's, literature suggests that it may not be appropriate to feed olestra to children under two.

DR. FEINLEIB: Another question--I think it is both to Proctor and Gamble and Dr. Jacobson--about the use of an asterisk next to either the fat content or to the vitamin content to give it further explanation. Are these consistent recommendations and would they satisfy the needs of either party?

DR. TREIBWASSER: The recommendation that we made for asterisking the vitamin content was very consistent with the other NLEA labeling procedures that are already in place. I won't comment on whether it is consistent with Dr. Jacobson's recommendation.

DR. JACOBSON: On the vitamins A, D, E and K, I don't think that is an unreasonable suggestion, so that people aren't confused by the addition of those nutrients and what they mean. But just having an asterisk for those four vitamins ignores the loss of carotinoids. That should

be stated explicitly on the label so that people who have concerns about potential long-term risks of consuming olestra would be advised and could make a purchasing decision based on that information.

DR. BENEDICT: This question is for Dr. Jacobson. It explicitly does not pertain to fat-soluble vitamins. It pertains to the question of symptomatology like abdominal cramping and loose stools. I would like to hear your response to the statement that says, "We do not require labeling of bran. We do not require labeling of psyllium. And we certainly," which I am adding, I am appending, "don't require labeling of things like Slim Fast, known to cause loose stools and some cramping."

How would you respond to the fact that labeling, as Proctor and Gamble and Frito-Lay have said, labeling olestra is not in line with what we do with these other items.

DR. JACOBSON: I am not an expert on the effects of psyllium, for instance. But, in the Federal Register, the FDA says, "Well, high-fiber diets have been associated with increased gas manifested as belching, flatulence and mild abdominal distention. Diarrhea and staining of underwear have not commonly been reported."

The FDA is distinguishing olestra from natural high-fiber foods or diets. There was a previous comment

from Dr. Chassy about how people are expecting some laxative effect from--I think bran cereals was the example mentioned, foods like that, whereas potato chips, people don't expect any kind of--all they expect is their tongue to be tickled, no adverse gastrointestinal symptom.

As far as sorbitol goes, that has been discussed. I think it might be appropriate to revisit that issue. I wouldn't use that as a benchmark but I would put up a question mark suggesting that maybe we should reexamine that kind of a label and do better studies, try to find out is there a threshold level and so on.

We are fortunate that sorbitol and mannitol and xylitol are very rarely used, used in a few dietetic chewing gums and candies, as opposed to a product like potato chips that is consumed in enormous quantity by many, many people.

DR. BENEDICT: So, do I understand you to be acknowledging that there is a discrepancy in consistency but, to be coming on the other side, meaning we should revisit the ones that were previously listed as not being labeled.

DR. JACOBSON: Some of them. Sorbitol, I think, in particular--

DR. BENEDICT: Slim Fast.

DR. JACOBSON: I don't know anything about it. I'm sorry.

DR. FUKAGAWA: Dr. Jacobson, I was trained as a pediatrician. My understanding is that the issue of fat substitutes and low fat is really for children who are under two years of age because of CNS development and things. I think the broader issue is not so much whether or not it has been proven or disproven that these fat substitutes are unsafe for those who are over the age of two but not quite to the age of consent which would be 18.

It is not the issue, I don't think, as much, of using a fat substitute as it is whether or not including foods that contain this are appropriate to have in the food supply for the children. Do you follow me with that? I do think that it is unfair statement for you to say that it should not be used at all in all children.

I do agree with the fact that it is under two, that one should not use fat substitutes or low-fat foods. But beyond that, it may, indeed, play an important role in some of the management of issues like obesity in children but a more important, broader issue is the food choices the children do make. I think we do have to instill appropriate selection of foods, not necessarily substituting snack foods for what is considered a nutritionally balanced or well-balanced diet.

DR. JACOBSON: I certainly agree with you. We do need more educational programs. In response to your

question a half hour ago, Proctor and Gamble discussed their vigorous educational campaign. I think we would be misleading ourselves if we think that is going to be a truly objective educational campaign.

They are spending $100 million on advertising telling everybody that olestra is practically a substance practically squeezed out of soy beans and, therefore, is safe, with television ads. Their campaign among dieticians and other health professionals is completely one sided, obviously.

They are not going to talk about certain studies that they don't want to talk about. If that is the educational campaign that we are going to have in place of a label, I think that would be a terrible judgment on the part of the FDA. There is no way for the FDA or independent medical associations, if there are any, to mount a reasonably responsible and intensive ongoing campaign.

Look at the top of a Pringles package. It says, "Once you pop, you can't stop," which, I think, is a not so subtle urge to eat the whole can of 6 ounces of chips.

DR. FUKAGAWA: I would think, in terms of public interest, it does not also help to continue to negatively slam something. You really don't help, I think, by just bringing up all the things that are wrong. I think both your side, CSPI, and Proctor and Gamble, in many ways, could

effectively work together to help educate the public rather than using one side versus the other and making it so adversarial.

It is unfortunate that it appears to be that this is the kind of presentations we are having.

DR. JACOBSON: And, perhaps, it is. I guess we live in that kind of society where a company can spend $100 million putting forth its point of view. My organization tries, with its paltry budget--we spend less in a year than P&G spends on advertising in one day--to try to get out some other information.

DR. BRANDT: I have promised Dr. Treibwasser two minutes to clarify--oh; Dr. Rulis?

DR. RULIS: Thank you. In light of this recent discussion, and because Dr. Jacobson did mention the fecal-parameter study and attribute FDA conclusions, and I know we are not supposed to be talking about "old data," but, for the sake of the record, I wanted to--

DR. BRANDT: That is what the FDA says.

DR. RULIS: What I would like to do for the sake of the record is just read into the record the statement coming out of the Federal Register in relation to that fecal-parameter study. It covers, essentially, a page in the Federal Register, but I am going to read a sentence here.

"FDA notes that there appears to be an increased weight in stools in those subjects reporting diarrhea when eating 20 grams per day olestra." That is not completely accounted for by the presence of olestra in the stools." FDA concludes that, "The results of this study indicate that there is no difference in stool composition, for example water and electrolyte content, between those subjects consuming olestra who reported diarrhea and those who did not." And then there is a reference cited.

Thank you.

DR. BRANDT: Dr. Treibwasser wishes to give a response to certain charges that they feel questioned their integrity yesterday. So you have two minutes, sir.

DR. TREIBWASSER: Thank you very much. Yes, we would like to respond to Dr. Colditz' presentation yesterday which made some suggestions about our carotinoid review.

DR. PETERS: In the interest of not being adversarial but, rather, clarificational, perhaps, to coin a new term, I did want to say that, on a personal level, I was really disturbed by the presentation and, on a professional level, scientific level, I was, I guess, more disappointed about the characterization of the review that we did of the carotinoid literature which was characterized by Dr. Colditz on CSPI's behalf as "selective and unscientific."

[Slide.]

There were accusations of both omission and commission. I just wanted to clarify a couple of things. With respect to accusation of omission, I would first say that our comprehensive literature review that we handed out yesterday was just that. It was comprehensive for the past couple of years, since 1996, as we portrayed it.

The executive summary that Dr. Colditz reviewed was clearly identified as a summary and, in fact, on page 30 of that summary, it said that the full referenced, complete, comprehensive report was submitted to the FDA and, therefore, would be available to the public.

Our comprehensive review cited over 217 references published since 1996, and there were dozens of references that Dr. Colditz mentioned in his presentation. I can tell you that exactly three of those were not included in our review. One of those was a paper that was in the peer-reviewed literature which was talking about carotinoids and carotid artery thickness, not specifically talking about disease.

The other two were abstracts which, while they are in the published literature, they are not yet presented to the public. They will be presented at the end of this month at the Society for Epidemiologic Research. The data were not available to look at, so that is why we didn't include it in our review.

Finally, we take particular exception to Dr. Colditz' characterization about our looking at the literature that he did discuss. Namely, this would be errors of commission. Let me make one specific example, and I would be happy to provide this slide-by-slide interpretation of his talk if committee members would like.

[Slide.]

He characterized our assessment of the prostate literature as grossly misleading. He indicated, on this slide, that, the consistency of the data is strong. The implication from this slide is that there are 66 new studies that have indicated that there is protective effect of carotinoids against prostate cancer.

I would just point out that he also held up the report from the American Institute for Cancer Research which summarized thousands of references, not just up to 1996 but beyond. I would just make the point that this prestigious body, which he cited as evidence that there is consensus on this issue, reviewed the literature.

[Slide.]

They found only 14 studies which referred to carotinoids and prostate cancer. Since this is a little bit small, I will just finish by reading the paragraph. "Both increased and decreased risk with higher carotinoid intake have been observed in various studies. Differences in the

direction of risk estimates for younger and older men are apparent in several studies, but some studies show decreased risk in other men and others show decreased risk in younger men.

The evidence is not more consistent for any particular carotinoid than for other individual carotinoids or for carotinoids as a whole. Based on the inconsistent nature of the available evidence on dietary carotinoids, no judgment is possible.

So I just wanted to provide that clarification. As I said, we have further information on each and every slide that was presented and I just wanted to make sure the committee did not go away thinking that, somehow, we had picking and choosing amongst the literature to make particular points. It is comprehensive since 1996 and we are prepared to stand behind that.

Thank you.

DR. BRANDT: We do have the material.

Committee Discussion

DR. BRANDT: Now, we are down to crunch time, folks. I am now going to go poll the committee. I am going to do it alphabetically with two exceptions and that is, one, I am going to lead off. Okay; three exceptions. One, I am going to lead off. Second, we are going to go to Dr. Fukagawa and then Dr. Askew, both of whom have to leave

early.

So, addressing the three questions, my conclusion is to question, no. 1 concerning--

DR. BLACKBURN: Excuse me. You are a wonderful guy, Ed, but I find it very prejudicial that the chairman of a group would give us his vote first. Not even the Vice President gives his vote until the Senate is finished.

DR. BRANDT: I was thinking that you wanted me on the line.

DR. BLACKBURN: We want you on the line, but--

DR. BRANDT: If you don't want me to go first, that's fine.

DR. BLACKBURN: I just find it a little unusual. Why don't you go last.

DR. BRANDT: All right. Can I go with the two that have got to leave early?

DR. BLACKBURN: Do what you like.

DR. BRANDT: Dr. Fukagawa.

DR. FUKAGAWA: Therefore, I get put into the position. So, with regard to the first question on passive surveillance and GI effects, I do not believe that there are new significant unanticipated gastrointestinal effects obtained from the passive surveillance reports and that the effects were, indeed, extreme in some individuals but merely troublesome for most of the consumers.

However, I do not believe that we have sufficient information to assess longer-term effects which may be detrimental to good health. So that was an editorial comment, I think. And the answer to the first question was no.

The second new data obtained from the active surveillance with respect to absorption of fat-soluble vitamins or other lipophilic substances, my conclusion from the information provided was that the data presently available have not demonstrated a significant adverse effect on health due to interference with the absorption of fat-soluble vitamins by snacks containing olestra which contain vitamins A, D, E and K.

However, I do think that the data are not available at the present time regarding other lipophilic substances and, more importantly, I think the long-term effects still need to be monitored and the effect of olestra availability on public-health education must be examined for adverse health consequences with respect to what I had been sort of seeming to be harping on which is related to nutrient choices by children when they finally achieve adulthood since, if olestra is thought of as a macronutrient being present in the food supply, I think it is very important that children, especially, who develop their eating habits and food choices in childhood do not continue

to view it as a substitute for a macronutrient.

This is also important with respect to the prevalence of obesity as we have discussed and heard about earlier. I also do believe that the public deserves choice in the food supply just as I think industry deserve the opportunity to profit from a new development.

But I think together both have a societal responsibility to assure that the public is appropriately educated, that a synthetic food designed to alleviate a health problem does not equate or is a substitute for "responsible nutrition."

I think that is, in a sense, a thing that we have been tangentially addressing with all of these issues of food substitutes and I think is an important thing for the FDA to consider in its deliberations

Finally, with respect to labeling, I believe, after listening to this morning's presentations, that, at a minimum, the labeling of olestra-containing products should not change its content. However, I would recommend that the label be placed on the front of the bag and clearly note that olestra should not be viewed as a means to meet the goal of reducing calories in the food supply or in one's diet.

I think it should be used initially as an aid, or I don't know if you have enough room on a label to say

something like that, but it could aid in calorie restriction or reduction. However, it should not be viewed as a true means to achieving the healthy 2000 diet of overall decreasing our caloric intake.

The GI side effects, as well as interference with vitamins or lipophilic drug absorption, I think, should remain on the label and I do not agree that olestra, as a synthetic substitute for a macronutrient, falls into the same category as fiber or sorbitol, the latter of which is really a sweetener, an additive or an enhancer of foods rather than substituting for a macronutrient issue.

I think when more data does become available regarding long-term use, now that olestra is being nationally available, it would be appropriate to reexamine this issue of labeling.

Thank you.

DR. BRANDT: Are you reasonably comfortable, then, with the laws requirements which say that there is reasonable certainty of no harm?

DR. FUKAGAWA: I was just blanking out because I was passing my written word down to Dr. Larsen and I didn't hear what you said.

DR. BRANDT: I said are you, therefore, comfortable with the law's requirement with respect to reasonable certainty of no harm?

DR. FUKAGAWA: Yes.

DR. BRANDT: Yes is the answer. We will now turn to Dr. Askew.

DR. ASKEW: Thank you, Mr. Chairman. Having sat through the '95 review, I feel considerably more comfortable since there has been a good deal more research conducted by Proctor and Gamble and I think all of us appreciate the opportunity to view that research and use it to help us make some judgment with regard to the safety of olestra-containing food products.

I think that the new data collected by the postmarket surveillance, the passive surveillance, the rechallange test, the Q consumption studies, the home consumption study, are all consistent with the 1995 review that the use of olestra in savory snacks, with reasonable certainty, will result in no harm.

I see nothing in this to alarm us further than what we were. In fact, there were some assurances in the data. The new data collected were pretty consistent with the predicted effect of olestra snacks on stool consistency, the frequency of bowel movements, the level of serum-fat soluble vitamins and carotinoids.

In other words, olestra snacks seem to be, according to the preliminary data that has been collected--need to continue to be monitored, and I understand that it

will be. It seems to be consumed to a great extent not with meals and has, therefore, a relatively negligible effect on serum carotinoids and other lipophilic substances which concern most of us as nutritionists.

There has been no new compelling evidence, as near as I can tell, that has emerged since 1996 that has conclusively demonstrated that carotinoids are especially essential to health and the prevention of disease. I still view them as an important class of nutrients which we do not know enough about but I do not see any effect in the new data on olestra consumption in savory snacks on carotinoids or any new data that say that any small effect would be particularly worrisome.

So, to get to the questions do I see any significant unanticipated GI effects that are adverse to health in the data that has been presented? No. Do any of the new data indicate significant adverse effects on health due to the interference with the absorption of lipophilic substances? No; there is nothing in the new data that suggests that.

Now, with regard to labeling, considering the unusual nature of olestra and especially with respect to its appearance in things such as savory snacks, I do believe that a label should be retained. Perhaps, it can be improved with some wording changes but I do think that the

label needs to be on the package.

However, I do agree that the average consumer is not interpreting the label correctly and I do support efforts that will, perhaps, improve understanding of the label. I would, personally, like to see a statement on the label that said, "For optimum dietary nutrient absorption, this product should not be consumed with fruits and vegetables, or at the same time." But that is just a personal preference of my own.

Thank you.

DR. BRANDT: Thank you very much, Dr. Askew. For the two of you who may get out without me noticing it, thank you for being here and for participating and so forth. Have a good and safe flight back.

Dr. Applebaum is next.

DR. APPLEBAUM: Thank you, Mr. Chairman. Mr. Chairman, I would love to provide my independent scientific opinion on the three questions before the panel but my desire to insure the process and the deliberations and the conclusions of the panel remain above reproach. This desire is greater.

Two and a half years ago, I was disappointed that the integrity of several panel members was challenged because they had, at one time or another, consulted with the petitioner, consulted with members, other members, of the

food industry. Furthermore, there were scientists that met the gold standards as it relates to the peer-review process, these researchers were challenged simply because the research was supported by the petitioner.

These challenges were done to cast aspersions on the process. In view of these past incidents and the fact that I work for the National Food Processors Association, a trade association that is based in science and technical information that represents the food industry, I am concerned that if I were to provide my independent scientific opinion, the potential for it being misinterpreted and the potential for it to adversely impact the process is too large a risk.

I respect the integrity and I respect the scientific credibility of the process. More than that, I respect the integrity and the scientific expertise and the opinions of this panel. Consequently, in order to avoid any perceptions of conflict that may adversely impact the process, I respectfully abstain from providing my opinion.

Thank you.

DR. BRANDT: Thank you, Dr. Applebaum.

Dr. Benedict?

DR. BENEDICT: First of all, I would like to acknowledge Proctor and Gamble for their cooperation, their diligence, in carrying out these extra studies on a product

that was already approved. I would like to recognize Dr. Treibwasser, Dr. Zorich and Dr. Peters for their clarity of presentation of the information that they brought before us.

It seems that we have encountered a very organized, a very well-run operation. I would also like to express gratitude--I sound like a politician, don't I? It is my last meeting; all right?--gratitude to CSPI for providing opposing viewpoints in facilitating an opinion discussion and, finally, the FDA for the crispness with which they summarized everything and distilled things down to make it a little easier for us to come to, perhaps, I hope, a more objective opinion.

As part of my editorial comments, since I am leaving, I want to express my gratitude I hope on behalf of my fellow graduates to the people at the FDA with whom we have interacted regularly, including Lynn Larsen and Kathy DeRoever and Linda Hayden and Sylvia Washington for facilitating these meetings in an extremely competent way and finally to the chair for my post-graduate education in how to run a meeting which I have already put into application many times.

With respect to the comments, A, based on new data or information, are there any significant unanticipated GI effects captured in the passive surveillance reporting, et cetera. It seems to me that the validated symptoms that we

have been presented with are similar to those from other foods including bran and psyllium and, in fact, anecdotally to Slim Fast in some people and scientifically the data we were presented with suggests that the background levels of discomfort in the general population were similar to those reported in the passive surveillance.

In addition to that, any thoughts of an immune or allergic type response have essentially been removed from my thoughts. So my conclusion is that there is no new indication of symptoms that would cause a problem. However, forgive this phase, my gut feeling is that there may be a very, very minor unrecognized group of individuals who will respond negatively to olestra. I just would encourage Proctor and Gamble to remain alert to that possibility for the future.

B, active surveillance, based on the new data, this is the thing dealing with fat-soluble or other lipophilic substances. I confess, I was prepared to make an issue of prescription drugs when I arrived and I was somewhat mollified by being reminded of the '89 estrogen data and by the realization that the number of lipophilic drugs is pretty low and things like cyclosporine are generally administered intravenously.

So it is not an issue in my mind any longer, but I would like to request that Proctor and Gamble keep an eye on

this in the future, and I am sure you probably will. I would like to emphasize the statements that you have made about physician outreach and dietician outreach and pharmacist outreach. I would like to encourage you to continue along those lines.

In regard to fat-soluble vitamins, et cetera, I do recall the statement from the original meeting that we had that if any data appeared to suggest that a carotinoid or any other agent was important, good solid data, Proctor and Gamble mentioned that they would add that as well. And if I look over and see a nodding of heads positively that that is still an operative statement, that if real good data shows up, you will throw that in as well. I am certainly comfortable with this.

So I see no significant adverse effect with respect to these fat-soluble things that you haven't already taken care of.

The label, C, should the label be changed? First of all, concerning the statement, "fat-free," which we are not supposed to deal with, my feeling is that I am in agreement with Dr. Fennema that it is a lipid. It doesn't seem to me to be a fat. I am fat, but I am not knowledgeable about them.

But the operative phrase seems to me to be if a tree falls in the forest and no one is there to hear it, it

is not a fat. I can mix anything I want to mix. I favor the suggestion of moving the vitamins to the nutrition panel with an asterisk. And I favor that for the simple reason that I don't want people to be misled into thinking they are going to get these vitamins from ingesting olestra.

To say that it is not nutritionally available but it is there seems to me to be the more prudent option.

Now we come to my own personal dichotomy that Dr. Clydesdale and I discussed earlier. I won't put words in your mouth. I am of two minds, the scientific mind which, I hope, is the dominant one, says that all the data we have seen suggests the label should be gone because the symptoms are not that different from other things on the market because of a lot of things that have been said.

However, I think it is still possible that confusion exists in the minds of consumers now. I think it is unfortunate. I think the reason this happened is because it is due to a lot of negative advertising and, perhaps, misrepresentation of the FDA's position by the press. But, nevertheless, I think that producers have to contend with this, as I stated earlier.

I think it was compounded by the fact that we were unable to acquire clean data in the test markets because, perhaps, things were led in certain directions that, had we just been able to test people with no pre-assumptions, we

might have found what I consider more solid, more clean data.

So I think we still have to deal with it. And so what I would favor is keeping a label for another couple of years because I would like for us to be able to let things reach an equilibrium where the public has a saturation and the public understands what risks are or are not there, and word of mouth will take care of more things than anything else.

Removing the label at some later time, I might be able to support once I saw that we had reached an equilibrium. For now, I think the label might best be a combination of No. 4, as listed, which is, "The product contains olestra which has been found safe for consumption by the FDA," combined with part of No. 2 which says, "olestra may cause," and it doesn't say "temporary" but I would insert that from no. 3, "olestra may cause temporary intestinal discomfort or laxative effect."

My scientist mode tells me that this is what the data have presented to us. I have this gut feeling that there are some people who need to know that they may have an uncomfortable effect.

And I have a soapbox issue that I was going to bring up having to do with symbols that I think the FDA might be able to use, not in this occasion but in other

occasions or in the previous occasion where we had this first two years. I still think that a number or some sort of FDA imprimatur on the front of any package saying that--FDA with a 1 on it would say, "This has a benefit for health."

FDA with a 2 on it says, "This may benefit you, but we are not sure yet." FDA with a 5 says, "This might kill you." And then the labeling can be on the back and the public can learn what the symbol looks like. I realize there is absolutely no support for this anywhere in the known universe. But since it is my last opportunity to put it into some record somehow somewhere, I have done so, and thank you for your time.

DR. BRANDT: Are you comfortable with the statement of reasonable certainty of no harm?

DR. BENEDICT: I am comfortable with that statement.

DR. BRANDT: Thank you very much.

DR. BLACKBURN: I guess I am having the same trouble with the intellectual dissonance as Dr. Fukagawa and Dr. Applebaum and Dr. Benedict have had. I, too, am impressed with the intensity and the devotion and the integrity and the energy of the Proctor and Gamble research team and what they have presented to us in such an effective way.

An intellectual dissonance for me is that focus and that integrity and energy in contrast with the commercial pressures and distorted values that are driving the exploitation of this strange product.

The dissonance continues for me in that it seems that we are trying to have it both ways, promotion of this product as a significant contribution to healthy eating choices and a health lifestyle in contrast with the promotion of it as a very comfortable, attractive food that can be eaten ad lib. For me, the image of this meeting I will go away with is the image of a group of obese diabetic hypertensive people in the Howard University Diabetes Clinic meeting and agreeing and accepting olestra chips as a desirable choice, a healthy choice, for their management.

I think this whole idea that it is part of a healthy choice of a healthy eating pattern is as illusionary as the Proctor and Gamble ads that show this beautiful green and golden sunset across a soybean farm in attempting to assure us that this is a natural product coming from the bounty of nature when it is the most synthetic, most man-made, contrived product that we have ever been exposed to as a mass experiment in the course of human evolution.

To get to these questions, I find it very uncomfortable to respond to the very carefully worked out legalese and phrasing of these questions. It not only

restricts us, I find it misleads and misdirects us. I find the questions violate a central guideline of FDA in arriving at its rulings of reasonable certainty of no harm which is to consider the whole body of evidence, and there is nothing in there about the whole body of evidence since January 25, 1996.

It may be appropriate to focus on the new evidence, but certainly not to exclude the whole body of evidence. As Mr. Levitt pointed out yesterday, the wording assumes that we accept the FDA ruling of January '96 as a correct one and this infringes on my rights, having been one of five people who came up with a dissenting opinion.

I think that that question is further misleading and restricting in that it refers to undefined significant and unanticipated effects since all the pathophysiologic GI effects of olestra were earlier observed. We are directed to ignore them because now they are anticipated. This is misleading and manipulative in the present form of the question.

So if the question 1 were allowed to have other information and simply significant effects without unanticipated effects, I would have no problem with the question. As it is, I have to reject it as misleading and abstain.

Question 2 requires that we accept only new data

and also that we accept that these data are appropriate and that they are sufficient when, in fact, they are quite inadequate to evaluate the likelihood of harm, of regular use by many people over many years in the mass exposure.

It also admits that the essential qualification of potential or possibly significant adverse effects of the lipophilic action. I have to reject that question as misleading and abstain.

Question 3, I guess it was opened up a bit that we could suggest more than just factual data to be added to the warning in which case, I would answer no, I would not change the label. I would certainly support an alerting symbol in the front of the package. I guess we are not really here to consider the very interesting point of whether this fat-free labeling is appropriate. I think it is probably as inappropriate as the labeling of "no cholesterol" that has been handled by either FTC or FDA in the presence of cholesterol-elevating hydrogenated fatty acids.

But I think fat free is misleading in that sense. So I would say no, I would not change the label as it is and I would like to have some sort of alerting symbol in the front of the package.

DR. BRANDT: Thank you very much, Dr. Blackburn.

Dr. Blaner?

DR. BLANER: I came to this committee as a

temporary member and really had no involvement with olestra in the past. I had not even carefully read the literature so my evaluation of the data is really starting from last Friday and basically, from what we have been given.

I do have one general concern and I think it has been expressed by everybody. Not knowing long-term what the likely effect of olestra is, and so I would express this concern over ten years, 20 years, 30 years, it is not clear to me but, certainly, from the data which has been presented in the last three days, it seems to me that, based on the new data, there isn't significant data for GI effects. So I would vote no on that question.

The second question dealing with new data regarding fat-soluble vitamin or lipophilic substances and their availability, let me express--I do feel a bit, as a scientist who earns my living by doing science, I do feel a bit disturbed by some of the data presentation that, clearly, there is insufficient data with regards to our knowledge of carotinoids.

I think for either side to present consensus one way or the other, I think we need to keep our eyes open. Maybe the field is leaning toward carotinoids having no apparent impact besides serving their provitamin A function, but I would urge caution on that.

Nevertheless, I saw no data which would make me

believe that consumption of chips with olestra would interfere with this. So, again, I would vote no.

The third question regarding labeling, I actually do have a problem that the label apparently says, "Olestra will cause abdominal cramps and loose stools." To me, the data I saw did not indicate that olestra causes abdominal cramps. So I believe that, from the data which I was privy to, that is not true. So I would have a slight problem with that statement.

I also guess I would agree with Dr. Benedict. I would sort of like to see the fat-soluble vitamins in the asterisk mode. I think that that is appropriate and would, I guess, prefer to see it there. So I think my overall answer to the third question, because of the data I saw about abdominal cramping leads me to say no, I would say that the label should be changed, at least in that respect, and I would prefer to see it changed so the vitamins were asterisked.

DR. BRANDT: Can you agree with the statement of reasonable certainty of no harm?

DR. BLANER: Yes; I can.

DR. BRANDT: Next on the list is me if I know my alphabet. As far as I am concerned, this has been an interesting two days, two-and-a-half days, whatever it has been. I sat through, of course, the last thing in October

or whenever it was of '95 when we talked about this material.

My answer to the question is no, I have not been provided with any new data that, in any way, suggests any significant change although I agree with Dr. Blaner that I think the abdominal cramping data is encouraging and so on.

The second question I would say no, I am not convinced there is scientific agreement on the issue of carotinoids. Whether or not other lipophilic substances may be affected such as medications and so forth, I think, certainly deserve study.

With respect to the label, I have to express the same concern I expressed in '95. I think the label is much too strong. I think it prevents people who may have significant gastrointestinal illness from seeking medical help and evaluation. I think the testimony we heard from several people, consumers, certainly suggests to me that they have something that can't be explained by simple consumption of olestra and yet this label suggests to them that that is the explanation.

I would say the same thing is true of my colleagues who practice medicine. I think that is also misleading to them. I would prefer, as Dr. Benedict and Dr. Blaner, to accept the asterisks on the nutrition label for the vitamins.

I would suggest that, rather than say what it says now about digestive problems, that I would prefer it to read something like this; "There have been reports that ingestion of olestra may be followed by," rather than, "may cause," because I don't think I have seen any evidence that would suggest or that would be very scientifically conclusive that this causes those symptoms, rather only that it is followed by those symptoms.

I am comfortable that there is reasonable certainty of no harm.

Dr. Byers.

DR. BYERS: Could I ask, just for the record, you failed to ask Dr. Blackburn his reasonable certainty of no harm.

DR. BRANDT: Since he declined to answer two of the questions, I wasn't sure what he was going to say.

DR. BLACKBURN: No. I would be happy to respond to that.

DR. BRANDT: Go ahead.

DR. BRANDT: I am not satisfied that there is reasonable certainty of no harm.

DR. BRANDT: You are not.

DR. BLACKBURN: That's correct.

DR. BRANDT: All right, sir. Go ahead.

DR. BYERS: My answers to the three questions are

no, no and yes. With regard to unanticipated GI effects, I think there have been none demonstrated. I think there are effects and they are mild and they are anticipated and they are really related to dose in a way that we could have anticipated.

With regard to the specific wording of the second question which is the second charge to the committee, if I had known prior to my accepting the invitation to be part of this process the narrowness of that question, I would have simply provided my answer in advance and not attended the meeting, in fact, because had we, the day after January 30, 1996, immediately enrolled the necessary 50,000 people into the large trial in which they would be eating olestra with all meals and then randomly half would be eating something else that looked like olestra with all meals--had we done that, now, two years later, we still would not be able to answer this question even though that could be the definitive trial eventually because the endpoints of interest, with regard to health, are heart disease, cancer, macular degeneration, conditions which, had we started that trial at that point, we still would not have an answer to the health effects.

So that question, as specifically worded, the answer is, obviously, no, we don't have that information at this time. There is, however, an informative study in the

last two years that I think is important to consider and that is the carot trial, considered in conjunction with the ATBC in Finland, indicate that, much to our surprise, a substance which we had reasonable confidence of no harm, beta carotene, in fact, is harmful.

That is sobering in part for that reason generally but in part, also, because the explanation for this adverse effect on cancer and heart disease of beta carotene in high doses is still unexplained.

The hypothetical explanation offered by Dr. Ommen at this meeting that beta carotene in high doses may be metabolized into a pro-oxidant I think is a reasonable hypothesis. I think there is very limited or no direct evidence, however, that that is the explanation at this point.

I think the alternative explanation is that high-dose beta carotene might interfere with apoptosis and thereby result in higher cancer rates is reasonable. That doesn't explain the adverse effects on cardiovascular disease, however. So it is a little bit unsettling.

I think the list of explanations continues to include the possibility that taking high doses of a single carotenoid somehow interferes with metabolic effects of other similar compounds. That still being a reasonable hypothesis, given all of our ignorance about carotenoids and

other lipophilic substances contained in plants and fruits and vegetables, that possibility still being, I think, a reasonable option leads me to conclude that one could, in fact, interpret the result of the carot trial which was published in the last two years as evidence that interference with carotenoids can lead to cancer and heart disease and, in that sense, could be consistent with the larger body of observational epidemiologic studies that include blood-based studies prospectively that indicate that carotenoids seem to lower or are associated with lower risk for heart disease and cancer.

So I find that sobering in the context of a national campaign to increase fruit and vegetable consumption and in the context of, in fact, international campaigns to eat more colored foods, naturally colored foods. IN Asia, for instance, they call it "color your plate."

The purpose of that is to increase pro-vitamin A carotenoids for vitamin A deficiency. But, in this country, we are emphasizing a fruit and vegetable intake and with much effort have been able to increase intake, I think, importantly but in small amounts, for instance, large trials indicate, perhaps, half a serving per day effects.

In the context of this, it is also sobering to me to realize that, in fact, if we eat in technicolor with

olestra, we digest it in black and white. Many of the highly colored compounds, the carotenoids, which we continue to have reason to believe are important for chronic disease prevention, are not absorbed with that same meal.

I was disappointed that we did not see a presentation of very clear estimates of the proportions of the population who are likely to be regular consumers with meals. The 14 percent figure we looked at yesterday is a population average which includes non-consumers, but I think it is reasonable to conclude that many of the people I know, the teenagers that have grown up in my family, for instance, will be regular consumers with meals.

One more comment. I think the postmarketing surveillance system data we looked at yesterday was very reassuring and I think that we have in place now a system that can properly track this. I am a little concerned about the power of the study even though it is large mostly because I didn't see a clear presentation of the proportions of people that would really be very high consumers from that.

So I would just encourage Proctor and Gamble and their contractors in the universities to reconsider and make sure that you are adequately powered to look at carotenoid effects with people who are regular consumers with meals.

Finally, with regard to the label, where I did

answer yes, I think that it is reasonable to make changes. I changes I think would be reasonable would be to remove cramps because, for reasons that you mentioned, I think the best evidence is that there are minor effects on laxation and stool softening. I think that that is the only thing that needs to be on the label.

I think that the listing of vitamins A, D, E and K, at that point in the label, is potentially confusing and I think that the suggestion to move it to the other part of the nutrient content label is a reasonable one and I would support that idea.

Finally, though, there is an aspect of the label that I think does need to be clarified. As the consumers suggested, they are confused about what "other nutrients" means. I think that we should be specific and to say that olestra-containing foods can interfere with the absorption of nutrients from fruits and vegetables.

DR. BRANDT: And reasonable certainty of no harm?

DR. BYERS: Based on both the new data and the old data, I do not think that there is reasonable certainty of no harm.

DR. BRANDT: Do not; right?

DR. BYERS: Right.

DR. BRANDT: Dr. Chassy.

DR. CHASSY: In the interest of brevity, I will

try not to repeat many of the same themes we have heard already. I am in general agreement with most of what we have heard, but I do have three points that I would like to note.

One relates to what I would call the need for lifestyle changes in a whole variety of ways that was certainly what Naomi Fukagawa is concerned about. I think CSPI in all of their publications focusses on the need to make wiser diet choices.

We have just heard it about carotenoids. Even if we don't know that there is a scientific consensus that carotenoids do specific health-beneficial things, there is certainly enough epidemiological evidence that eating fruits and vegetables are part of a healthier life style, that it is alarming that we have had what Tim Byers just referred to very small changes in the consumption of fruits and vegetables in response to really a massive campaign, which is a worldwide effort.

It is very hard to get a population the change its lifestyles. I would suggest there is much more to be gained from education about wise lifestyle and diet and health choices than there is to be relying on a product like olestra. Olestra may be part of the marketplace that we have today.

We have a system of regulation, a system of laws.

This committee is part of it, the way the regulations play out. I, in a way, begrudge Proctor and Gamble the right to be developing products and putting them on the market. That is just how we operated. And it is certainly not their responsibility solely to change the lifestyles of the American public.

In fact, I think they would argue, correctly, that they are giving people an intermediate choice and they see their product as part of a larger dietary lifestyle context but only one part. I think they are very clear about that. But I would much rather be focussing on getting people to get two or three helpings of fruits and vegetables a day and, especially, with young children, getting them to make a choice not for a potato chip but for a healthier diet.

That having been said, we do have the issue at hand of what to do within the context of the present system in which we operate. I am going to go to the three specific questions in a moment, but I have to make a comment about labels. This committee has, in another context, been looking at labeling.

FDA, of course, has devoted a great deal of effort to labeling. Some of the studies that they have done themselves, Dr. Levitt and others in FDA, have addressed in another context the issue of what consumers do with labels, what they learn from labels.

Without trying to summarize out of context the data from that study, I am distressed that we would try to educate a consumer on a label at this point. Consumers, as we have heard, do not uniformly read labels. And, if they do read them, they don't necessarily understand the meaning of the label.

We need a massive educational campaign about what olestra is and what it isn't and, hopefully, that will unfold with time and experience. But we are not going to do it with a label, no matter what we decide to put there, where we decide to put it. Even if we agreed, for example, completely with the content of what Dr. Jacobson suggested for a label, I can guarantee you that studies show that nobody would read a label that long.

It is just not going to happen. In fact, if anything, the studies show that shorter labels are better understood. So I think the issue of labeling, to me, relates very much to the issue of lifestyle changes. It is an educational challenge that we are not going to satisfy on a potato chip package.

I guess the other interesting thing, as the olestra approval process has unfolded--interesting to me and, I think, others because we never have talked about it very much as a society is the level of gastrointestinal distress which we all seem to suffer as part of the human

condition but haven't chosen to share with one another.

But I think we do it with great dignity in this committee. I went home after the first hearing and my wife asked me what we talked about and I told her what we talked about for two and a half days.

I think you should recognize, we all should recognize, that it is extremely difficult to collect reliable data about what olestra does and doesn't do against that background and that it clearly points to a need for a great deal more research to be directed at gastrointestinal conditions of humans.

We have clearly not paid as much attention to this as we need to. But it makes it very difficult to pull out of the data, to tease out of the data, what we can attribute to olestra. So let me get to the first point about passive surveillance.

I see no evidence of any cause-and-effect relationship in the passive surveillance data. In fact, I see a lot of what we call in logic "post hoc fallacies." Just because you get sick after you eat an olestra-containing product along with maybe three days of other food products and other medical conditions and the possibility of food-borne illness and all the other things that could have caused the condition, I think it is really a jump in logic to say that it was because you ate olestra that you got

sick.

It is, however, a very good departure point to investigate whether olestra was related with that specific episode. As we all understand, we can't tell whether that episode was caused by olestra but we can take that person and use them as a subject because they may be a very good indicator or marker for sensitivity to olestra.

I would encourage Proctor and Gamble, if we could require them, to continue rechallange studies. I, like Dr. Jacobson, was concerned that the size of those samples are really not big enough to draw any solid conclusions from. They point in the right direction. I am not at all troubled by what I have seen. I think what we have seen is about what we expected, but we need a lot more "n" to be able to make conclusions that olestra has only the anticipated level of not so severe kinds of symptoms, those symptoms that we considered not harmful.

I guess I would answer that question as no. I think we would have anticipated what we've seen. We need considerably more studies. I do think the passive surveillance system is set up to do that except that it needs more cases.

Turning to the carotenoid issue, I think it was amply demonstrated that there is not a consensus of scientific opinion about carotenoids and, as we have heard,

it is going to be a long time before, with these particular markers, we can tell whether there was any effect of lowering carotenoids.

Again, if you ate another vegetable a day, you would be much better off whether you are eating olestra or not, so I am not concerned that we have seen anything that would cause us to change our opinion about fat-soluble vitamins and carotenoids.

As we move to labeling, I think Dr. Jacobson's point about fat points to the novelty of dealing with a macro food additive for the first time. My interpretation of that is that fat is an acylglycerol, as Dr. Fennema pointed out. But I add something to it. It is one which can be metabolized because what we have on the nutrition fact statement is a nutrition analysis, not a biochemical or chemical analysis of the product.

That nutrition label isn't a contents statement. From a nutrition point of view, there is no fat in this product. Nonetheless, what Dr. Jacobson pointed out is absolutely correct. It also is a tube full of stuff that the consumer has no way of knowing is in there unless they understand what olestra is and that it is a significant portion of that product. That is the paradox of this kind of product.

I favor putting asterisks on the vitamins and

putting them in the ingredient declaration. They are simply ingredients from which you can derive no nutritional benefit.

Objectively, I can see no reason to have a caution label or a notice on olestra from everything I have heard. I, like Steve Benedict, subjectively feel like it is too early to take the label off but that is an emotional opinion. I don't feel that anything we have seen really justifies it.

In fact, besides the fact that it is ignored, I am afraid it is confusing more people and it is maybe confounding people about the source of their illness and that it is likely to do more harm than good. I would not be at all distressed if the FDA took the label off. So I guess yes is my answer to the third question and I do have a reasonable certainty that no harm will result from the use intended.

DR. BRANDT: Dr. Clancy?

DR. CLANCY: Yes. I will just go through the three responses and then I am going to take the same prerogative that Steve did to make a departing statement.

On the first one, I find myself immediately going to giving my response within the parameters of a public-health priority setting framework which is what I teach and how I think. I think that we have definitely some greater

surety that for the majority of users, there would appear to be no significant adverse effect from the consumption of olestra. Significant and adverse are both important there.

Although I find it odd, and I have been constantly thinking about this, that FDA has approved the addition of a stool softener to the food supply in the form of a snack food. That seems somewhat inappropriate to me.

And I was also, along that line, dismayed by the testimonials given yesterday, I think, in most cases unwittingly and I think, in some cases, wittingly, that we talked about the benefits of a food additive when we really should, at least some of those physicians should, have been aware that we should only be talking about the benefits of the drug unless they were suggesting that we would be thinking about olestra as a drug.

I don't believe anybody was, but the language would lead us, legally, to that conclusion. So, for the majority of people, I think we can say there is no significant adverse effect, just loose stools which they should be told about.

On the other hand, in a very small percentage of the population, and we have no idea what that percentage is, I believe that there is strong evidence that that could be that there are significant adverse effects. In that case, I would still maintain that there is not a reasonable

certainty of no harm with regard to the GI effects of this product.

I understand that the public policy compromise, in terms of these two populations, is the label, is the labeling. It makes the labeling very critical then. Given my position, the label becomes very critical, that some kind of statement be on the label that makes it possible for that second group, even if it is quite small, to be able to have some information, a warning--it is not a warning if they don't read it and apparently many of them don't--but at least some information post facto to help them determine what they want to do.

With regard to the second charge and my response, I am going to repeat this again and I just think it is very critical, particularly, again, legally. Olestra is an unsafe food additive. Everybody acknowledges this. Proctor and Gamble acknowledges this.

It is the conditions of use that have made it safe, not olestra, per se. It is unsafe because it eliminates fat-soluble vitamins from the GI tract. Let me read this statement from the Federal Register notice where FDA stated, "The agency has not previously approved an additive which interferes with the absorption of vitamins to a degree that necessitates requiring that foods containing the additive be compensated with such vitamins to mitigate

the effects."

I stated, in 1995, and I still believe, that this was a very bad precedent on the part of the agency. But they have, in fact, set this precedent. New studies, within that framework, show that, as expected, the laws of physics and chemistry have maintained, thank goodness, in the last two-and-a-half years, there is no interference, in that sense, with the absorption of fat-soluble vitamins because of the compensation.

It worked. And I was very glad to see that it worked. But I feel that particularly as the public might become more sophisticated, and I am going to a point that several other people have made, maybe, in some number of years, there will be enough information that you do not have to provide the material regarding the interference with nutrients I am going to talk about with the label.

But I have a very different response to carotenoids. I feel very strongly that the science is too young, my way of saying what other people have said, and very much so because a lot of confounding of the fact that seemed appropriate--I mean, this is how science works--that people ran with including somebody as respected as Gil Ommen ran with beta carotene, moved into that trial.

But I think it is critical, again, that we not forget that that was beta carotene given in isolation from

foods, given in moderately large doses but given in isolation from foods. I see the carotenoid discussion as being quite critical in making sure that our hubris quotient stays down a lot, that we be very careful about how few studies we accept in particular areas, particularly those that are really matters, in some cases, of quite severe possible health risk.

So I see, on that, that we need to be very prudent. So, in fact, the new evidence that I do believe we were presented, and I feel, was a greater ambiguity about the issue of carotenoids because, in fact, we got more surety about what happens when you feed beta carotene but we haven't done this with the other carotenoids, in isolation from foods and in fairly large amounts.

On the third question, I feel that, in fact, again, in terms of public policy and in terms of science, that the aspartame precedent is a much better precedent that psyllium or bran fiber for reasons that other people have stated but not in this context.

I don't believe that there is any evidence that we have been given to dismiss the real probability that some people might have a sensitivity to olestra. Again, that goes back to a very new food product and a young science. I feel that, because of this, there has to be a label statement to warn consumers particularly because we have--

again, I don't want to repeat what Dr. Byers said, what Dr. Blackburn said; this is a very new product and this is really a major experiment--that we need to make sure that people have a way of knowing that this could exist.

Given my concerns about the food additive olestra above, I still support the label statement on nutrients as it exists now. I could not support the asterisk option, especially because I thought I remember now, and I could be wrong, that the statement that you were proposing was not nutritionally significant.

I think that is quite misleading. The statement could say factually that they are nutritionally not available, which I think would not be misleading in the sense that nutritionally not significant would be misleading.

I do feel that, in some way, the carotenoids and other lipophilic substances must be somehow incorporated into a cautionary label. It is up to FDA to find the statement that is not misleading. I think we should give ourselves a little credit. It is not surprising that it has been very hard for all of us, including Proctor and Gamble, to decide on the right wording for this label.

We have never tried to do anything like this before. But, because of that, it puts quite a burden on us--I will leave aside the educational question--to work on

label statements that are not misleading. I am not saying that it is going to be easy, but I think that is the challenge, not to say take it off the label, but to let's work on statements that will not be misleading.

My only other comment would be that I do believe, from all the studies and what Dr. Byers was saying, the possibility of moderation, but there should be, quite appropriately, on this food but I could say this on many other foods, that there be a statement about moderation.

Susan used the word "excessive consumption" sometimes. But as I translate that into the label statement, it would be something about moderation.

I would just like to make one other statement. As I sat here at my last meeting, again, and coming out of my background in teaching public policy and being engaged now in a full-time public-policy project, that I am incredibly struck by the imbalance in resources that exists in the society for debating these issues.

I am incredibly impressed with what Proctor and Gamble was able to bring to us but know that they have enormous resources to do that with. I am sorry that there is only one consumer organization that has been in a position to take on the discussion of this incredibly important new food additive in the food supply.

I think CSPI has done an admirable job in that

position without the resources that the other side has had. I really wish there was a way of improving these debates. I wish there was a way of having a broader continuum of participants in the debate. I wish there was a way of providing resources to more people besides just petitioners to participate in this debates.

I would just leave that to the committee as I go off.

DR. BRANDT: And reasonable certainty of no harm, please?

DR. CLANCY: No; I do not believe there is a reasonable certainty of no harm.

DR. BRANDT: Dr. Clydesdale?

DR. CLYDESDALE: First I would like to thank Proctor and Gamble for the scientific studies they have performed and for the evidence they brought to us and commend them on the amount of work that they have done in the last two-and-a-half years. I would also like to thank CSPI and Dr. Jacobson for raising issues that must be raised and for insuring that we look under every rock and see what is there.

I would also like to thank, although they are not here, the public who came and gave testimony and I think enlightened us as to the cross section of the public that is out there that eats the food that we provide.

Going off the committee, I would also like to thank everyone. We did nominate Dr. Benedict as our poet laureate. So I won't be as eloquent, but I would like to thank everyone. He was our poet laureate and Dr. Wang was our social organizer. And Dr. Brandt, I am not quite sure how to characterize that contribution, but it has been a wonderful experience.

And I would like to thank all the staff, in particular, at FDA who have really made a chore rather an enjoyable chore.

The new data from the surveillance report combined with the results from the rechallange study provided reassuring evidence that there were no significant new unanticipated GI effects. This conclusion was further advanced by the understanding provided in the stool-composition study, the acute-consumption study and the six-week consumption study.

Although several interesting interpretations of the data were suggested, none of these dramatically changed the overall conclusions of these studies nor those put in the original proposal.

Anecdotal accounts and speculation were interesting but somewhat irrelevant in the face of the science provided. Therefore, I concluded that there were not any significant new unanticipated GI effects that could

be attributed to the ingestion of olestra that are adverse to health.

A review of the published peer-review literature along with preliminary results from the first year of the active-surveillance study indicated little reason to be concerned with the health effects of olestra on fat-soluble vitamins and other lipophilic substances

Although speculation exists among scientists concerning the health effects of carotenoids, the scientific foundation to support this speculation is not available in the literature at the present time. However, speculation does exist and was indicated earlier. It is a young science but the fact that only some 24 percent of all snacks are eaten within one hour of meals, the evidence from the lipophilic partition coefficients of many carotenoids and the lack of evidence of inhibition in the active-surveillance study provides some comfort assessing the inhibition of absorption of these compounds while fortification of the fat-soluble vitamins compensates for any interference of their absorption.

Although I am most interested in seeing the active-surveillance results in the future from groups consuming larger amounts of olestra along with data on carotenoids and macular degeneration and other possible effects, I conclude that new data provided to the committee

does not show that the consumption of olestra-containing savory snacks has a significant adverse effect on health due to interference of absorption of fat-soluble vitamins or other lipophilic substances.

On the labeling issue, in light of the new data, I feel that the label of olestra-containing products should be modified. As Dr. Benedict indicated in our discussions, this is not based solely on the scientific evidence but because I think there is confusion in the mind of the consumer and possibly confusion in my mind.

The data clearly differentiates effects of olestra, if any, from warning labels on other foods. I think that is clear. Further, the effects on high levels are not more serious than some other foods and food components. This combined with the confusion of the consumer and possible misdiagnosis of GI effects demands some changes to clarify that this is an information label and not a warning label in the same sense as used on other foods.

I feel that the nutrient asterisk on the ingredient label for the nutrients is an excellent suggestion. What that asterisk refers to, I think, should be discussed between Proctor and Gamble and FDA and others, the particular wording.

The label of the GI effects should be modified

after study by the FDA and P&G, as noted previously. I believe that the possibility of removing the label entirely should be revisited within the next two years dependent on the weight of the evidence at that time.

Thank you, Dr. Brandt.

DR. BRANDT: How about reasonable certainty of no harm?

DR. CLYDESDALE: I feel that there is reasonable certainty of no harm.

DR. BRANDT: Dr. Feinleib?

DR. FEINLEIB: Thank you, Mr. Chairman. I would like to reiterate the thanks and acknowledgments of the previous presenters. I think this has been a very interesting and energizing meeting. I have learned a lot, have found a number of exercises for post-graduate students and I think I will walk away enriched in that sense.

First, some comments. Olestra has been in the developmental phase for approximately 25 years and I am a little bit surprised at, in a sense, the sparsity of information that is actually available and, even more so, the sparsity of any explanatory analyses of what somebody's relationship should be.

I hope that this situation will be improved in the future and that extensive follow up will be conducted. I will come back to that in just a little bit. But, in terms

of the charges, one thing I think I got out of some of the analyses of the FDA staff is that we can now estimate quantitatively that eating olestra savory snack chips raises the risk of certain GI symptoms on the day of consumption by a measurable amount.

This amount is on the order of 1 percent in absolute terms, the attributable risk, or about 30 percent in terms of relative risk. In the charge, though, in the question as stated, I have to accept the FDA's decision of two-and-a-half years ago that the kind of GI symptoms described were not defined as adverse health consequences.

I am not completely satisfied with this but I will abide by the FDA's previous decision.

One of the things that is lacking in any model that I was able to conceptualize here was how many people might be impacted on this because, although these might be of very minor significance in an individual, when they are multiplied by a potential group of people at risk of the order of 20 or 50 million, something like that, that is a lot of excess GI symptoms during the course of a year. In cumulative amount, it may be a great inconvenience to the country and its general well-being.

In terms of active surveillance, I think we have gotten evidence that the current levels of fortification of vitamins A, D, E and K, as Dr. Clancy said, are adequate to

avoid the problems that were identified or suspected previously. So, in that sense, I think that new data confirm the intentions that the advisory committee was worried about last time.

I think the information on carotenoids, age-related macular degeneration, is very weak and does not really contribute or advance our knowledge much further. In this regard, I think it is essential that we implement now some long-term surveillance studies so that may be of the order of magnitude of 25 years from now, we can go back and say, "What have been the long-term effects?"

I think it is essential to make sure that large-scale studies such as the National Health and Nutrition Examination Survey contain detailed information gathered about now on how many people are eating olestra-containing foods and that this be tracked on a continuous basis and that such a survey might have the resources to look back 20 years or so from now to see what the outcomes were among those people who were consuming such foods.

I think that the question of carotenoids will be with us for another generation or so and that this type of information might be useful at that time.

With regard to labeling, I think I am about as confused as many other members of the committee. I think we have all sat in the movie house and seen a screen come up

that says, "Note the nearest exit. In case of fire, proceed to the nearest exit. This notice is required by law."

I never understood what the last sentence was for. I thought the first two sentences were pretty self explanatory, but why they warn us that it is only there because it is required by law, I never understood.

I am not sure what the impact of the labeling message is in this context. Is it supposed to be an announcement, "If you see this label, do not buy this product?" Or is it supposed to be an announcement, "If yo use this label, think twice about buying this product?" Or is it, "Read this label to learn more about good nutrition," or something like that?

I don't know what message is being conveyed by having that label there. I think the suggestion for asterisks is a very good one and I think FDA could modify it sufficiently that it would be clear to most people who do read such labels.

But, right now, I am leaning in the direction, much to my own surprise, of removing the warning label altogether, sharing some of the concerns that, sure, if you get the indigestion, or whatever, don't worry about it, it will go away in the morning and it is only due to the olestra. I don't think that is what I want a label to tell me. So I, at the moment, would opt for not having that

label.

Finally, I think on the basis of the current evidence, there is reasonable certainty of no harm but that this should be reviewed several decades from now.

DR. BRANDT: Dr. Fennema?

DR. FENNEMA: Thank you. I, too, appreciate the great amount of information, good information, that has been presented to this committee over the last couple of days. That represents a huge effort and a lot of dollars expended in the hope and desire of gaining a maximum amount of information about olestra.

So, with respect to first question, my answer is no based on normal conditions of use. So I put a contingency on that. For the second question, with respect to vitamins and how that is being handled, I have no concerns whatsoever about the fat-soluble vitamins.

The carotenoid issue, I am in line with, pretty much, what everybody else has said. The scientific data there is simply not sufficiently convincing at this time for Proctor and Gamble to take any kind of action with respect to carotenoids. We don't know which carotenoids are essential, if any are. And we don't know what concentrations are essential, if, in fact, any of them are, that are required in the diet.

Until we get that information, there is simply

nothing that can be done by Proctor and Gamble to supplement olestra with carotenoid ingredients. So no action is deserved there. So my answer to the second question is no.

My answer to the third question is yes, and I have a great deal more to say about that. First of all, I have no concern about consumption of olestra products at usual levels which would carry us up through the 90th percentile and, perhaps, even higher than that.

But, based on many things that have been said here during this meeting, I have increased concern about the severity of the effects in individuals which are consuming very high levels of olestra. These clearly would have to be deemed as unusual and improbable, but they are certainly possible. And I am talking about individuals who would consume greater than 20 grams of olestra over a period of several days.

There is evidence here of severe effects. And I mean they are truly very, very severe and something that troubles me, that any section of the population could get into a situation of encountering those kinds of effects.

So I think this warrants some sort of acknowledgment and treatment. This brings me to the label and what changes I might suggest on the label. First of all, I do favor retaining the information statement that is on the label. I would suggest along the lines of some of

the remarks I have already made a somewhat modified GI statement.

I am not sure that what I have to say is the final wording that you would want to use, but I am offering it as a suggestion; something like, "Olestra has no significant adverse effects under normal conditions of use but may cause abdominal cramping and loose stools when olestra potato chips," this is a product-specific kind of a statement, "are consumed in excess of 2 ounces per day."

This would have to be tailored to each of the products and some thought would have to be given as to where that level would be. But that is a level of consumption that is far beyond anything that you have encountered, that Proctor and Gamble has encountered in any of their households studies or surveys of this.

But, nonetheless, it is a level conceivable that somebody, particularly a teenager, could find himself or herself consuming over a long period of time and could result in very severe consequences. So I would suggest something along those lines for a revised statement.

Now, this kind of an approach does indeed, which has been suggested, depart from FDA's treatment of other sorts of ingredients such sorbitol, but it seems possible to me that FDA's approach to sorbitol is wrong and this new approach may be correct. I think FDA needs to rethink this

issue.

It is important, I think especially important, with respect to olestra because, first of all, it is not only a food additive, by legal definition, it is also a macronutrient of a sort which potentially can be consumed at quite a high level in the diet.

These kinds of food additives are new for FDA. They are new for the public. They are new for regulatory agencies to deal with. I think we need to be very, very careful on how we approach this and how the regulatory framework is put together for a substance of this kind because we are setting precedence for other macroingredients, food-additive macroingredients, which are going to come on the scene, no doubt, in future years.

So all of that needs to go into consideration of how these statements are made and not necessarily giving very much consideration to how things have been done in the past.

The vitamin statement on the label with respect to A, D, E and K, I favor that asterisk approach in putting it into the nutritional label with an appropriate statement for those because that issue, in my judgment, has been very carefully taken care of and imposes no problem to anyone any longer.

I also favor having the 800 number put on this

information statement. That is a relatively small matter. I think that should be done. Finally, what I am saying applies to the here and now. I think this is a dynamic situation which should be revisited as more data are collected and, in a year or two or three or four, it may, indeed, be possible that we have no need for an information statement to be on a product of that kind, but that will depend, in my judgment, on the data that is collected over the next few years.

Thank you.

DR. BRANDT: Reasonable certainty of no harm?

DR. FENNEMA: I agree with it; no reasonable certainty of harm. We have reasonable certainty of no harm.

DR. BRANDT: Thank you, sir.

Dr. Harlander?

DR. HARLANDER: As one of the graduating members of this, I would like to make a statement, also. It has become profoundly clear to me the complexity of the issues that face the FDA as a result of participating on this committee. As a non-voting member, I am an industry member, I would really strongly encourage FDA to continue to include representatives from the regulated industry, the food industry, on these panels.

I would like to thank both Land o' Lakes and the Pillsbury Company for their encouragement for me to stay

involved in this committee, recognizing that statements are going to be made that might be attributed to them, even though they are my personal comments only. It has been a very enlightening experience for me.

I was also struck last night as I was thinking about and preparing statements for today how little we actually know about the chemical structure, the bioavailability, the impact of other nutrients or the impact on bowel function for a lot of the things that we consume in our diet, not just new food additives like olestra.

In fact, I feel like I know more about olestra than I know about fiber right now and I am actively trying to include fiber in my diet. Few of those components contain warning labels. Most of us have figured out by now what causes these effects--I know, in myself--and what effect they have on our GI tracts.

I have a little statement hanging in my bedroom that says, "Mirror, mirror, on the wall. I am my mother after all." I have told my children, "Please shoot me if I ever talk as much about bowel function as my mother does." Now, I understand that there is a huge percentage of the population that has a lot of interest and concern about this.

It is interesting to talk about these things. And it is interesting for us to understand them. And I really

applaud P&G for their responsible follow up on all of the data that they have brought to us.

I would guess if we added up how much they have actually spent in funding, it would more than the federal government spent on nutrition research in the last couple of years. I think a very paultry amount is spent on understanding things that are so basic to all of us. Even though statements have been made about the enormous resources that food companies have, as a representative of a food company, I can tell you that those dollars are coming from somewhere and it is extremely expensive.

The other thing that I would share is, as a representative of industry, we have a 1-800 number on all of our products at the Pillsbury Company, also. For those of you that are not familiar with getting those, I read those on a regular basis. We tape record consumers and we listen to the passion with which they talk about our products.

For 30 percent of the comments received by P&G being positive comments and, in light of some of the comments we heard from consumers, a set of consumers want these products. The food industry is a consumer-drive industry.

It was painfully clear to me when I joined the food industry that I am not a consumer of all my products. I produce a lot of products, and the Pillsbury Company

produces a lot of products I do not consume. But we produce them because there are a set of consumers out there that are demanding and wanting these products. The food industry is responding to that demand.

I also want to applaud P&G for including very many well-respected academic experts who were asked to independently evaluate the results of their passive and active surveillance studies. I think it is extremely important. And it is a way to insure that the information that we are receiving is nonbiased and examined by people that the public and those of us that are on this committee and at FDA respect greatly.

So those are my general comments. Now I would like to answer the questions. The answer to question No. 1 is no, no significant unanticipated GI effects were captured in the studies that we have seen that are adverse to health. I think the results are predictable based on the chemical properties of olestra and that would should really recognize that there is a big difference between inconvenience and harm.

Inconvenience is in the eye of the beholder. Softer stools, for many of the people my age and older, are a blessing, not an inconvenience. The rechallange, to me, I would like to see those continued because I think it will give us even more confidence around the impact, the GI

impact, of this on health.

With respect to No. 2, new data does not show that consumption of olestra snacks has an adverse effect on health due to interference with absorption of fat-soluble vitamins or other lipophilic substances. I think it is prudent to continue the active surveillance study and it is prudent to monitor the literature and consider fortification of olestra if and when carotenoids receive significant scientific agreement that warrants addition.

I do encourage us to monitor the vitamin K, though, to determine if fortification levels should be reduced in the future.

With regard to labeling, It was very revealing to me, as we participated and discussed on keystone, some of FDA's own data on consumer testing of consumers' understanding of labels. One thing that I think, despite all of the education that we have had on labels, consumers believe that the front panel of the food label is controlled by food companies despite the fact that FDA controls the entire food label.

So, in terms of consumer understanding, they would rather see statements on the nutrition panel which they believe is controlled by FDA. So I don't know that we necessarily want to move that label to the front of the package if we are going to maintain the label.

In the consumer testing that has been done so far, I don't think enough label options have been explored with consumers. There is clearly a tremendous amount of confusion and I do believe the label does need to be changed.

We have to have labels that are meaningful to consumers and the only way we are going to find that out is to go and talk to consumers. Again, I will say, we are not the consumers, necessarily, of the products that we are talking about. So I would hope that we would not put our own biases on to what is meaningful to consumers, that we actively go out and explore what options are meaningful to consumers.

I do believe that the vitamins should be asterisked on the label in the future. I think that that was a good suggestion. I would really like us to modify the statements that refer to the GI effects because, as we have seen, the real experience has not reflected that.

I am not going to provide possible labeling statements, but I think something about olestra causing digestive effects under exaggerated usage would be more amenable to me if, in fact, a label is even needed. I am in the same camp as Steve and Ferg on this one. My gut tells me we should take the label off and just let people know, in the ingredient statement, that olestra is present.

But I just have this little "oooh" that tells me maybe consumers aren't ready for that yet and that we revisit this labeling issue again in a couple of years. But my gut feeling tells me would should get it off there.

I would answer yes to the last question.

Thank you.

DR. BRANDT: Which last question?

DR. HARLANDER: Reasonable certainty of no harm.

DR. BRANDT: Dr. Lamm?

DR. LAMM: With respect to the first question, GI symptoms, I don't think we have had any new data here to indicate anything other than they anticipated. I will make the point I made earlier and that is my concern with respect to the Center for Science in the Public Interest that you have a surveillance system that seems to be picking up unusual cases or types of cases not being reported to P&G and if these turned out to be the sentinel cases of other things that are going on, I would like to see you taking responsibility to moving these four individuals on to further medical evaluation, in particular to appropriate challenge testing.

I would imagine that you might be able to work out with P&G some sort of grant application for a rechallange program established at some medical school somewhere where individuals could go to be rechallanged with bags that have

been previously labeled by P&G in their coding fashion or something like that and then be able to identify whether there are particular sets of symptoms, particular sets of circumstances, of individuals that are those who are particularly sensitive to olestra and then the medical-industrial community can move forward from there.

With respect to the issue of the non-GI effects, I have heard nothing here that I found disturbing, either in the older and the new data. Previously pointed out was the issue of the increased levels of vitamin K and I think FDA will, obviously, be watching that and reach some resolution over the next period of time.

I agree with the recommendation that the vitamins be moved into the nutrition statement with the asterisks. And I don't hear enough evidence of the certainty of health risks of the reduced carotenoids that it is, for me, an issue that I think needs to be focussed to the attention of the consumer.

I find myself with the typical ambivalence on the question of the label. My own personal suggestion would be to place on the front of the bag a statement that indicates that this product contains olestra, maybe at the same place that one indicates fat-free, "contains olestra," or something like that so that the decision on whether someone wants to use an olestra-containing product as opposed to a

sucrose-containing product or whatever substitution is used for the fat, there is something that the consumer is able to confront up front in their decision-making process.

And then, on the back, I might suggest, rather than a warning label, an information label where P&G and FDA would get some agreement where there would be a description that olestra is non-absorbable fat, that it may permit you to consume the things with a lower calorie intake, speaking about what they would see as some of the benefits of it and, in the same area, having the statement that speaks about some people having gastrointestinal discomforts, or whatever vocabulary you folks worked out together.

I would also agree that there is no reason for making a specification of abdominal cramps. It does not seem to be a relevant issue with respect to olestra.

Thank you.

DR. BRANDT: What about reasonable certainty of no harm?

DR. LAMM: I say yes, there is a reasonable certainty of no harm.

DR. BRANDT: Thank you.

We go on now to Dr. Potter.

DR. POTTER: Thank you, Mr. Chairman. The data and anecdotes presented on the GI effects look more like those presented earlier. I see no reason to encourage FDA

to modify its regulatory position. P&G continues to sponsor well-designed surveillance in clinical studies and I am hopeful that these will help explain the pathogenesis of the sporadically occurring rapid-onset GI symptoms that appear temporarily related to consumption of olestra-containing snacks.

Perhaps, it would be useful to look at product lots associated with substantiated complaints for unintended reactants or other contaminants and to carefully rule out, perhaps, unrelated infectious causes of gastroenteritis, as has been pointed out.

Like others, I am satisfied that fortification takes care of problems of the fat-soluble vitamins and there are still too many unknowns for other lipophilic substances to answer question No. 2 other than no.

We heard that the current label may be misunderstood by some consumers and could probably be improved. However, unless we decide that all foods should have a benefit-risk statement, I heard nothing that makes me believe that manufacturers should be required to change the label.

FDA has demonstrated extraordinary competence in assimilating a large amount of information from a variety of sources independently analyzing and interpreting it and drawing reasonable inferences from it. However, I am

concerned that the large number of very important and complex food safety issues facing the agency make it inappropriate to continue devoting such a large amount of expertise on this single issue.

Thank you.

DR. BRANDT: And reasonable certainty of no harm?

DR. POTTER: Reasonable certainty of no harm.

DR. BRANDT: You agree?

DR. POTTER: Yes; I agree that there is reasonable certainty of no harm.

DR. BRANDT: Ms. Richardson?

MS. RICHARDSON: I want to preface my answer to the questions with the fact that I am a consumer representative on this committee and also a consumer who works with a large segment of the population that has been identified as large consumers of these euphemistically termed savory snacks.

I am also concerned that we saw a number of diabetics who came from the ADA and from Howard University Hospital's patient support group who see these potato chips as a dietary option. Even if you remove the fat, they are still made out of potatoes. They are still a carbohydrate. And that needs to be reinforced with those diabetics.

Yes; a lot of these foods are potatoes, contain potatoes, and they contain corn. But they are not in the

produce department. They are not in the vegetable department. I think that needs to be stressed, especially since I represent a group of women who have been recently told that 52 percent of are overweight.

To question No. 1, I would say no. I think the symptoms that we have heard reported were anticipated and, although people suffered some discomfort and they were unpleasant symptoms, I don't see them as changing FDA's original statement.

I am also encouraged by the fact that P&G is going to continue to do post-surveillance reporting and studies, especially since it looks like olestra consumption is an employee benefit for their employees. I, like Dr. Benedict, also believe that the symptoms that were experienced with the olestra products also have been related by a number of the people who were trying to diet by drinking some of the liquid diet drinks.

To question No. 2, I would answer no. I think that the science around carotenoids is still an emerging science. There doesn't seem to be an agreement at this point, but I am concerned about the information that we have heard on vitamin K. It appears that there may not be a loss of vitamin K, but maybe an addition with vitamin K. That concerns me as a nurse who works with patients who are on anticoagulant therapy and who have a history of clots.

We spend a lot of time telling them not to eat a lot of collards and kale because of the concern about their anticoagulant therapy. So I think that further research needs to be done with regard to vitamin K and, also, on the ingestion of olestra products for those people who are on anticoagulants.

With regard to labeling, I would answer yes. I think that the label is still necessary because of the newness of the product. We have heard a lot from consumers saying that--it wasn't that they were confused about the label but that they didn't notice it. So I think that there needs to be a step to place it where it can be more noticeable.

You can't force consumers to read labels. And, once they have read them, you can't make them act up them. We know that from cigarettes and seat belts. The only time consumers pay attention to labels is when they look at the tags on pillows. Everybody still has that tag on there because they are afraid that the police are going to come in and arrest them if they take it off.

The other reason why I think that the label should be on is because I think consumers have to make informed decisions about what they are going to eat, just as what mascara they are going to put on their eyes and what carotenoid they are going to drive. So I think the label is

necessary.

I would suggest some changes in language. I would recommend that we look at the language that was suggested by Dr. Reeser, but I also think that her language needs to be more user-friendly. I do like the suggestion that the label contain the phrase, "nutrients from fruits and vegetables," because I don't think a lot of consumers understand what carotenoids are and they don't know what a nutrient is.

The thing about labels is we know that a lot of people don't read them. But I think they should be there, especially so that if people do have problems, that the label is there and can provide them some guidance. I think having the toll-free number on the label is an excellent idea.

I would encourage FDA to look at whether or not they can send out the same kind of alerts to healthcare professionals that they do with regard to some medications so that healthcare professionals would have an understanding about what olestra is and what it isn't so that when patients do present with symptoms that they can have physicians who are as thorough as Dr. Brandt is with regards to looking at is there an underground or a background GI disorder that needs to be examined or is it because someone ate olestra products.

I think the label allows a consumer to relate

information to their healthcare providers so that it can be used also so that the consumer does not incur costly and uncomfortable medical tests and examinations.

The discussions about digestive systems, and I know there were some consumers who were concerned about what they saw as disgusting, distasteful language on the labels. I would say that if we were more open about talking about GI involvement and our bowels, a lot of people like Dr. Harlander's mother, talking about it among themselves, but they are not necessarily talking about it with their healthcare professionals. That is why the screening for colon cancer is so low.

So if we could have a lot more open discussion, and I would love to see people talking to their physicians about their bowel movements and the color of their stool.

I would also like to take the opportunity to endorse what Dr. Applebaum said. It concerns me that the professional integrity and character of some members of the committee were called into question because people didn't agree with their statements. This is a democratic process and, as a former regulatory attorney, I think it works very well and I think it does provide industry to bring information to the floor and for consumers.

Unfortunately, we can't regulate--FDA can't regulate what the press does, but I think, certainly, those

who represent the consumers and the industry can regulate what they say with regards to what happens at these hearings.

Thank you.

DR. BRANDT: Reasonable certainty of no harm?

MS. RICHARDSON: Yes.

DR. BRANDT: You agree? Please say it. Mr. Larsen makes me do this.

MS. RICHARDSON: Yes; reasonable certainty of no harm.

DR. UNDERWOOD: Thank you, Mr. Chairman. I have appreciated this opportunity to participate in this exercise as a temporary invited expert. I feel I was brought here primarily for my background and understanding of fat-soluble vitamins and absorption. I think probably it was partly to my advantage that I haven't been involved in the process before now so that I am able to respond to the questions based on, really, what I have been provided in the background documents and what I have heard over the last two and a half days.

I have been impressed with the quality of the presentations from Proctor and Gamble and from the other groups that have presented. Based on the information that I have heard, my answer to question 1 is that, based on the new data and the other anecdotal information presented in

the background documents and over the last two and a half days, I find no scientifically documented evidence of any significant unanticipated gastrointestinal effects that can be convincingly attributed to ingestion of olestra and that are adverse to health.

I acknowledge the reported adverse effects following an exposure to an olestra-containing savory snack from testimonials presented but such reports lack the critical elements in medical workup necessary to eliminate other likely potential causes.

My response to question 2 is active surveillance data available to date do not indicate that consumption of savory snacks containing olestra has a significant adverse effect on health due to the interference with absorption of fat-soluble vitamins or carotenoids.

I cannot comment on other lipophilic substances as we have not been provided data that we could evaluate these other substances. I would go on to say that the available data for this evaluation is, as yet, quite limited. I do encourage, therefore, continued surveillance and particularly among those who could be most vulnerable to adverse consequences. By these, I mean the youngest and the eldest age groups and among families least privileged economically.

I also encourage that the analysis include

monitoring the full distribution of values and not just medians and means. I want to make one other comment related to the beta carotene issue. I do not feel that there is evidence for beneficial effects of high doses of carotenoids. But I make this distinction. I think that most of the studies in which harmful effects have been shown have been when using high doses of a beta carotene supplement.

I work in the international field and I work with children in developing countries who get the majority of their vitamin-A-active substances from carotenoid sources. In some of those instances, it is important that you use carotene supplements. I would not like to see the image of a carotene supplement always in the negative because at low doses, in fact, recent studies in developing countries have suggested mortality-reduction effects at levels that are consumed in regular dietary sources. This is related to maternal mortality.

My response to the labeling question is that I think that there is still reason to retain the label on the package. I think there is reason to rethink some of the statements that, in fact, they are statements that are informational and no seen as a warning.

In doing that, I am not sure of the exact wording for that but I do think that the statements related to

gastrointestinal effects should be related to what we have actually seen and not that we haven't seen real evidence for diarrheas and these things that would cause people to have undue concern.

I do agree with the idea of an asterisk on the vitamins and placed in the nutritional label. I also think that there is reason to think about the placement of the label on the package. I bought a package of Wow and looked at it this morning before I came. And I do think that putting it at the bottom of the back cover, it is not going to be noticed there.

I think there is reason that it should be in a more prominent place on the package and I think it should also contain the toll-free number. Finally, based on the information I have seen in the last two and a half days, I agree that there is reasonable certainty of no harm.

DR. BRANDT: Thank you.

Dr. Wang.

DR. WANG: Thank you. I am the last one but not the least. In the last two days, I have seen the due diligence. I want to define the term where I have read somewhere, sometime, that it is a $5.00 Wall Street term that we have looked at the issue very hard. I think we have.

Regarding the question No. 1, my answer is no,

based on the new data and other information presented. Also I would like to thank P&G for bringing a lot of their information to share with us. I felt that there was, really, no standards, per se, as their standard for review for food-additive approval, there is the rulemaking procedure but this passive surveillance information are all extra that is volunteered, I believe, two years ago that they would do that.

Regarding No. 2 on active surveillance, I am honored to serve on this group because I realize here, in the last hour or so, that we have a general scientific agreement on the emergent science on the carotenoid issue, the fat-soluble vitamins. And my answer is no from this first year's surveillance, active surveillance data.

Regarding No. 3, again, since I represent the state, as a state representative, we recognize that food labels are very important, that the information should be material facts and, since the label is small, any warning statement should be reserved for a very serious health effect.

Two years ago, we recommended the labeling because the information presented to us at that time showed that there could be GI effects. But now, with this information right now that was presented to us, the materials, and I am kind of torn in between as well whether they should be

required or not.

So I am offering basically three things I am going to talk about. Regarding the vitamin section, I do support moving it to the nutritional labeling with an asterisk indicating either it is not a significant source or what Dr. Clancy suggested that it is nutritionally not available, probably something that is going to be new for future food products.

And then, regarding the label statement about olestra, again, if we are talking about olestra as an oil, since it is already listed in an ingredient statement, I would like to see a placement near the ingredient statement, a shortened statement, describing olestra, itself. It could be a non-caloric, indigestible oil, describing what olestra is.

Also, maybe I would like to suggest that FDA consider a sunset clause along with the savory snack that the term "indigestible fat that may cause stomach discomfort," shorten it so that it is punctual.

Lastly, the educational effort. This is not scientific. It is more like political. P&G may want to help fund the FDA to launch an educational campaign with brochures or such that can be distributed through their public information officers regarding olestra and all the scientific information that is available.

In addition, the sunset clause may be tied in with the ongoing active surveillance that P&G is doing right now, maybe the time frame.

Lastly, I want to thank all my colleagues. Again, I am in the graduating class this year and I want to thank all the FDA Food Advisory Committee staff for doing an excellent job, and I felt that I finally graduated and it was really a learning experience.

Thank you.

DR. BRANDT: Reasonable certainty of no harm?

DR. WANG: Yes; I have reasonable certainty of no harm in savory snacks.

DR. BRANDT: Mr. Levitt and others from the FDA, you have gotten everybody's views. I want to, again, thank our temporary members who have helped us, Dr. Feinleib, Dr. Blaner, Dr. Underwood, Dr. Lamm, Dr. Byers. I want to, again, thank all of the graduates. It has been four reasonably pleasant years. It has particularly been pleasant with our social director. I don't know who is going to replace her but I am sure we can find somebody.

I want to thank Lynn and Kathy DeRoever, Linda Hayden, all the other folks who have helped all of us including getting us plane reservations and other kinds of stuff that has to go on.

Some of you can expect to be recalled. I am sure

because of your contributions to what is going on, recalls in this instance are positive, not negative, as automobile recalls are generally considered to be.

I wish you a safe trip home and all kinds of luck and I hope the graduates find jobs before long.

[Whereupon, at 12:30 p.m., the proceedings were adjourned.]

CERTIFICATE

I, **ALICE TOIGO,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

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