

FOOD AND DRUG ADMINISTRATION
OFFICE OF FOODS AND VETERINARY MEDICINE
CENTER FOR FOOD SAFETY & APPLIED NUTRIITION

PUBLIC MEETING
USE OF THE TERM "HEALTHY" IN THE
LABELING OF HUMAN FOOD PRODUCTS

Thursday, March 9, 2017

8:38 a.m. to 5:00 p.m.

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P R O C E E D I N G S

(8:38 a.m.)

Greeting and Housekeeping/Logistics

MS. BARRETT: All right. Good morning again. If we could have folks go ahead and take their seats in the room, that would be appreciated. We will get started.

I'm going to start off by welcoming you all to today's FDA public meeting that's focused on the term "healthy" in the labeling of human food products. My name is Kari Barrett, and I'll be moderating the main sessions of today's meeting.

I do know, and certainly there's been a lot of interest generated by this meeting, and there's a lot of interest from all of you, both personally, I'm sure, as well as professionally. So I do want to thank you for joining us today and really looking forward to your active participation.

This meeting, for those are physically in the room, is meant to be one of engagement and discussion and interaction. So please bring that forward when we have our breakout sessions and also

during the Q&A sessions, and later today when we offer time for public comment.

I also want to thank everyone who is webcasting in today. I know that we have quite a large group who is with us virtually, and I want to thank you for your time and interest in the subject as well.

I do have a few housekeeping announcements before we go to our first speakers, and so I'll try to move through those fairly quickly. But I do have a few things that you may be interested in.

One is, all of you should have received a folder when you came to the registration desk. And it does have some handouts in it that I think will be helpful for you today, including a copy of the breakout session questions and I think some examples that might be helpful for you as well to reference.

Also in the packet is a list of the speaker biographies. And so what we're going to do as we move through the day is I'll just introduce folks by their name and title since you have details of

their background in your folder.

I also wanted to mention, for any PowerPoints that are shared today, we will post those on our FDA website. We also will be transcribing the main sessions of today's meeting, and that transcript will be posted.

For the breakout sessions, we will have a summary document that we will be posting. And everything that occurs in this room, the main sessions and breakouts, will be webcast. And that webcast will also be posted on our website.

For anyone who is with the media, press individuals, if you haven't had a chance to check in with our press person, she's standing in the back. It's Deborah Kotz. So please be sure to let her know that you are here. We'd appreciate that.

For those of you who are offering public comment this afternoon who have signed up in advance, if you can see Juanita Yates -- Juanita, do you mind just raising up your hand? Juanita's by the back door. Please see her at the break this morning or at lunch just so she knows that you're

here and we can get our final count together.

We do not have a sign language interpreter. It's something that the federal agencies offer, but we didn't have anyone request that. So I just wanted to note that. We also don't have WiFi in this room, and I apologize for that. But it is available in the common areas of the hotel.

Then in regards to parking, the parking is free of charge, is my understanding. I'm looking at Juanita. So what you need to do is you'll need to bring your ticket to the registration desk, and I believe a voucher will be provided to you.

Then just in regards to lunch, there is the hotel restaurant. There's a coffee shop. Both are located on this level. At lunch, they will be offering a buffet or you can order from the menu. There are also many different restaurants available on Rockville Pike.

But we just ask, if you venture out of the hotel, if you'll be mindful of the time, because once we get back, we really want to stay on schedule, and the breakout sessions will start at

the time noted on the agenda.

I would also ask that you just look in the room and be sure that you know where exit signs are. I always think that's important when you're at a large meeting, just as a safety measure.

For your phones, if you'll silence them, please. If you have multiple phones, don't forget that. It's just always awkward when someone's phone is going off. So if you could just take a minute to pay attention to that, we'd really appreciate it.

Then if you have any general needs or questions, please see the folks at the registration desk. They're happy to assist you. They do have badges with a black label at the bottom, so they are there to provide any assistance that you need.

I think, in summary, that's the housekeeping. So now I'm pleased to really turn to the content of the agenda and jump in. I'd like to introduce our two first speakers this morning.

We have Susan Mayne who is with us. She is our director of the Center for Food Safety and

Applied Nutrition at FDA. We also have Doug Balentine, who is our director of the Office of Nutrition and Food Labeling at the Center for Food Safety and Applied Nutrition at FDA. And they're both here to provide opening remarks and an overview of the term healthy.

With that, Susan?

Opening Remarks

Susan Mayne and Douglas Balentine

DR. MAYNE: Thank you, Kari.

Let me begin by adding my welcome to the audience and my appreciation for taking the time to help participate in this meeting. I'm really delighted that we were able to schedule this meeting during the month of March, and that's because it's National Nutrition Month.

Because nutrient content claims such as healthy help consumers make those informed choices in their daily diet, having this meeting during the National Nutrition Month is appropriate.

Ultimately, it is the consumers who will benefit from redefining the term "healthy" as it is used on

food packages.

Today's meeting provides an exciting opportunity for FDA to continue our public process on modernizing the nutrient content claim healthy. As you know, there are lots of questions surrounding this issue. Several questions were asked in the Request for Information, and I'm sure that there will be additional questions today.

We at FDA can't answer those questions alone, which is why we're having this meeting today. Your input today, as well as input from the many people that we've heard from so far and will help throughout the public process is crucial to helping us determine how to proceed with modernizing this term. Transparency and active stakeholder engagement are important to FDA's regulatory approach and our policies.

Thank you all for joining us today to provide information, to share your experiences and your perspectives, and raise issues specifically related to the nutrient content claim healthy. We have a very busy and full agenda today, and we want

to give you as much time as possible for discussions and questions and answers.

Therefore, I'm going to be very brief and turn the discussion over to Dr. Doug Balentine, the director of our Office of Nutrition and Food Labeling at the Center for Food Safety and Applied Nutrition, and he will briefly review the changing landscape on the meaning of the nutrient content claim healthy.

DR. BALENTINE: Good morning. I'd like to also welcome you to today's public meeting on the nutrient content claim healthy. I'm looking forward to an exciting, engaged day, and really encourage you to engage with us over the course of the day and really help us to really discuss a lot of the issues around healthy.

Healthy as a claim may mean different thing to different people. It's important from a marketing industry point of view, as a tool for signaling information about the foods that they are producing and providing to consumers. Different consumers may have different views on what healthy

means to them and how they might use that term in making food choices in the grocery store as they shop every day.

We know that many consumers make food choices very quickly. They only oftentimes make a selection in 3 to 5 seconds. So while we have lots of nutrition information on food packages, oftentimes only some of the information on food packages are used by consumers in making their food choices.

What we'd like to really understand as we look at the options for how we might modernize and redefine the term healthy is such things as: should we have a narrow definition of healthy, a set of criteria that might apply in a common way to all foods, or should we consider a more flexible approach, which may be relative to certain food categories and where that approach might be a better approach to how we might explore the definition of healthy.

In either case, I think what we really want to do is consider the underlying principles, is

that healthy is a term that hopefully will be used by consumers as part of defining their food choices. And we really need to put the consumer first and try to come up with an approach that might best help consumers build diet patterns that are more consistent with those such as the ones we have in our Dietary Guidelines for Americans.

We also look at the term healthy as an important term for industry because if industry can use the criteria we set to either reformulate or innovate with new products into the marketplace, the more foods that are in the marketplace that might meet the criteria for healthy gives consumers more options in the grocery store to choose that might be a healthier choice.

I've asked you all to think about some of those things as we go through the day and help us to explore what some of the pros and cons of each of those approaches might be.

As you know as background, the term healthy has been around for quite a long time. It came shortly after NLEA, the Nutritional Labeling and

Education Act, was passed in 1990. This provided new authority to the FDA to change food labeling in a number of ways, including the nutrition facts label.

In 1994, FDA issued the first nutrient content claim for healthy. At that time, the agency viewed healthy as a unique nutrient content claim. It was focused on the nutritional value or the nutrient content of foods. So it was set up in such a way that it looked for foods that contained those nutrients that were in shortfall, those nutrients of major public health concern to the consumer, while not having excessive amounts of those nutrients that are public health risks such as total fat, saturated fat, cholesterol, and sodium, for example. So the original definition was very nutrient-based.

The current -- and why are we undertaking looking at the definition, there's a number of reasons why we're doing that. Science has changed. The way we're talking about food and building diet patterns has changed.

We've moved from a nutrient-focused dialogue to more of a food-based dialogue. So that's changed the landscape. We now have MyPlate, which focused on more food groups as a way of getting nutrient adequacy as opposed to talking specifically about nutrients.

As these change, the science has changed. At one point in time there was a call to limit total fat in the diet. Now we've moved to saying, well, total fat may not be as important as the fat quality.

We encourage intake of foods that are high in unsaturated fats such as nuts and seeds and salmon and healthy oils. But we are now looking at limiting those fats that are more at risk to public health, such as saturated fat or trans fats, for example.

The foods that are of public health concern or the nutrients of public health concern have changed. So the original definition was focused on vitamin A, vitamin C, calcium, iron, protein, or fiber as the key nutrients that a food must have in

order to qualify for the definition of healthy.

But today, consumers are now getting adequate amounts of vitamin A and vitamin C, for example, but are not getting sufficient amounts of vitamin D and potassium, for example. And that's been reflected on our update of the nutrition facts label, where we're now requiring the labeling of vitamin D and potassium on food labels.

The dietary guidelines have evolved over time, and we've provided some handouts for you in your packet that talked about some of the key messages for dietary guidelines. We do have very food-based messages now: nuts and seeds, whole grains, fruits and vegetables, lean sources of protein, low-fat dairy. So that's very much the food dialogue that we have in place. And as I already said, we've updated the nutrition facts panel.

The landscape of food and how we talk about nutrition to consumers has shifted as science has shifted. And we feel that because of that shift, along with input we have from other public

stakeholders, this is the appropriate time for us to engage in considering how we might redefine the term healthy for use on food labels.

The process of where we're going is we started this process about four months ago. We issued a Request for Information to the public and the interested stakeholders. And we've been watching for people providing information into the docket around the questions that we've asked in the Request for Information.

That Request for Information will remain open until April 26th, and we'd encourage all to continue to provide input into that docket because we find the public comments to be extremely helpful.

We also are holding this public meeting today as a way of engaging stockholders further to have more of a dialogue rather than a one-way conversation where people put things into the docket and we don't have the opportunity to ask questions.

We really are looking forward to today as a

way of looking at some of the questions that we've raised in the Request for Information and further engaging with you all today around a number of the key issues that need to be addressed in order for us to consider how we might update the definition of healthy.

With that, I'd just like to close and encourage you all to engage today, ask good questions, and we really are looking forward to getting some thoughtful input from you all during the day. And with that, I'll close, and we have a little bit of time for some questions and answers. Thank you.

(Applause.)

MS. BARRETT: Thank you both. We do have a few minutes for a couple of questions. I'm looking over to make sure we have some mics available. It looks like those are coming over.

If you have a question that you'd like to ask at this time, please feel free to come up to the microphone. We would ask you to state your name and affiliation. I know it's early. Nobody

wants to be first? It's a great opportunity.

Anyone?

(No response.)

MS. BARRETT: All right. I'm going to pause. Janesia, I'm going to look to see, is there any questions from our webcast audience at this time?

LCDR ROBBS: No.

MS. BARRETT: Okay. Well, I want to -- wait. Do you have a question? If you could come up to the microphone, please. And again, if you'll just state your name and affiliation for the transcript.

MS. SCHNEEMAN: I just hate to leave 10 minutes with no questions. Right?

MS. BARRETT: Yes. There you go.

MS. SCHNEEMAN: I'm Barbara Schneeman, affiliated with UC Davis. And part of the discussion, I know, has also been around dietary guidance statements. And while the topic here is healthy, I'm just wondering if you might comment on how that fits into the agency's thinking right now.

MS. BARRETT: Okay. Doug or Susan?

DR. BALENTINE: I think that we are, and have been, looking at providing guidance on how dietary guidance statements might also be used on food labels as a way of providing information to consumers in a different way on food packages.

I think that's something that we still have on our list of things that we're contemplating doing, and we think providing that kind of guidance would be helpful. But when we'll get that done, I can't really predict at this point in time. But it is something that's still on our agenda.

DR. MAYNE: I'll just add, this is a dialogue. So if people have specific recommendations, we'd like to hear those. This is our opportunity to hear from you through the docket, through dialogue today. Any specific recommendations that people have, we're interested in hearing those.

MS. BARRETT: Thank you. And it looks like we have another question. Please come on up. If you'll say your name and affiliation, please.

MS. LEVY: My name is Julie Levy, and I'm affiliated with the P.G. County Transforming Neighborhood Initiative, and also alternative health solution is something that I'm building for everybody.

Okay. My question is, do you think it's time for the word healthy can be used for -- like you say, everyone's healthy is different. So I think a lot of consumers have been talking about, let us choose our own foods so when they go in the grocery store they can see a low glycemic carbohydrate meal. And then they may see medium or high, based on their health status and lifestyle.

If you got diabetes or blood pressure, high blood pressure, and it's been going on for year, you don't want to keep picking up a box of scalloped potatoes that'll continue to rise it up. So that's my perspective, and that's what the consumers are looking at. Thank you.

MS. BARRETT: Thank you for sharing your views. Thank you.

Any other questions? Must we get started?

Okay.

Yes, please. Again, if you could state your name, please, and affiliation.

MS. THORSTEN: Lisa Thorsten with Campbell Soup Company. We're pleased to be here today and really understand the underpinning of the Dietary Guidelines for Americans emphasizes nutrient density as a very key component toward meeting the objectives, as does healthy.

We would propose that we, as a group here, address what that term means in specific ways as it might help us to define what healthy means.

MS. BARRETT: Okay. Thank you. Thank you for making that comment.

Yes, please.

MS. RAINEY: Hi. I'm Charlene Rainey with Foods Connect. I have a great deal of experience in doing nutritional labeling and creating nutrient databases. I have done this for 35 years. And in creating the nutrient databases on foods, a lot of the unintended consequences of shifting from a food base to a nutrient base, this happened in school

food service with USDA.

Instead of doing component-based food service for schools, they shifted to a nutrient-based. And they said a fruit group could be represented by a food that had vitamin C. So they allowed doughnuts to be sprayed with vitamin C, and doughnuts with vitamin C, fortified, were given to children as a fruit.

I've done a lot of the nutrient databases on fruits. And in our epidemiology and nutrient databases, we have about a hundred nutrients that we use, that we sort, to see what a healthy individual gets from eating real fruit. But we know that there are a lot more compounds in fruits than just these hundred compounds.

I wanted to make that statement, that a food base, there's a lot of compounds that we're discovering new information about how these compounds in whole foods have benefits way beyond just the nutrients that are in them.

MS. BARRETT: Great. Thank you very much for sharing your experience and perspective.

We will have time for one more.

MS. ZIEGLER: Yes. Good morning. I'm Robin Ziegler. I'm with the Maryland State Department of Education Child Nutrition Programs. Just to follow up here, and then a question.

We are in a food-based menu planning system, not any longer a nutrient-based system, so I just wanted to clarify that, in the school meals program and all the programs.

Just as a question. What are your thoughts about sodium in terms of this objective?

DR. MAYNE: I guess I'll start with that one. We look at sodium from an FDA perspective in multiple different ways. As I hope everybody knows, FDA put out voluntary draft targets for sodium for approximately 150 different categories of foods. So we have been actively working on an issue of feasible approaches to reduce sodium in the U.S. diet gradually.

In terms of how sodium fits into today's dialogue, that's again what we want to hear from you. Are we looking at nutrient-based approaches?

Those are some of the questions we've been asking.

Are there other things we should be considering as we look at the definition of healthy. So we want to hear dialogue on that today.

What I did want to indicate is that FDA has multiple approaches where we're trying to work on some of these issues like sodium, not just through a nutrient content claim like healthy.

The same thing holds for one of the earlier comments that one of the speakers made, is for people who have specific health issues, again, remember the importance of the nutrition facts label, that that's another tool that consumers have. And we are committed to helping consumers understand how to use that tool as well to address the specific situations that they have with regard to their health.

MS. BARRETT: Thank you.

DR. BALENTINE: Just to add to that a little bit.

MS. BARRETT: Yes. Go ahead, Dr. Balentine.

DR. BALENTINE: I think that in the current nutrient content definition, there are disqualifying levels that are set for saturated fat, sodium, cholesterol, for example. Today, clearly we would imagine that we need to consider the level of sodium in foods in whatever new definition of healthy that we might propose.

So the question that we'd like to hear from you about is related to what Dr. Mayne just said. We have proposed some voluntary targets for different food categories as approaches to sodium.

Would using those particular sodium targets be a more appropriate benchmark to determine whether a food might qualify if they were below those thresholds, or should we use the current approach, which is based on foods containing a specific level of sodium relative to the daily value?

I think that's, again, something we'd like to hear and have a debate on which of those approaches, from both a food industry and public health point of view, would be the most helpful for

us to consider as we move forward in this space.

DR. MAYNE: The last thing I'll just add onto that is that the sodium targets that FDA put out are draft voluntary. They're out for public comment. So I wouldn't want to imply that we'd be using those specific targets, but the concept is commodity-specific versus one uniform target, which is what the current healthy claim includes.

So just to clarify, those are draft comments that are out for public comment.

MS. BARRETT: Great. Well, thank you both. I want to again thank our first speakers this morning, if we could.

(Applause.)

MS. BARRETT: We're going to do a switch and bring up our first panel of the morning. Thank you very much.

If we could have our Consumer Attitudes panelists?

(Pause.)

MS. BARRETT: All right. It is my pleasure to turn the podium over to Conrad Choiniere, who is

our director, Office of Analytics and Outreach of FDA's Center for Food Safety and Applied Nutrition. Conrad will moderate our Consumer Attitudes, Beliefs, and Behavior panel. And with that, Conrad, it's yours.

DR. CHOINIERE: Thank you, and good morning. Today's first panel discussion is focused on the consumer. What does healthy signal or convey to consumers, and what does that imply for consumer choices? Food behaviors? And how might we use the term healthy to help move or nudge consumers closer to dietary patterns that resemble the Dietary Guidelines for Americans?

The session will open with a presentation from Dr. Linda Verrill, who will talk about what we currently know and understand about how similar types of claims work in the marketplace and provide some preliminary observations that we've made with respect to the term healthy.

We also have a panel. One of our panel members was unable to attend today, but we have a panel composed of a few experts that we identified

that could provide some insights on consumer behaviors with respect to healthy and food choices.

The panel will help us foster a discussion, ideally among the panel members here as well as participants in the audience, about the consumer perspective, and that discussion will continue in the later breakout sessions.

No FDA public meeting would be complete without some sort of disclaimer.

(Laughter.)

DR. CHOINIERE: So I just want to indicate that although we've selected some panel members here, we do recognize that there are other experts and other perspectives; that FDA has not endorsed the particular viewpoints that will be expressed today by the panel members, nor have we vetted what they're about to talk about.

But we do think that they will provide some interesting and different perspectives that can help foster a lively discussion among all of us in the audience.

I'll briefly introduce our panel members.

The more full descriptions of their roles are provided in the materials you got at the registration.

But our speaker today is Dr. Linda Verrill. She's a senior scientist at FDA's Center for Food Safety and Applied Nutrition. She's a sociologist, and she provides research and expert consultation on issues related to food safety, nutrition, and food labeling.

We also have, to her left, Ms. Liz Sanders, who's the associate director of nutrition and food safety at the International Food Information Council Foundation. In her role, she conducts a nationally representative consumer research effort that examines Americans' beliefs, perceptions, and behaviors on various food and nutrition issues.

We also have Mr. David Portalatin, who is from the NPD Group. He's a national expert on all aspects of food and beverage consumption. And in his role as a vice president and food analyst, Mr. Portalatin provides information, insights, and analysis on how U.S. consumers eat and drink, their

attitudes and motivations, diet and nutrition, snacking, and personal characteristics.

With that, I will turn the podium over to Dr. Linda Verrill for her presentation.

Presentation - Linda Verrill

DR. VERRILL: Thank you, Conrad.

Good morning, everyone. Thank you for attending this important meeting. I'm glad to get this session started with some of what FDA has learned about how consumers respond to the food label.

After providing a bit of background, I'll report what the research tells us about how consumers respond to claims on the food label, and I'll finish up by sharing some unpublished results from one of my recent experimental studies, where I looked at how nutrient content claims affect consumer product judgments and behavior.

But before I get into the weeds on claims, FDA began conducting consumer research on the food label in the mid-1970s, about the same time that nutrition science really began to highlight the

association between diet and major diseases such as heart disease, cancer, and hypertension.

From the very beginning, FDA's research focus was on consumers' understanding of the food label, which had always been seen as one of the best tools for providing consumers with information that can help them make informed dietary decisions.

There is no doubt that the food label plays an important role, not only for selling food but also for providing information to consumers that can help them maintain a healthy diet.

So the most recent FDA health and diet survey, a telephone survey of about 2500 randomly sampled U.S. adults, found that 77 percent of adults report using the nutrition facts label most or some of the time when buying a food product, 79 percent report using the label often or sometimes when buying a product for the first time, and lastly, almost 9 in 10 adults say they use claims, such as "low in sodium" or "rich in antioxidants" when buying food products.

The data shows us that consumers do consider

the food label an important source of information. And I'm going to go into a little bit more about claims on the next slide, but first, FDA's mandate is to protect and promote the public health. And by law, the food label must be truthful and not misleading.

Food labels are required to have information on them that defines and describes what's in the package, such as the nutrition facts and the ingredients list. But many companies want to be able to say something more about the benefits of the product. And this something extra falls under the FDA regulatory schema on claims, which are regulated under four large categories based on type.

Health claims are those that establish a connection between diet and a specific disease. Health claims have to be preapproved and supported by significant scientific agreement. Calcium-rich foods such as yogurt may reduce the risk of osteoporosis, as an example of a health claim.

Then we have qualified health claims. These

are claims made then the evidence does not meet the significant scientific agreement standard, but there is some evidence supporting the claim. And here is an example of a qualified health claim.

Another kind of claim is the structure-function claim. These claims don't specifically include a diet-disease link. Instead, they mention how a food or nutrient supports a structure or function of the body. So "calcium builds strong bones" is an example each of a structure-function claim.

Finally, we have nutrient-content claims. These claims either state or imply a certain level of nutrient in the product. So, for example, "milk is a good source of calcium" is a nutrient-content claim. And as Dr. Balentine mentioned, there are requirements for being able to use nutrient-content claims, and these are based largely on qualifying or disqualifying amounts of nutrients.

This brings us to the healthy claim, which is a nutrient-content claim. Taking a new look at the requirements for using the healthy claim is

what brings us together today.

There's a great deal of research on the effects that claims have on consumer purchase and consumption decisions, and this work goes back to at least the last 25 years. You can find hundreds of scientific articles evaluating the effects of claims. But this research mainly shows that claims work. That is, they influence what consumers think about the product and contribute to their decisions about whether or not to buy it.

Claims don't work entirely the same across the board and between different kinds of people with different education backgrounds. But overall, if you put a claim on a food product, you're going to get measurable effects on perceptions, judgments, and behavior. And here is some of how claims work.

Claims have what we call a truncation effect. That is, when there's a claim on food package's principle display panel, consumers are less likely to look at the nutrition facts label. This is one reason why it's so important to ensure

that claims communicate accurate nutrition information to the consumer. Many of them don't flip the product over because the claim has already satisfied some information need.

Claims sometimes have a magic bullet effect, that is, claims seem to influence consumers' judgments about nutritional qualities not mentioned in the claim. So, for example, if a claim of low fat makes consumers think that the product is also low in sodium relative to a product not carrying the claim, this is called the magic bullet effect.

Another way that claims work is they can have health halo effects. Health haloes are when claims make consumers think that the product have positive health qualities that aren't all related to what is said in the claim. So, for example, a health halo would be when a consumer, responding to a claim of low fat, believes that the product will help their susceptibility to cancer, for instance.

A couple of years ago, I led an experimental study where we evaluated the effects of some nutrient content claims on vitamin-fortified snack

foods. The purpose of the study was to see how consumers might be influenced by claims about added nutrients when they were put onto snack foods, foods that people can enjoy in moderation as part of a healthy and a well-balanced diet.

Based on previous claim research, we hypothesized that the claim would indeed have an impact on what consumers think about the product. That is, all of the claims would have an impact.

Our main research questions for the project were: Does the presence of a claim have an effect on whether or not participants would look at the nutrition facts label? Would participants be more likely to purchase the product with the claim versus one not carrying the claim? And would participants think that the product carrying the claim was healthier than the same product not carrying the claim?

Not to keep you in suspense, the answer to all of these questions is yes. Claims do reduce the likelihood that consumers will look at the nutrition facts. They influence purchase decisions

and they make consumers think that the product is healthier, even for snack food products.

We published these results last December in the Journal of the Academy of Nutrition and Dietetics, and there is a citation on the slide there. But if you're interested, I can send you a copy of the article.

Before I move on, though, let me tell you just a little bit more about the study, and then I'll share some results with you where I looked just at the data for just the healthy claim, and those results aren't published yet.

This was a controlled, randomized, experimental study with U.S. adults. It was administered over the computer to randomly selected members of an online consumer panel. The experiment was divided into two sections.

First there was a choice task, where participants saw two kinds of chips, and they were asked to select one of them for purchase. One product carried a claim and the other did not. The other part of the study was a single product

evaluation, and in this part, participants saw just one snack product, either with or without a claim, and they were asked to respond to questions about the product.

Here's what the choice test looked like for participants. They always saw a potato chip and a veggie chip, which could be either in the A or B position. Also, there was always one product with a claim and one without a claim, and the claims were all shown in the same place on the label. And we also rotated the claim between the A and the B position.

If the participants wanted to see the nutrition facts label, they clicked on the link beneath the package. And when they were ready to make a choice, they clicked on one of the response options at the bottom.

Here are the mock food products that we used in the single product evaluation part of the experiment. We had two kinds of cookies, a jelly bean, chocolate candy, and a soda. And you can see that the claims on these products are in the same

place where they were on the chips, and again, each claim that we tested was in the same location on the package.

We tested ten different nutrient content claims in total, just one of which was the word "healthy." We fielded the study in the fall of 2014, our sample size was 5,076, and we did quota sampling so we could closely match the 2010 U.S. census.

Now, here are the results of the substance analysis of the data, comparing just the products with the healthy claim, which are the red bars, to the identical products not carrying the claim, the blue bars.

For example, the first set of bars shows the results for the healthfulness scale. This scale is the average of six statements that we ask the participants to say how much they agreed or disagreed with how healthy they thought the product was.

They could respond anywhere from "strongly disagree," which is coded as a 1, to "strongly

agree," which is coded as a 6. And as you can see here, all products scored low on the healthfulness scale, but the ones with the healthy claim scored higher than the identical products not carrying the claim.

The results are pretty consistent across the board. On the "healthy as" scale, products carrying the claim scored higher than the no-claim controls, and they also scored higher on a question about being more nutritious source of energy. Here products with the claim, the red bars, were perceived as lower in calories, lower in sugar, and lower in saturated fat.

In summary, the food label is an important resource for helping consumers make good dietary choices. Claims on the food label have been shown to have truncation effects, magic bullet effects, and health halo effects.

Our preliminary work on the healthy claim suggests that it may also have some of the same effects on consumers. So because the healthy claim may have an influence on consumers, it's important

to ensure that products with this claim have healthful attributes.

Now I'm going to turn the microphone back over to Dr. Choiniere to get the discussion part of this session started.

(Applause.)

DR. CHOINIÈRE: Thank you, Dr. Verrill.

Before I pose questions to the panel, I would like to give them each an opportunity to provide some general reactions to Dr. Verrill's presentation. And in particular, if you could focus your comments on whether or not the hypotheses that Dr. Verrill presents about how healthy claims might opt in the marketplace, if those conform with your experiences and your research in this area. And I'll leave it to you to decide who goes first.

MR. PORTALATIN: Go ahead, Liz.

Presentation - Liz Sanders

MS. SANDERS: All right. Thanks, David.

Those are really interesting findings.

Thank you so much for sharing, Dr. Verrill. We've

probed a lot of similar topics in our yearly food and health survey, which Dr. Choiniere alluded to earlier, and that's our yearly nationally representative consumer research effort. And all those findings are publicly available online at foodinsight.org if you're interested.

One thing that I found particularly interesting about Dr. Verrill's presentation was how a nutrient content claim could reduce the likelihood of consumers checking the nutrition facts panel before making a purchase.

In our food and health survey, we ask every year what factors, what items of information consumers check on food packaging before making a purchasing decision, and we find year after year that over half of consumers report that they check the nutrition facts panel before making a purchasing decision.

But we know that this isn't exactly always how it plays out in the real world. And we also know that consumers do report checking nutrient content claims, claims about health benefits, and

claims about nutrient content before purchasing as well.

It was just interesting to see -- maybe not surprising, though -- that nutrient content claims may reduce the amount of times that consumers check the nutrition facts panel before purchasing when they're faced with a more real-world purchasing decision.

As a dietitian, I would love it if consumers checked the nutrition facts panel every time they made a purchasing decision, but we know that in the real world there are other competing priorities and time constraints that make this not an option.

If you have a simple piece of information, like a nutrient content claim, in order to make a healthy decision, we know that this might reduce their urge to seek more in-depth information. So I think it's interesting to see how these competing priorities play out, not only in our food and health survey but in other research as well.

Presentation - David Portalatin

MR. PORTALATIN: Hi. David Portalatin with

NPD. And thank you, Dr. Verrill. It's fascinating stuff. As a consumer research guy, I love it.

This is what I do for a living.

We've studied about 30 years of what people actually eat, whether they've sourced that from home or away from home. And among that research includes things like whether they're looking at the nutrition facts label, what attributes they say they want to get more of in their diet or what specific things they're trying to avoid, whether they adhere to any kind of established diet, whether that's a Weight Watchers or a Paleo and whatever that is.

I think today the consumer is bombarded with more information than ever. "Bombard" is not a good word because I think the information is a positive thing. We wear our Fitbits. We have information about our bodies, about our exercise routines, and we have more information available about our food than perhaps ever before.

I think that is changing the way we approach information on a label, whether that information

is on the front of the package in the form of a claim or whether it's on the nutrition facts label.

For example, over time, you could characterize consumer attitudes about health historically either as from a standpoint of avoidance -- when the national dialogue was all about carbs, you could see avoidance of carbohydrates spike up in our data.

We saw gluten come along. We could go back to the '80s, when we talked about cholesterol was the big thing consumers were trying to avoid. Or at various times there were things that consumers -- it was about a positive enhancement. How can we add calcium to our diet or protein to our diet?

All of those things are more or less stable or even declining in our research right now. So what our data would suggest is that consumer motivations about healthy now have more to do with not necessarily an avoidance mindset or an enhancement mindset, but just a "what is the nature of the food that I'm eating?" mindset.

In other words, this bias toward fresh foods, the perimeter of the store, if you will, the catch-all umbrella term of "natural" -- in fact, when we look at what special labels are on products in the store, consumers report purchasing "natural" or "made with natural ingredients" is the largest one. Now, I know that opens up a whole nother can of worms: What does natural mean?

(Laughter.)

MR. PORTALATIN: Because I could have my bowl of natural ice cream right now, and it could be high fat and high sugar, and that could counteract everything else that -- by the way, I love a good bowl of ice cream.

(Laughter.)

MR. PORTALATIN: Number two on special labels would be "organic." And after that, believe it or not, now is "non-GMO." And the two fastest-growing special labels are organic or made with organic ingredients or a non-GMO project-verified label. So I think consumers are changing what it is that they're looking for on packaging

information as well.

DR. CHOINIERE: I want to follow up on that point that you talked about with all these different types of special labels that are out there. What do you think that implies in terms of the presence of the term healthy in the context of those special labels? What does that signal to the consumer?

MR. PORTALATIN: I think what's happening now is healthy in the mind of the consumer is very, very personal. As I said, information is ubiquitous now. We can get an app. We can go online. We have our Fitbits. We have all this information at our disposal.

So it's not surprising, then, perhaps that among consumers that report following some form of a regulated diet, the most popular diet in America is simply my own diet, one of my own making. I don't believe that consumers are saying, I'm on the doughnut diet and that's okay. That's really not what they're saying.

I do believe that they have some specific

motivations. I just think that there are so many attributes today that a consumer could consider to craft a diet that they believe fits their own personal, unique needs that that's exactly what they're doing, and they're crafting "my own" as opposed to, in the past, they may have chosen to follow, say, a Weight Watchers or a Paleo diet, or Atkins diet was big at one point in time, and all these things -- fad diets that come along.

Now, part of that is probably true in the absence of a big popular fad diet right now. But that's the consumer motivation, is simply my own diet. So I think more information is better. Whether it's on the front of the package or on the nutrition facts label or on a QR code that links to somewhere else, I think the consumer desire today is to have more information and be empowered to make their own health decisions.

DR. CHOINIERE: Ms. Sanders?

MS. SANDERS: I also have a comment related to that. One thing that we found when we had an open-ended probe on how consumers define a healthy

eating style is that when we asked it in an open-ended way -- we did a split sample, actually. We asked it in open-ended and also closed-ended.

In the open-ended, we were getting a lot of very dietary guidelines-friendly messaging about balance, variety, moderation, general comments about how a healthy eating style contains everything in moderation, and it's heavy on fruits and vegetables and other healthy food groups and nutrients.

But then when we asked it in a closed-ended and we provided options, including that a healthy eating style contains natural foods or is non-GMO or is organic, that's when we were seeing those options rise up to the top.

It's interesting that when consumers think about healthy eating style or healthy eating pattern from a very holistic standpoint, they're not necessarily thinking of those fads like natural, non-GMO, or limited or no artificial ingredients.

But when we provide them in front of them,

that rises to the top of mind. So I think that that's an important thing to keep in mind in the labeling discussion as well when consumers are thinking about healthy from that perspective.

DR. CHOINIERE: So in your open-ended responses, when you called it that -- you say that people were thinking about their diets in a holistic way. So what does that imply, then, for defining healthy, which would be a claim that is on an individual product, and how that might be useful for moving people to more diet-based, overall diet-based, pattern decisions?

MS. SANDERS: That's a great question. So one thing that we saw come up time and time again in our open-ended probe on consumer definitions of healthy was that consumers are looking for the right mix of different foods or different food groups.

One way that healthy can be employed to move them towards that right mix, to help them align their diet more with the dietary guidelines and dietary guidelines messages, is perhaps using

healthy in a way that helps them incorporate more food groups where we know we need shifts to be able to meet the recommended daily values, so helping them consume more whole grains, consume more dairy and more fruits and vegetables, of course.

Yes. How can we use healthy in a way that encourages consumption of these food groups that we know are of public health concern?

MR. PORTALATIN: I think you are starting to see more alignment over time with consumer sentiment and some of these recommended guidelines. So, for example, sugar now, according to our research, is the number one thing that consumers do look at on the nutrition facts label.

Forever, it was always calories. With all the concern and dialogue about sugar recently, we've seen sugar become the number one thing. And I think some of these behaviors are reflected when you look at actual consumption patterns that we're tracking.

For example, consumption of carbonated soft drinks is in decline pretty significantly. When we

look at what we term fresh consumption, so if we aggregate fruits and vegetables and fish, meats, and poultry, typically the things that you would find in the perimeter point of the grocery store, we find that after decades of moving into more convenience-oriented food products, we finally are seeing the gradual shift back.

Now, I'll be clear about this. We ate more "fresh foods" in the '80s than we do today. I don't think that's because people in the '80s were more health-aware or health-educated than they are today. I think it's just the opposite.

But I think what we're doing is we actually change our consumption behaviors very slowly. So we're beginning this gradual shift back into fresh consumption. Convenience will always matter to the consumer, and consumers today, I think, are really responsive to convenient solutions that help them achieve some of these dietary goals. But you're starting to see the shift back.

For example -- and it's generationally driven, by the way. Anybody under age 40 today is

consuming 23 percent more, quote, "fresh foods" than that same age group did a decade ago. And by the way, historical aging curves will tell us that that consumption will just continue to increase as we age. Kids don't eat their peas and carrots, and adults eat their peas and carrots. Right?

I think you will continue to see that. And we actually forecast that fresh food consumption will continue to grow over the next decade.

DR. CHOINIERE: In a few moments, I will be fielding questions from the audience, if anyone is interested in doing so. But I'm going to ask a couple more questions.

Based on what you have experienced and seen in your research with consumers -- well, earlier, Dr. Balentine discussed in his opening remarks -- talked a little bit about having a fairly narrow definition for healthy versus a more flexible definition for healthy.

What do your findings imply or say about the benefits or risks of either of those two types of definitions for consumer behavior?

MS. SANDERS: I think I might be able to kick that off by talking about how consumers perceive the term healthy. We've done some work on how consumers define the term healthy when it's applied to food, and we found that when prompted for an open-ended definition, consumers have a lot of expectations around the term healthy and what that means.

We found that primarily, the largest number of consumers, the top theme that came up in our open-ended definition of healthy was around what the food didn't contain, so that healthy foods are low in items like sugar, salt, and fats.

But then we also found that a lot of these definitions tended to be very multi-faceted. There were so many consumers that were saying that healthy food is both low in components that they viewed as less healthy, but also high in components they viewed as healthy, too.

Also, we saw an even smaller subset, so maybe about 1 in 10, in this open definition of just healthy food, bringing up terms like, healthy

food is natural, healthy food is non-GMO, or healthy food contains little or no artificial ingredients.

As you can see, expectations for this term healthy, when it's just left open-ended, are across the board. They tend towards being what -- defining healthy in terms of what the food is low in. But overall, they expect a lot of things from the term healthy.

MR. PORTALATIN: I think maybe a good example is the discussion that was mentioned in the opening today about fats. The consumer is awakening to the understanding that all fats are not exactly the same, and I think that's where this halo of natural comes into play.

If it's a fat that's naturally occurring in the food and it's intended to be there, then it possibly has some healthy benefits. I think consumers are looking for these, for lack of a better phrase, maybe, whole foods that exist in their natural state. And if that carries with it some fat content, they figure that's okay.

What they don't want necessarily if they're trying to reduce fat intake in their diet, and a significant percentage of consumers tell us we're trying to reduce or cut back on fats, they're more likely to try to do that today, again with the consumption of foods that are naturally low in fat as opposed to foods that may be labeled as reduced fat or having undergone some process that takes the fat out.

Or if they're trying to cut back on sugar, they're less likely today to try to do so via an artificial sweetened product and look for things that are naturally low in sugar. Or if they have something sweetened, they want to different to the natural sugars in the products.

I think that's where this idea of natural plays into a flexible definition of what's healthy.

DR. CHOINIERE: Now, we currently have a nutrient content-based definition for healthy. Given what you understand about consumers, do you see the potential for some unintended consequences with either shifting a definition away from the

nutrient content perspective or maintaining the definition in a similar fashion that we currently have in terms of the consumer choices, patterns of eating?

MS. SANDERS: I think there is something to be said for the similarity of our data, where we see that there's a lot of expectations around the term healthy when used in isolation and the data that Dr. Verrill presented about how nutrient claims, even if it's a claim about being low in maybe one nutrient or being high in a particular healthy nutrient, that can create health halo around the product as a whole.

I think that that's important to always remember, is that if we're talking about something being healthy or low in one nutrient on the front of the package, it might create other assumptions about the product as a whole.

I'm not sure how that's exactly addressed by taking a nutrient-based definition or a food-based definition, but I think it's just something to keep in mind in the conversation.

MR. PORTALATIN: Again, all I have to look at is consumer behavior and what they tell us they eat and what they purchased and why. But I think what you've seen over time is that momentum around trying to purchase foods based upon the desire to add a certain nutrient -- and there are a couple of exceptions to this; we still see more than half of consumers say I want more protein in my diet. And that's actually increased maybe a percentage point or two over the last year, nothing crazy.

But in general, this idea that I either want to avoid something or add something is generally losing a little bit of momentum. So maybe that's because the consumer mindset is turning more to the food-based outlook.

DR. CHOINIERE: I want to open this up to members of the audience and broaden the discussion a bit. So are there any reactions that people would like to share? Any questions that you would like to pose to the panel? You can just go right up to the microphone and introduce yourself.

MS. MOORE: I'm Melanie Moore with USDA AMS.

You mentioned something about consumers wanting guidance to be able to meet the dietary guidelines.

I'm just curious, from any of the panelists, where do you think that the majority of consumers are placing their confidence in terms of the information they're getting? Because we all know consumers will rally around an individual study from a university now because they have access to that type of information.

Can you comment generally on it, just broadly?

MS. SANDERS: Thank you. That's a great question, definitely very relevant to this conversation.

I think that there are two kinds of questions there, and I think that who consumers say they trust and where they get the majority of their information are two different things. Every year in the food and health survey, we ask, who do you trust the most to get information on the types of food you should be eating? And year after year, we see registered dietitians and health professionals

coming to that topical list on trust, followed by, actually, U.S. government agencies are very trusted, especially when it comes to food safety and even nutrition as well.

But then when we look into shifting opinions of the healthfulness of different nutrients or shifting perceptions on other nutrition topics, we find that the sources cited that cause these shifts are not necessarily registered dietitians or government agencies. These are news articles, conversations with friends and family, and scientific studies, more like headlines about scientific studies.

So it is interesting to see the dichotomy between sources of trust and sources of opinion change. And I think the real question, as communicators and as people working in this field, is how do we bring those two together and get those tested sources in a place where they are relatively sought after for opinion change?

MR. PORTALATIN: Yes. And I think that it's hard for any single source of information to cut

through today. Right? Because there's so much out there and there's so many places to go.

I think entering into the dialogue in any way that you can is going to -- from a consumer research perspective, I've always encouraged food manufacturers that we work with that now is the time to engage the consumer with authenticity and transparency about all this information because they're going to get the information anyway. It's out there. Let's be in dialogue.

The Grocery Manufacturers Association actually has the Smart Label Initiative that is a way to -- there's only so much information you could put on a package. Right? But fortunately, today, we're not constrained to a package. It's very easy, via QR code or some other thing, to go to more rich sources of information.

I haven't answered the question about who people trust because I frankly don't know who they trust.

(Laughter.)

MR. PORTALATIN: But I just think more

information is better. I'm encouraging, whether it's government, whether it's the manufacturing community, and maybe even in partnership, to see what we can do to put more information in the hands of consumers.

I think the consumer wants to be in charge, as, again, I said they want to personalize everything. And we see the personalization trend coming into play, not just in how we eat but in virtually every category that our company tracks in consumer behavior. So that information is going to drive that.

MS. SANDERS: Yes. And I think it's also important to mention that this is very dependent on subgroups. So not all consumers are going to trust the same sources. Not all consumers are going to turn to the same sources for information.

We see boomers and above tend to trust more of the traditional sources of information and the experts, like registered dietitians and government agencies, while millennials are turning more to their friends and family for information as well.

So it's really going to depend.

DR. CHOINIERE: Next?

MS. GORE: Hi. I'm Hilda Labrada Gore. I'm the Wise Traditions podcast host for the Weston A. Price Foundation. And I was very heartened by what Dr. Verrill showed, the study that showed that even if it had the label of healthy, that the consumers or the people that were in the study still rated it fairly low because they knew soda and cookies and snack food weren't going to be really up there.

But I was just thinking from a personal perspective, if I see a package that says "healthy" on it, my first feeling actually is probably one of relief and that this is okay even though I'm educated. I'm a health coach.

My concern is, how many people are influenced by that who don't actually find all that information, who are still getting -- they're really trusting this label to tell them all that they need to go.

It's just a comment for consideration, that I believe the FDA and others are trusted more than

they realize, so I think this conversation is really important today.

DR. CHOINIERE: I would like to follow up on that comment. One of the questions I have in my mind is, do you think consumers understand or believe that the term healthy is regulated and doesn't matter?

MR. PORTALATIN: I don't have any empirical data on whether they understand if it's regulated, so I don't know how to comment there.

MS. SANDERS: Yes. And I think that we have our data on consumers putting trust in the government for information on food safety and nutrition, but it's hard to be able to connect that with -- maybe they trust the government for information, but they don't necessarily know that it's the FDA that's putting out that label or interpreting that label.

DR. VERRILL: Well, in my years of doing some focus group research, anecdotally, we hear a lot that consumers think that whatever is sold in the marketplace or put on the label is approved by

someone.

(Laughter.)

DR. VERRILL: It's a little bit surprising and unfortunate. And when that comes up in a focus group, nobody questions it. There's general agreement.

DR. CHOINIERE: Yes?

MS. RAINEY: Charlene Rainey with Foods Connect. Does any of your consumer questions distinguish total sugars from added sugars? For instance, would they be avoiding a whole fruit for the sugars, like there's too much sugar in a banana? Or are they looking at sugar as added sugars? Are there any distinctions in your data?

MR. PORTALATIN: I can address it from a consumption perspective. Consumption of fresh fruit has increased pretty significantly over the last decade in the American diet. And if you look at something like consumption of packaged juice, it's struggled, while at the same time we can look at the retail sales of juicers and blenders and mixers and all these things had a significant

spike.

Does that mean people were avoiding juice in the grocery store because of sugar? Well, their fruit consumption was going up. I think you'd argue they were just making more of their own juice at home.

Again, I think the bias from the consumer perspective would be for the natural sugar, and the avoidance would be an added sugar or refined sugars, and certainly artificial sweeteners are on the decline. It's a consumption behavior in our diet.

MS. RAINEY: So you think a healthy definition that distinguished between added sugars and total sugars would go along with what consumers are thinking?

MR. PORTALATIN: Well, again, I'm going to step out of the research role and just my personal opinion. I think more information is better.

MS. SANDERS: I can speak to that from a data standpoint. For those that are trying to limit or avoid sugars in their diet, we've asked

follow-up questions about how are you trying to do so. And we find that the typical answers are added sugar production strategies, like switching to low or no-calorie beverages, skipping dessert, those kind of things. And we don't really see avoidance of fruit as much as of a sugar reduction strategy, which is a positive thing.

MR. PORTALATIN: And the consumption data clearly shows that the biggest change in the American diet is the avoidance of a beverage other than tap water. And so that's clearly -- part of that is cutting back sugar that's coming in through a beverage of some sort.

MS. RAINEY: And NHANES still shows that 80 percent of Americans aren't getting just their recommended servings of fruit. So if we could get them shifting back to a consumption of fruit as a sweet taste.

DR. CHOINIERE: We're running short on time, but let's have these two last quick questions.

MS. SCHNEEMAN: I have two questions, but I'll be quick. One is, I'm curious whether or not

FDA is paying any attention to the class action lawsuits that do in fact show that consumers define healthy in a very different way than the regulatory definition, just as another source of information. That's one question.

The second question I have is for certain nutrient content claims, disclaimers are required if they exceed certain levels. And I'm just wondering about the research on how well do those types of disclaimers work. Do consumers understand what they are about?

DR. CHOINIERE: Do you have any thoughts?

DR. VERRILL: In this experiment that I discussed this morning, we actually -- well, we didn't test a disclaimer, but we tested a referral statement, and it had no impact on the consumer. We actually said to check the nutrition facts, and it didn't seem to have an impact.

It wasn't a disclaimer. We didn't test any disclaimers with any of the nutrient content claims that we tested.

MS. SCHNEEMAN: But by saying no impact, it

didn't increase their looking at it?

DR. VERRILL: Yes.

MS. SCHNEEMAN: Yes. So it had an impact. It didn't increase that.

DR. VERRILL: Okay. So that was the impact. It didn't make them do anything different than any of the other claims that we tested did.

DR. CHOINIERE: As for your first question, in general, FDA does pay attention to the environment in which we are attempting to regulate.

MS. SCHOENFELD: Thank you. I'm Pam Schoenfeld. I'm a registered dietitian, and I have a comment/question.

This data that consumers are now getting more of their information from news, conversations with friends, media headlines, et cetera, so how can the government and registered dietitians like myself retain and avoid erosion of the trust that consumers have in what their messages are if they continue to promote information that is not up to date, especially since consumers are now accepting natural fats in foods, which was also stated, and

that would also include saturated fats, which incidentally happen to be essential -- contain several essential nutrients, and one of which, choline, which only 10 percent of Americans get the adequate intake?

I'm not sure there is an answer to that. I just pose that almost as rhetoric question. I do think, over time, the government is going to lose the trust and confidence of the American public if they continue in the outdated dietary guidelines direction.

I see that the FDA seems to want to model their label according to the dietary guidelines, which in some cases are very helpful and in other cases where they discourage saturated fat and recommend a limitation of cholesterol as low as possible, and in place put polyunsaturated vegetable oils.

I don't know if anyone wants to respond to that, but --

DR. CHOINIERE: Do you have any --

MR. PORTALATIN: Well, I think some of

this -- again, the consumer is so empowered with information today that I think they're seeking out a lot of this on their own. Let's just take cholesterol for an example.

As stated in our research, the desire to avoid cholesterol just has no momentum behind it whatsoever because some people have figured out that, hey, maybe in some cases that's not exactly what I need to avoid. And it manifests itself in our actual food consumption behavior.

I could show you a chart that goes back to the early '80s when cholesterol was the big bogeyman, and we just quit eating eggs altogether. I mean, egg consumption just fell off of a cliff.

Eggs is one of the items that is growing in consumption in our diet now. Why? Because it's inexpensive, it's a good source of protein, and it's perceived as a natural whole food. And I think more than anything else, that's the underlying shift in consumer sentiment, is this desire for some authenticity in our food.

MS. SCHOENFELD: And I think they're also

looking for good sources of nutrients, which more and more people are becoming aware that Americans don't get enough of from this diet that the dietary guidelines has been promoting for over 30 years with very, very little change.

DR. CHOINIERE: And with that, I'll thank you for your comment. And I want to thank the panel -- I'm sorry, we're over time. But we look forward to continuing this discussion at the later sessions. And I want to thank the panel for their very helpful insight.

(Applause.)

MS. BARRETT: At this time, we do have a scheduled break. I would ask if folks could come back at 10:05, and we'll get started promptly at 10:05. Thank you.

(Whereupon, a brief recess was taken.)

MS. BARRETT: Okay. We're about to go ahead and get started. So please, if folks in the room could take your seats. Again, if everyone in the room could take their seats, we'll go ahead and get started. We don't want to lose any more time with

this session, so let's go ahead and begin. And again, I want to welcome back our webcast audience.

Now we're going to move on to our second panel this morning, which we have a number of stakeholders here who will be offering perspectives on the healthy definition. And to moderate this session is Dr. Doug Balentine, again our director of Office of Nutrition and Food Labeling at FDA's Center for Food Safety and Applied Nutrition.

With that, Doug, I'll give the podium to you.

DR. BALENTINE: Thank you, Kari.

Now that we've heard a bit about the consumer and the challenges that consumers face in the way they're going about thinking a food, we thought it would be useful to hear from a variety of other stakeholders about views around the term healthy in the context of food.

We've asked some consumer groups or public health groups and some industry representatives to come and share some of their perspectives around the definition of healthy. And I think this will

be a really good way to provide some further input into that.

So without further ado, we have an interesting panel. We have Lindsay Moyer from the Center for Science in the Public Interest, who will share some thoughts with us. We have Justin Mervis, who's the senior vice president and general counsel of KIND Snacks, who will provide us some interesting thoughts from their perspective.

We have Pepin Tuma from Academy of Nutrition and Dietetics. And then finally, we have Kristin Reimers from ConAgra Foods, and they have a long history in the use of the term healthy, particularly around their Healthy Choice branch.

With that, I'll pass it on to Lindsay and ask her to start the session. Thank you.

Presentation - Lindsay Moyer

MS. MOYER: Thank you.

Good morning. I'd like to thank the FDA for organizing today's meeting and putting together this morning's panel.

CSPI is a nonprofit health advocacy group

that focuses on nutrition and food safety policies, so we appreciate the opportunity to make sure that healthy means what it says on food labels and does not mislead consumers.

We know that healthy eating patterns are linked with a lower risk of type 2 diabetes, heart disease, obesity, and certain cancers. And hands-down, higher intakes of fruits and vegetables have been most consistently identified as being a part of healthy eating patterns. But to see what that means for healthy on food labels, I'd like to start by looking at a grocery store.

You can see here up top are fruits and vegetables. I see hardly any food labels. But if we want Americans to buy healthy foods, this is where we need to start. The vast majority of Americans are not getting enough fruits and vegetables. And these are the foods we need to market aggressively to consumers who are seeking healthier diets.

On the bottom are some of the snack food aisles. We know the marketplace is saturated with

heavily processed foods, and sometimes it can be easy to forget that the point is to move consumers away from these aisles and back into the produce section.

Here are some examples of why that matters. Consumers are genuinely confused about what is and is not healthy, and there are food companies that will take advantage of any type of dietary advice that we can give.

Whether it's to eat more fruits and vegetables, eat more whole grains, or choose healthier fats, they can find fruit snacks, vegetable chips, vegetable pasta, cookies, even chocolate milk, that are appealing to these claims. So FDA needs to define the claim healthy so that these types of foods are not competing with fruits, vegetables, and other truly healthy foods.

The current system for defining healthy has worked well in some ways but not in others. Here are some examples of foods that are labeled healthy now. The first two are a Campbell's Healthy Request soup and a Healthy Choice frozen entree.

Both of these are significantly lower in sodium than many competitors. Defining the claim healthy has encouraged some major brands to produce products that have less salt. That's a step forward, although we have a lot of work to do on the rest of the food supply.

The next two items are a box of white pasta and a can of SpaghettiOs. Both of these pastas are made with entirely refined grains. But the word "healthy" on a food with grains should mean that it's 100 percent whole grains. That's an example of where FDA needs to update the definition.

I had to search the entire grocery store for these four examples. That's another clue that the system is not working as well as it could. The healthy claim appears on very few foods. It's been overwhelmed by other healthy-sounding claims in the marketplace, and many of them are unregulated.

The food industry doesn't need to bother developing a food that's low enough in sodium and saturated fat to call itself healthy when you can sell a soup that let's you eat positively or an

entree that's "smart" or "fit." And the Fit Kitchen entree I'm showing here has about double the sodium of the Healthy Choice entree on the previous slide.

Here are a few more examples. Foods can call themselves "wholesome," "nutritious," "good," or "nourishing," or claim "to support a healthy heart" instead of using the term healthy. The FDA should consider claims like these to be implied healthy claims.

FDA originally set the criteria for healthy based on a food's nutrients. That framework needs some updates, and I'd like to briefly summarize seven of the updates that we would recommend.

Number one is that products labeled "healthy" should be made from foods that are the foundation of a healthy dietary pattern. That means whole fruits and vegetables rather than fruit juice; also, 100 percent whole grains, fish, beans, nuts and seeds, low-fat dairy, and lean poultry.

A combination of food and nutrient criteria would ensure healthy eating patterns while limiting

the nutrients we typically over-consume. Nutrient limits also help us single out the most nutrient-dense foods, the ones that are truly deserving of a healthy label. And the latest dietary guidelines define nutrient-dense foods to mean "healthy foods that contain little or no solid fats, refined starches, sodium, and added sugars."

Number two is to exclude foods that contain more than a few grams of added sugars. They're empty calories. And we know that too much added sugar promotes heart disease, type 2 diabetes, and obesity. Last year, FDA made a major improvement to the nutrition facts label by adding a line for added sugars on a percent daily value.

The FDA could limit added sugar in healthy foods to 3 grams, or about 5 percent of the daily value. This is similar to the approach that FDA took previously to set low levels of fat and saturated fat.

Number three is to maintain limits on sodium. The FDA should also consider whether current sodium limits in the healthy definition are

low enough to encourage companies to meet the agency's draft voluntary sodium reduction guidelines across a wide vary of food categories.

Number four is for FDA to address total fat in one of two ways. Either eliminate the limit on total fat or exempt foods that fit into a healthy dietary pattern from a total fat limit. We know that the goal of eliminating "low-fat" from the healthy definition is of course to let in foods with healthy fats. But even if French fries or potato chips were made with mostly unsaturated oils, allowing those foods to call themselves healthy is not going to move Americans to a healthier diet.

To ensure that chips, fries, and other foods with a low nutrient density do not carry a healthy claim, FDA could keep the total fat limit and specifically exempt certain foods like nuts, avocado, fatty fish, and most vegetable oils from the limit.

Number five is to exempt foods that fit in a healthy dietary pattern from any limit on saturated

fat. And the agency should continue to require that healthy foods are low in saturated fat. This would sharply limit unhealthy fats from fatty fish, full-fat dairy, and palm oil, among other foods.

However, that limit should not stop us from putting a healthy label on foods that form the basis of a heart-healthy diet. So, for example, FDA could exempt foods like salmon, walnuts, or sunflower seeds from a low saturated fat requirement.

Number six is to keep a cholesterol limit, for several reasons. FDA did keep a daily value for cholesterol on the new label, and the dietary guidelines still advise Americans to limit cholesterol.

Dietary cholesterol raises LDL cholesterol in the best-controlled studies, and among people with diabetes, those who eat more eggs do have a higher risk for heart disease. Given these concerns, we'd just like to exercise caution and think it could be unwise to put a healthy label and encourage consumers to eat more of something like

eggs.

Number seven, finally, is to exclude red and processed meats. A healthy label should encourage consumers to choose the very best protein foods by eating more lean poultry, fish, and beans, and excluding red and processed meats.

We know there's strong and consistent evidence that healthy dietary patterns that are lower in intakes of red and processed meats are associated with a lower risk of heart disease. In a recent review, the World Health Organization's International Agency for Research on Cancer found that frequent consumption of processed meat is carcinogenic.

In closing, if all of this sounds like rigorous criteria, it is. A healthy label should not be marketing tool that helps marginally-better processed foods compete with fruits, vegetables, and other truly healthy foods. Consumers should be able to trust the label to identify the most nutrient-dense foods that fit in a healthy diet. Thank you.

(Applause.)

DR. BALENTINE: Thank you, Lindsay.

We'll do our Q&A at the end of the session. So next I'd like to ask Justin Mervis from the KIND Snacks Corporation to come up and share their thoughts with us.

Presentation - Justin Mervis

MR. MERVIS: Thank you, Doug, and thank you, Lindsay.

You might seem to think that Lindsay and I compared notes before I prepared my presentation because we really cover a lot of the same themes. And they're really all themes we've been hearing as well this morning from the consumer panel. So it's nice to see that we're even already, this early in the morning, starting to converge on some ideas that seem to be pretty common-sense in defining the healthy regulation.

Before I get into KIND's recommendations on how to update the healthy regulation, I thought it would be useful to spend a few minutes sharing some background and context on what brings me and the

KIND organization here today.

In March of 2015, KIND received a warning letter from FDA, which indicated, among other things, that KIND needed to remove the word "healthy" from certain of our snack bar labels.

After receiving the letter, KIND worked diligently to bring our labels into compliance in accordance with FDA's standards. But at the same time, we did a deep dive into the regulation itself to try and better understand what it meant and what its implications were for our food, for other foods, and for the American diet at large.

As I'm sure most of you know in this room, prior to FDA's interim guidance, which was recently issued toward the end of 2016, in order to bear a healthy nutrient content claim, a food product was required to contain 3 grams or less of total fat and 1 gram or less of saturated fat, regardless of the source. And of course, our products, which have a substantial amount of nuts in them, exceeded these thresholds due to the fat content in the nuts.

As we looked at this and looked further out into the food landscape, we acknowledged that this didn't just apply to nuts and didn't just apply to KIND bars, but it applied to other nutrient-dense foods like avocados, salmon, olives, and other items that are generally recommended as good for consumption.

As we looked even further, what we found really striking was that foods like low-fat chocolate pudding, sugary children's cereals -- which, by the way, I feed to my children and think are just fine -- but those foods could be labeled as healthy. And when you look at that on the one hand, and you look on the other hand at almonds and avocados that can't be, you realize that there's something incorrect about the way that the regulation is written.

While it seems very surprising, when you look at it in context, you actually start to understand that this regulation was written in the early '90s at a time when reducing fat consumption was the key focus of dietary guidance, and really

there was very little focus on sugar consumption and certain other issues that we think about today.

With all of that in the background and really just using this chart as kind of our guiding beacon in moving forward, we filed a citizen petition with FDA in December of 2015, requesting that they take a look at the regulation and bring it up to date with modern nutrition principles.

I'm pleased to be here today. I think this is a great meeting and a great opportunity for us to tackle this issue. And now I'll share with you the four ideas that KIND has as building blocks for constructing this new regulation.

First, we believe that healthy food products should contain a meaningful amount of foods that are part of a healthy eating pattern. And to identify these foods, we looked to the 2015 dietary guidelines, which describes health-promoting foods as vegetables, fruits, whole grains, low-fat dairy, lean protein, and certain oils.

In our view, any view that's labeled with the term healthy as a nutrient content claim must

have a substantial amount of one or more of these foods either in their whole form or that are processed in such a way that hasn't materially degraded their nutritional value.

For example, one we've heard is a whole fresh fruit, or a dried fruit with the moisture removed, would be a health-promoting food, whereas perhaps a fruit juice concentrate that's primarily the sugar left over after the nutrients have wholly been removed would not be a health-promoting food. And that's consistent with FDA's recent guidance on added sugars. While a different topic, I think there's an analogy there, and that same principle can be used here.

We think another important aspect of this meaningful amount requirement would be for food companies choosing to use this term on their label to actually clarify what they mean, to help educate consumers. So you're going to say this food's healthy. Well, that's because it has two servings of whole grains.

I think that kind of information, by

actually connecting the dots for the consumer, you're starting to educate them rather than just produce what's maybe a health halo or provide a perception without explaining why that perception ought to be. And to me, I think that might actually be the most critical way we educate consumers and help them learn how to eat healthier diets.

Second, we believe the healthy definition doesn't need thresholds for good nutrients. Under the current regulatory scheme, in order to be labeled with healthy as a nutrient content claim, a food needs to have 10 percent more daily value of things like protein or vitamins.

We, of course, don't think that these nutrients aren't important. Of course, people ought to be consuming more of these nutrients in the foods they're eating. But in our view, under the first principle I shared, the nutrients will follow. And so rather than over-complicating the issue, let's focus on the right foods, constructing the right diets, and overwhelmingly people are

going to end up eating the right combinations of nutrients.

Third, the healthy definition should include limits on nutrients to avoid if those nutrients are not intrinsic to the foods that are part of the healthy eating pattern. So here we're talking about saturated fat. We're talking about sodium. And we're talking about added sugars.

Like this evolution we've had in the sugar space, where we started distinguishing between added sugars and total sugars, I think we can apply similar principles to things like sodium and saturated fat, where we don't demonize them if they come from the whole foods we're trying to encourage people to eat more of.

But we do acknowledge that in large quantities, they can be harmful, and try and limit adding them from other sources. And so that's what we mean when we say limit them to the extent they're not part of foods that are part of a healthy eating pattern.

Finally, in KIND's view, the healthy

definition should exclude food products that contain low- or no-calorie sweeteners or synthetic color additives. I'll acknowledge there's considerable uncertainty and debate in the nutrition community about the short- and long-term health effects of these ingredients.

For example, the 2015 dietary guidelines note that, "While replacing added sugars with non-caloric sweeteners may reduce caloric intake in the short term, questions remain about their effectiveness as a long-term weight management strategy." And there are credible studies showing potential adverse health consequences from some of these ingredients.

What we do know, while there's still uncertainty, is that artificial sweeteners and synthetic colors don't have health-promoting qualities in and of themselves, and more research is needed to determine their impact on people's diets and on their health. And until we know more about them, we feel it's appropriate that they not be included in foods that are labeled with a term

like healthy.

Thank you very much for your time. I look forward to hearing questions and having more discussion, and I'll turn it over to the rest of the panel.

(Applause.)

DR. BALENTINE: Thank you, Justin, for your thoughts, and I think they continue to bring some points for us to discuss during the day forward in the breakout sessions.

Next I'd like to ask Pepin Tuma from the Academy of Nutrition and Dietetics to share some of their thoughts with us.

Presentation - Pepin Tuma

MR. TUMA: Thank you very much. I make the worst PowerPoints in the world, as anybody who's ever seen them can attest. My strategy is usually more bullet points and more words on them, so I'm going to avoid having them today.

I will say, however, Justin, well done on your algorithm on Facebook because that healthy divide slide with the Fruity Pebbles and the

avocado kept popping up in my feed over the last few days. So you're doing something right in figuring out how to target people interested in a subject.

The Academy of Nutrition and Dietetics, as many of you probably know, represents about 100,000 food and nutrition professionals across the country, registered dietitian nutritionists, food scientists, researchers, practitioners.

As part of our commitment to improving the health of Americans through food and nutrition, over the last several years, we developed a set of guiding principles as well to help us with labeling claims. And a number of those are particularly relevant, I think, for this question of healthy.

As we discovered in applying the labeling claims to the specific question of how should the FDA define what is healthy, as it turns out, it's a lot easier to make principles than it is to apply principles to the law.

Getting down into the nitty-gritty in asking our dietetic practice groups, asking our experts,

our researchers, our practitioners about exactly what it'll look like in the application of these principles to a regulatory definition becomes significantly more complicated.

First and foremost, I think, what we've discovered over the last 24 years since this definition of healthy was first established is that we recognize that nutrition, as with most science, is evolving, and significantly in the last 24 years.

We can see that the dietary guidelines, although quite a few of the recommendations have remained stable over the years, there have been significant changes and significant reinterpretations of how the guidelines should be -- of specific recommendations in them and also in terms of how we should talk about them.

I think, first and foremost -- and I'm going to reattach each of these principles that the Academy has as I talk about some of these issues. I think first and foremost is that there needs to be a recognition that any definition needs to

reflect the very best science and updated science.

Right now, what we've seen specifically in the 2015 to 2020 guidelines is a focus on three separate things that had previously not been quite as highlighted in previous guidelines.

The first is a real focus on shifting to questions of healthy eating patterns, healthy dietary patterns, instead of nutrients. And I think that's really critical. One of our fundamental principles is that labels should help provide understanding about the healthfulness of overall food rather than a focus on particular nutrients.

As part of healthy eating patterns, we need to make sure that this fits in with that section, that the application of -- overly focusing on a particular nutrient is not the goal of the dietary guidelines, and it may have unintended consequences, particularly when it comes to the labeling of food.

Which brings me to my second point, about questions of total fat. Unintended consequences, I

think many people are familiar with some of the results of the nutrient content claim of low-fat and the result of, for example, adding sugar while removing fat from products.

What the intention of this healthy diet patterns desire is in the dietary guidelines is to avoid some of those unintended consequences while including generally healthy and whole foods, I think. So that's the second point.

The third, I think, is that in terms of the questions of how the dietary guidelines are changing, there are some questions at saturated fat and polyunsaturated fats, and how we can ensure that as we lower the use of saturated fats, that we replace it with something healthier.

That I think is another critical question. And putting aside the issue that was raised earlier this morning of the potential differences in some of the new research looking at differences in saturated fats in dairy, for example, versus in meats; putting aside the question that the FDA just raised and set out for public comment recently with

regards to whether certain fruits and vegetables can meet a low-fat definition, which I think has direct implications for this question of whether or not they're healthy, we really need to recognize that as the nutrition science is changing and as a definition may be something that we're stuck with or we have for 24 or more years, we need to be very careful to ensure that the science is as up to date and as accurate as possible.

The second piece, as another principle, is that labeling should enhance consistency among the various government nutrition recommendations. Americans need to fundamentally not be -- to the extent possible, our government should not throw 700,000 different recommendations at us in addition to all the ones we're getting from our friends and our families and our experts and television and as consumers.

To the extent possible, if there's a recommendation about what it means to have healthier foods in schools, if there's a Smart Snacks definition for more healthful content of

competitive foods that are sold in schools; the more you can align those definitions so that Americans are not getting conflicting messages, the more able we are to ensure that Americans are going to be able to make the shifts towards a healthier eating pattern that the dietary guidelines are really pushing us towards.

We really are very supportive of working together to ensure that there is that consistency among messaging so that we can achieve those healthy eating patterns that are desired.

Where does that leave us? Well, in talking with our various practice groups, in talking with our member experts, we don't have an answer. I know that's a frustrating thing to say and it's unnerving. Even with the generous extension of the comment process that FDA's granted, we've not been able to come to a legal definition of how to apply the principles that we have that are very similar to the principles that Lindsay and Justin talked about to an actual legal definition.

Most often, I think we know what healthy

food is when we see it. But as it turns out, there's not a lot of need for labeling apples and oranges that are in the produce aisle. And so the question comes when it comes to non-fresh fruits and vegetables, when it comes to foods that are manufactured, how can that be applied?

The term "processed" isn't a particularly useful definition because almost every food, the majority of foods, are processed in some way. And most Americans don't know what it means for a food to be processed.

Given the lack of consumer knowledge and consumer information, given the conflicting messages about what healthy means, the Academy is frustrated to say that we do not have a good definition. We're certainly open to other ideas in the application of these principles. But I think, fundamentally, it may be one of those times where this definition is outdated.

Certainly, the current definition is outdated. And without a consensus idea of how to better define this in a way that makes sense that

is not nutrient-based that heads back to the idea of healthy diet patterns, the Academy is tentatively recommending the elimination of the implied nutrient content claim of healthy.

(Applause.)

DR. BALENTINE: Thank you. And the last speaker will be Kristin Reimers from ConAgra, and she will share with us some of their thoughts and from their long experience using the term in their brands. Thank you.

Presentation - Kristin Reimers

DR. REIMERS: Thank you so much. I'm delighted and honored to be here today. My name is Krissy [ph] Reimers, and I'm the director of nutrition and health at ConAgra Brands.

Now, not all of you may be familiar with ConAgra Brands, but I bet you're all familiar with some of our brands that we make, for example, Hunt's Tomatoes, Marie Callender's, PAM, Egg Beaters, and of course my favorite, Healthy Choice.

For my whole career, starting as a pediatric dietitian and then as an educator and researcher,

and certainly as a mom, I've spent a lot of my life helping people eat healthier. As I joined ConAgra 10 years ago, it became immediately apparent to me how helpful the food industry can be to help people eat healthier.

It occurs to me that foods that bear the claim healthy can be the perfect intersection between public health and the food industry. So I am delighted that there are so many stakeholders here today, that we can work together to help to establish a definition of healthy that really can help consumers move to healthier eating patterns.

I think I'm going to try to get closer to the nitty-gritty, and hopefully we can all leave here today acknowledging that healthy really is an important claim that needs to remain on the market.

Let me take you on the Healthy Choice journey. Since the claim was established, as Doug mentioned, ConAgra has been a major stakeholder because of our brand Healthy Choice. Healthy Choice launched in 1989 just as the NLEA was enacted.

The inspiration for Healthy Choice came from the CEO at the time, who had suffered from a heart attack and was disappointed at the lack of heart-healthy foods on the marketplace. So he took matters into his own hands, and the result was Healthy Choice.

ConAgra and FDA, because of NLEA occurring at that time, partnered closely to define the word "healthy," recognizing that in order for the word to be meaningful to consumers and for the food to consistently deliver the characteristics considered healthy, that healthy had to have a regulated definition for all manufacturers to follow.

Nearly 30 years later, we're very proud of our Healthy Choice heritage and are proud to offer foods that can help move people towards eating habits consistent with Dietary Guidelines for Americans.

We wholeheartedly support updating the criteria to reflect current science supporting healthy, just as FDA did when they issued guidance last September that permitted foods that were not

low-fat to bear the claim healthy as long as most of their fat was coming from mono- and polyunsaturated sources.

We embrace this kind of modernization of the healthy claim to keep in step with science. But we feel that modernization of the healthy claim can go even further to support updated dietary principles, and importantly, deliver foods that will reinvigorate consumer interest in the healthy claim.

Currently the healthy claim is losing relevance with consumers as they are lured to other foods that we've been talking about today that have appealing attributes that are perceived as healthy, but attributes for which there are no nutrition guardrails. A contemporary definition of healthy can bring excitement and consumer appeal back to foods bearing the healthy claim.

What does a modern definition of healthy look like? Our deliberations led us to this guiding principle. We want to base the definition on food groups to encourage, while preserving the

positive aspects of the nutrient-based definition.

The dietary guidelines' focus on diet patterns was the inspiration for merging a nutrient-based premise with foods, and specifically those foods we need to increase in our diet.

To activate this idea quite simply, we're proposing that foods to encourage are used as the basis for the healthy claim. And as these foods to encourage increase in the meal or the food product, we would also experience increased flexibility in nutrients to limit to be able to deliver these foods in a form consumers will accept from a sensory standpoint. It's important to keep in mind that taste is the primary factor that drives consumers to the foods that they buy.

Now, to get a little closer to the nitty-gritty, as Pepin mentioned, this slide describes the general framework that we're proposing, where the increasing amounts of food groups to encourage would correspond to increasing levels of nutrients to limit, of course while retaining nutrient limits that will move Americans closer to the dietary

guidelines.

Now, this isn't a complete departure from the current framework, as you'll see. To provide an overview of this table, the healthy criteria are listed across the top, with four tiers down the left side. Let's look at it column by column, starting on the left side with the tiers.

The tiers, 1 through 4, are based on composite amounts of food groups to encourage in the product. And for a clarification of terms, the food groups to encourage is the phrase we use to describe those foods that the dietary guidelines suggest Americans should shift toward for healthy eating patterns. Those food groups are: whole grains, fruits and vegetables, fish, legumes, nuts and seeds, non- or low-fat dairy, and the food component of oil.

Now, as we look across the criteria, in general, tiers 1 and 2 criteria are more or as restrictive as the current criteria in terms of limiting nutrients, with the exception of cholesterol. With the weakening evidence relating

cholesterol to cardiovascular disease, as noted in the dietary guidelines, we feel a cholesterol criterion is no longer needed.

As we move down the table, tiers 3 and 4 provide greater amounts of shortfall foods as the limiting nutrients show more flexibility. So I'll point out a few key examples.

For saturated fat, tiers 1 and 2 would retain the low saturated fat criteria. But as food groups to encourage increase, saturated fat would increase slightly. Likewise, sodium limits would increase slightly at the higher tiers.

Retaining or slightly increasing the sodium level may seem counterintuitive to dietary guidelines, but the levels that we are proposing for tiers 3 and 4 remain in line with the FDA sodium reduction guidelines that Susan mentioned.

Sugar. With the advent of added sugar on the nutrition facts panel, we anticipate inclusion of added sugar with the healthy definition. Here again, we are proposing more flexibility as shortfall food groups increase while retaining the

dietary guideline goal for preserving nutrient density of foods.

Finally, beneficial nutrients. We support current guidance of continuing with the current nutrients plus vitamin D and potassium. However, we are proposing that presence of positive food groups would replace the need for beneficial nutrients as we reach the higher tiers. Finally, we are aligned with exempting saturated fats from foods to encourage, a concept that's been brought forward here today.

In this table, we've populated some numbers. These are proposed values, not written in stone, that, as with all claims, the devil is always in the detail. So I thought this would spur conversation and creativity today if we really had some numbers to talk about, getting closer to the nitty-gritty.

First of all, the food groups. The food groups we would propose being based on the food pattern equivalence database used for MyPlate. A serving here would be defined as a half cup or cup

equivalent or an ounce equivalent, as appropriate. Tier 1 would be less than one-half serving. Tier 4 would include the maximum amount of positive food groups contained in individual foods, meals, or main dishes, which would be two or more servings.

Now let's look across each column. The total fat would correspond to the current FDA guidance. The saturated fats would start with the low saturated fat, as currently is in the claim, and stay low-fat for tier 2. But then we propose a small increase in tiers 3 and 4, not exceeding the extra-lean criterion already in place for seafood and wild game in the healthy claim.

Cholesterol. Again, we suggest this criterion be removed. With the saturated fat guideline, it would limit most foods that we feel would be problematic as far as providing too much cholesterol. Right now, the claim only restricts eggs, and we think that up to one egg would be appropriate to be called a healthy food.

Sodium. The first tier would be reduced by 4 percent to stay consistent with the new daily

value of 2300 milligrams. These levels reflect 20 and 25 percent of the DV for individual items and meals and main dishes, respectively, which is the current construct.

Then we ladder up to reach the 530 and 690 milligram levels in tier 4. 690 represents 30 percent of the DV, or the disclosure level. Using the disclosure level has been used previously with cholesterol, so we are applying that principle here.

Now, of course FDA has noted the importance of guideline sodium reduction for the population and has issued category-specific voluntary sodium reduction guidance. Currently, Healthy Choice is 40 percent below the short-term target for the frozen meals category, and is only 10 percent over the 10-year target.

These proposed sodium guidelines for the healthy claim would continue to offer foods that help consumers shift their intake downward while still providing a level that they will accept from a taste standpoint.

Now to added sugar. Here, to maintain consistency with FDA construct of basing the criteria on the DV, we started with 10 percent, or a low level of the DV, for sugar, for added sugar, and incrementally increased to tier 4, which is 30 percent of the daily value.

Beneficial nutrients we suggest would be unchanged, but using food groups for tiers 3 and 4 instead of nutrients would allow foods like oils and nuts and seeds that would otherwise be disqualified due to lack of a beneficial nutrient. It would also provide a path for vegetables and fruits without making them exempt from the 10 percent DV requirement.

Finally, exemptions. By exempting saturated fat from shortfall food groups, it would allow oils, seeds, nuts, and fatty fruits to qualify. Since these foods are contained in food patterns associated with reduced disease risk, it makes sense that there should be a path for qualifying. Without this exemption, even with the slightly higher saturated fatty levels in tiers 3 and 4,

they would not qualify. So the focus here would be on the foods we know are helpful moreso than on a single nutrient.

Now, finally, this chart highlights some examples of foods that would and would not qualify under this new framework. For tiers 1 and 2, the added sugar criteria would disqualify a few foods that currently qualify, for example, a frozen novelty, or meals that would have more than a low amount of added sugars.

Tier 3 is where we start to allow foods not previously included. Avocados, walnuts, olive oil, peanut butter, and sunflower kernels would qualify because of exempting saturated fat and not requiring a positive nutrient. Vegetables would qualify here, and need not be exempt if they don't provide 10 percent of a beneficial nutrient.

However, the guardrails remain stringent enough that margarines, even light margarines, are excluded, and something like French fries, even though they would fall in tier 3 because of being a vegetable, would have a higher saturated fat limit

than would qualify.

Tier 4: Here we might see a new food qualify, like a sandwich with a piece of whole grain bread, an egg, and an avocado. Popcorn and other 100 percent whole grain foods would qualify in tier 4, but it shows a good differentiation.

Even though a labeled serving of popcorn would provide two MyPlate servings of whole grains putting it in tier 4, the guardrails remain stringent enough to exclude traditional popcorn, while permitting popcorn lower in saturated fat. Likewise, not all foods with a high level of vegetables would qualify if they still had higher levels of sodium, saturated fat, et cetera.

Thank you for wading through all these details with me. My hope is that this will stimulate meaningful conversation as we work together to increase foods in the marketplace that are highly accessible, affordable, and taste great so that these foods ultimately help shift Americans toward healthier eating patterns. Thank you.

(Applause.)

DR. BALENTINE: All right. I want to thank all of our panelists. I think they've really done a good job at providing some really thoughtful and helpful insights into the current and the options we might explore for a modernized definition of healthy.

I think we've started to see some interesting considerations that really apply to the breakout sessions that we're going to have in terms of how to apply a nutrient-based criteria to how food groups might fit into our considerations.

We have about 15 minutes now for questions from the audience to our panel members. And so, at this point I'd like to invite those from the audience up to ask questions. Thank you.

Please introduce your name and affiliation so we can have it for the recording.

MR. HELLMAN: Yes. My name is Dave Hellman. I'm just here as a citizen who thinks about food systems. And it's a three-part question, but I'll try and make it brief.

First, we've heard a lot about the different

nuance where fat and cholesterol and different ingredients may or may not be healthy. And when you look at it at an individual basis, it may be healthy for one person and not the other.

Can that amount of nuance really ever be expressed in the real estate on a packaged food?

The second part of the question is, we heard in the first segment about maybe depending on QR codes and technology to fix that problem, so sending people offline.

How does that help people who don't have access to that technology? In this environment where people are told they have to make a choice between an iPhone and their healthcare, that makes it a tough problem.

In recognition of what Mr. Tuma said, I think, where we were talking about maybe the labels just don't make sense, what Ms. Moyer said about the healthiest foods seem to be the unpackaged foods, is the real answer here -- and I'm not intentionally being flip -- is the real answer packaged foods should carry a label that says, "If

you can read this, this may not be healthy"?

(Laughter.)

DR. BALENTINE: Thank you.

MS. SCHOENFELD: Hi. Pam Schoenfeld, registered dietitian, nutritionist, also representing the Weston Price Foundation, a nonprofit nutrition education foundation working to restore the healthful benefits of ancestral diets to Americans and people across the world.

I don't know if it's a rhetorical question, but Kristin -- which I thought you had a very good presentation, Kristin -- had mentioned exempting saturated fats from the dietary guidelines foods, which are considered part of a healthy diet.

Am I correct in that?

DR. REIMERS: Right. Specifically, food groups to encourage.

MS. SCHOENFELD: Okay. And I think that's a great idea. But when you come to something like lean meat, that is the definition of lean meat. You cannot really -- and correct me if I'm thinking improperly about this. But if you exempt saturated

fat, then the term "lean meat" doesn't mean anything more, as far as I can tell, although I have to say I don't, nor does our foundation, feel that lean meat has to be the only part of the type of meat that you can eat, especially since there's a number of foods that are probably very healthy, like liver, that may not be classified as lean meat.

So would that be a contradiction there?

DR. REIMERS: Let me clarify. So the food groups to encourage would not include lean meat. It wouldn't include lean meat and enriched grains because Americans eat adequate amounts of those foods. So in general, lean meats and refined grains would fall under tiers 1 or 2, where they would be then permitted based on the nutrients to limit.

MS. SCHOENFELD: Okay. But why doesn't a healthy food pattern encourage lean meat?

DR. REIMERS: The healthy food pattern in general includes lean meat. But as far as the food groups to encourage, or the ones that we want to

shift intake toward, it would not include lean meats.

MS. SCHOENFELD: And to that other gentleman's point, I would say lean meat is very important for young women, pregnant women, children, who need more iron, more zinc. And I think it is a food to encourage. I think we cannot across the board make these foods to encourage apply to all the American public. It's a very individualized thing.

I would agree meat is maybe not appropriate for people who tend to have heart disease or store a lot of iron in their body. But I think we are giving Americans a lot of bad information because we're trying to simplify. And I would really support Mr. Pepin's [sic] recommendation as an academy member. Thank you.

MS. SCHNEEMAN: I don't know if anybody wanted to comment on that.

MS. MOYER: I can comment just on the recommendation to remove or eliminate the term healthy as an answer to this. And while I

sympathize with the difficulties that we're all experiencing in trying to lay out these details and define healthy, I'm not sure whether FDA can ban the term healthy. And really, the only alternative I see is for food companies to define it themselves.

I think it's important that we engage in this discussion to make sure we arrive at a strong definition of healthy, one that protects consumers and helps them identify the best choices.

DR. REIMERS: Thank you, Lindsay. I would certainly concur with that. I think we need to have that term defined. Otherwise, it will become more like natural, where it would be used widely, with varying definitions.

MS. SCHNEEMAN: I'm Barbara Schneeman, affiliated with UC Davis. I'd just add to that, that if AND is going to go forward with that, be sure you prepare the legal brief for how FDA could prohibit the use of that term.

But my question has to do with the comments. I really appreciate the way people are thinking

creatively about how do we bring food groups into our definition of healthy. But both of you commented about not using the beneficial nutrient criteria as a part of how healthy is defined.

If you go back to the original thinking behind what's in the dietary guidelines and what sits behind some of that, is making sure that people can meet their nutrient needs from foods without exceeding their calorie intake. So that's part of trying to encourage the beneficial nutrient.

My question has to do with, have you done analysis to look at what the implication might be in terms of meeting nutrient needs? And the other part of my question is, do we have the right list of beneficial nutrients?

The problem is when we only focus on the ones that are currently listed, and we need to think a little bit more holistically about what to include in the beneficial nutrients, would we be eliminating that concept of meeting your nutrient needs from food if we take away the beneficial

nutrient part?

MR. MERVIS: Just a point of view here that I think it's -- I think there's a danger in all of this discussion in assuming that we're doing so much by defining a word, one word.

What I mean by that is when we look at the entire diet, and when we look at the entire population, who probably require a vast number of different diets, we're not going to solve everybody's needs by just simply coming up with one definition of the word healthy, and assume that, well, if everybody just only eats foods labeled with the word healthy, then we're all going to be just fine. That's too easy. Right?

Then you have to say, well, what do we actually accomplish by coming up with a definition of the word healthy? I don't think it's to construct diets for everybody. That can't be the purpose because I think it would be a colossal failure.

In my view, it's simply just a signal. It's a signal that this food meets some set of criteria.

And that criteria could be, well, it comes from foods that are generally recognized as good for you. It doesn't have too much of the bad stuff, and it's a whole lot better than perhaps a variety of other things you could choose.

Of course, we're all here today to debate what that set of criteria might be, but we also should probably spend some time debating, what's the purpose of having the definition in the first instance? What does it communicate to people, and then what do they go home and do with that? Because I think, at best, it simply just helps people make selections.

If they're only relying on that one thing, then they're missing the point. And of course people need balance and they need variety, and so if they're eating lots of different healthful foods, hopefully they are getting a good combination of nutrients.

But yes, if somebody simply said, well, nuts are labeled as healthy, so I'm going to eat nuts for breakfast, lunch, and dinner, well, then, that

would be a catastrophic diet, and they'd eat far too many calories. They would under-consume certain nutrients.

Just a thought on the why we're asking this question and what we hope to accomplish, I think, is something we need to explore to avoid maybe over-complicating this all.

MR. TUMA: I think that's a great point, which gets to the heart of some of the experiences that we've seen with prior labeling tools and consumers' responses to those labels.

Fundamentally, I think the question involves the use of the word natural. And one of the criticisms -- in fact, perhaps the fundamental criticism of that, we've been saying in lawsuits -- is that that term is, in fact, potentially misleading.

To the extent that FDA can regulate terms that must be truthful and not misleading, I think the question of what that term "natural" means is the way that that could be done, and the same way that healthy could be done.

I think you make great points about the way in which these foods can be incorporated into a whole diet, but may not be, in and of themselves, sufficient to be eaten just uniformly or by themselves.

I think that gets to the question of -- if you heard in the previous example, the previous panel -- what do consumers understand healthy to be? And I have not seen any research, and I think there were some allusions to maybe consumers expect a lot from what's included in the term healthy. But I've not seen any research that suggests that consumers think that the term healthy means what FDA says it means.

To that extent, maybe that's a fundamental problem with what this term means. If we're labeling something and people don't understand what it means, why are we doing it? If people are actually not just not understanding it but misunderstanding what it means, why are we doing it?

There's nutrition education that can be

done. Obviously, as I'm fond of saying, the single biggest problem with the Nutrition Labeling and Education Act is that there was never any real education or funding for education that went along with it. And there's a lack of nutrition education in schools, in curriculum, and we've really failed at that as a country.

I think that until Americans understand what it is that these claims mean, there is a lot of misuse and abuse of -- or misunderstanding, rather, of how they should approach understanding these terms.

DR. REIMERS: I would love to address your question a little more pragmatically on the 10 percent DV. I think that the premise, the philosophy, was an excellent one. But I think that now we can look at it in retrospect and say, what kinds of foods does it include and exclude? And that's almost more, to me, a driving force behind excluding nutrients, beneficial nutrients, than anything else.

Thinking about the small serving size of

fruits and vegetables, it's very hard to get 10 percent of the DV from a single serving. Likewise, with avocados and nuts, if we had vitamin E as a positive nutrient, then we could still keep that paradigm. But then you say, when do you stop, and do you make all of the nutrient, all of the beneficial nutrients, being the essential nutrients?

It to me becomes rather muddled. And going back to the -- if we do want to motivate, including those food groups that we think are, in fact, part of the healthy eating pattern, that relaxing that beneficial nutrient standard is helpful.

MS. SCHNEEMAN: Just to follow up on that, if you look at the way USDA has done their food pattern modeling, part of that food pattern modeling is to make sure that nutrient needs are met from food. So I agree with you.

We may not have the right nutrients. We may not have the right level. But I guess my career covers enough of a span of nutrition that I do remember the phase of worrying about making sure

nutrient needs were adequate, not just worried about the nutrients to limit in the diet.

MS. MOYER: I just wanted to clarify -- correct me if I'm wrong -- that the current definition does not require 10 percent DV for fruits and vegetables, a 10 percent DV requirement, because they're in a separate category of food. Because we do want to encourage all fruits and vegetables.

I think you raise an important point, that depending on how the other parameters of a healthy definition are defined, we may need to look at nutrient levels, the percent DVs, for example, to help us identify the best nutrient-dense foods within a category.

If you look at, again, to bring back to potato chips as an example, with the new DV being set up 4,700 milligrams, a serving of potato chips will not be a good source of potassium.

DR. BALENTINE: We have time for one last question.

MS. LEVY: I would just like to give my

perspective and healthy. I may have missed it.

I'm sorry. I'd just like to give my perspective on healthy. I may have missed it on the last session about the consumer's belief.

When I look at healthy, I view it from a faith perspective, involving foods that tell my blood glucose levels that you don't have to worry about me. I won't make you spike up or cause you to rise above your normal pressure.

I speak it this way because we are made with living organisms inside of us, and that they do a job. And when cells are well, invaders, they're nowhere to be found. On the other hand, when I look at cells are sick, invaders come out and attack those cells.

The other ones that are from the stresses in a form of a strange food nutrient, ingredient, that lacks nutrients, is what we're talking about. My health provider has always used the word "glycemic index," pertaining to my weight gain at the time, high blood pressure, and having type 2 diabetes at the time.

So after hearing the glycemic index often, I figured I was eating the wrong type of carbohydrates in my diet, high starchy foods like rice cake, French fries, French bread, white sandwich bread. I realized these foods were not in my best interest. So time after time, my health was declining, and I knew that I was not going to let it defeat me.

Glycemic index. So I decided I'd take a leap of faith and do some research on my own and what was the secret behind the glycemic index? That kept me in the red zone. Through the grace, I discovered I was eating more high-carbohydrate meals more than ever, more than the low ones, matter of fact, based on the numerical value of the carbohydrate.

I was consuming that left me broken inside, in other words, as a continued rising blood glucose levels. Now I've changed my eating habits, and my health is healthier because I eat faithfully from the glycemic index list of foods that has a nutritious criteria to them.

Even decades ago, researchers argued the fact that the food and health are interrelated of each other, but among its professional communities have seemed to be out of reach and have hidden behind a tightly locked door.

But I'm here to tell you that the door can be opened, allowing consumers to choose their own low, medium, or high-quality glycemic index value meals or that item in the grocery stores because it will serve the purpose of the health status and the lifestyle of those who are struggling with chronic disease like type 1, type 2, or high cholesterol, up and down weight control, and high blood pressure, as it did. And it's currently doing well for me.

That's all I wanted to say. Thank you.

DR. VALENTINE: Thank you for your comments.

Okay. One last one.

MS. RAINEY: Charlene Rainey. Adjusted, your KIND bars are using date paste. And I represent the California date growers, the California Date Commission. And California dates

are one of the foods that are in this predicament of having a very low serving size of only 40 grams, and having the low serving amount.

If we reduce it, we can't meet the 10 percent. But we're all nutrient-dense, where if you're putting some date paste in, the date paste is nutrient-dense.

So fruits and vegetables would not have to be exempt if it were nutrient density, and the serving size could be reduced if it were nutrient density because it's a percentage base. But that 10 percent criteria is based on the 200 calorie diet. So I just wanted to interject that nutrient density idea.

MR. MERVIS: Thanks for the comment. Just to clarify, I actually don't think we use date paste in any of our products. Date paste is a fine ingredient, but I just am not aware of a single KIND product that uses that ingredient. But in any event, thank you for the feedback.

DR. BALENTINE: Okay. Thank you all. I'd just like to -- as we go out to the breakout

sessions, where we're going to address in more detail, one of the things that I just picked up that I'd like people to reflect on is that as we move, we've talked about nutrient density and food groups and the 10 percent daily value.

So one of the questions I'd like people to explore is, if we have food groups and we don't have the traditional nutrients, and shortfall is the criteria, should those food groups have some sort of nutrient criteria put into them that would represent the nutrients that would be, for example, naturally associated with those food groups?

I think one of the things from the CSPI presentation that I'd bring up is you can see pastas that might have added vegetable powders, for example. So if you add them as a food group, should that vegetable material that's being added as the food group then provide some nutrient value that's associated with those vegetables?

So I'd like you to explore that as part of the breakout sessions.

Now I think, Kari, you're going to come back

and give the instructions on moving to the breakout sessions. Thank you.

MS. BARRETT: Great. Before I do that, I do want to give a round of applause for our last panel. That was very excellent.

(Applause.)

Introduction to Breakout Sessions

MS. BARRETT: Okay. As mentioned, we're now moving into the active participation phase of our public meeting. We do have three simultaneous breakout sessions scheduled for 11:15 to 12:30, and then those three sessions will be repeated after lunch from 2:00 to 3:15.

I believe when you all registered, you indicated which sessions you'd like to go to. Two of the sessions will provide an opportunity to discuss the term healthy generally, and in one session as a nutrient content claim, and in the other more as a food component claim.

In both, certainly other ideas and insights are welcome. Again, this is to bring out your creativity. Then in the third session, we'll come

back to the consumer meaning and understanding of the term healthy.

During the breakout sessions, we hope to generate good dialogue among the participants, and prompted by questions that we've shared advance to solicit your input, ideas, and comments.

I just want to pause. The breakout sessions are facilitated not by professional facilitators but by interested and enthusiastic FDA staff who are taking on this role today. So while we're in the breakouts, I would just ask for everyone's assistance in helping us make these go smoothly, to again be respectful of other people's ideas.

When you have a comment or something that you want to share, if you can keep that somewhat limited so we can get as many voices in the discussion as we can. So again, we're asking you to work with us as we go through this process.

Then for the logistics, just so that you know, for those who will be in the nutrient content claim discussion to start, it will be held in this room. And I would ask all of you, when the time

comes, to come over to your left and to sit in this section of the room so that we can continue to webcast.

The healthy food component-based claim discussion will be out the doors across the aisle, pretty much directly out across the way.

For those who are doing the consumer meeting, it's a little bit further on. You're going to go out the door left, and you're going to continue down the corridor, and the room will be on your right, and that is the Madison Room.

All the rooms are marked with signs. And again, I just want to remind people to refer to your agenda because as we adjourn, we are not going to come back as one large group until 3:15 this afternoon. So logistically, please stick with the agenda. There'll be plenty of time for the breakout sessions, plenty of time for lunch, and then after the second breakout, there is a break before we come back into the room.

In regards again to the questions that the breakouts will start with as part of the

discussion, you should have a copy of those in your folder. For our webcast audience, they are posted on the meeting site for today.

I think, with that, we're ready to adjourn and begin the breakouts. Thank you.

(Whereupon, the public meeting adjourned to breakout sessions.)

Report Out on Breakout Sessions

MS. BARRETT: All right. Thanks, everyone. You were a nice and prompt audience, and I appreciate that. I'm hoping folks have gotten a second wind. I know that right after lunch, there was a bit of a lull, so here we are in midafternoon. So if you need to stretch, feel free to do that. But we do have certainly more content to cover this afternoon, and we want to jump right into that.

The first thing we're going to do is give you a report-out from the breakout sessions. I know not everyone could be in every session, so we did want to give you some immediate feedback about some of the larger themes and comments that we

heard in each session. And to do that, we've invited our lead facilitators up to the stage, and they'll each speak on their different breakout sessions.

So with that, we'll start with Vincent de Jesus, who's a nutritionist, Office of Nutrition and Food Labeling, FDA's Center for Food Safety and Applied Nutrition. And Vincent will speak on "Healthy as a Nutrient-Based Claim." And let me go ahead and introduce the other two facilitation leads.

Vincent will hand off to Claudine Kavanaugh, who is our senior advisor, nutrition policy, the FDA Office of Foods and Veterinary Medicine. And Claudine will speak on "Healthy as Food Component-Based Claim."

Then following Claudine will be Robin McKinnon, who is our senior advisor for nutrition policy, FDA's Center for Food Safety and Applied Nutrition. And Robin will cover "Consumer Meaning and Understanding of the Term 'Healthy.'"

So with that, Vinnie?

MR. DE JESUS: Good afternoon. Our breakout session was based on healthy as a nutrient content claim with nutrient criteria. To that end, we had a number of different questions that were handed out earlier this morning in your packets, and we tried to go through all those issues and tried to address all of them.

Some of the high points that we talked about today, some of the general themes that we heard in both sessions, about should we be updating of modernizing this nutrient content claim? And I think it was unanimous for both sessions. Everybody said yes, this needs to be updated.

Second to that, we asked the question of, should it be solely nutrient criteria-based? Meaning just like the current definition, should the criteria for healthy just be nutrient content? And that was a pretty much unanimous no.

What it looks like is people favored a little bit of a mix of the current nutrient content, with incorporating some other features such as food groups and food categories that they

heard about in the other sessions. So the combined approach was really the approach that most were in agreement with.

There were a few comments that -- well, maybe having the healthy claim was not the best thing for consumers, and it should be eliminated in favor of different nutrient content claims more specific to individual nutrients. So we definitely did have a couple of those comments as well.

One of the last points was, people wanted to think about what was the overall objective for the claim healthy? What is consideration of the foods that would bear the claim healthy in considering what foods and food groups might be included, eligible to bear a healthy claim?

A couple comments involving process was that they wanted us to make sure that we aligned with any other policies and regulations that would be coming out of other agencies, such as USDA, that are also involved in food labeling.

There was also some general discussion before, talking about the individual nutrients, of

what is the general goal that we want to address, that we'd like to meet in order to better define which nutrients we should be looking at?

In looking at the nutrients that should be included in the definition for healthy, even in a mixed combination model-type system for healthy, there are still some points that they want to consider for the general nutrient criteria.

Nutrient criteria is important because there are still some nutrients that are under-consumed by the American public. And because this information needs to get communicated to consumers, it should still be included in the definition for healthy.

For food groups, not all food products within a food category are considered equal. So if you just use a solely food group-based criteria, you would be putting all products in one category on an equal playing field. And some comments were that maybe some products within a category are a little bit different, have different, a little bit, nutrient profiles, and maybe incorporating nutrient criteria is a better way to differentiate.

There was a lot of discussion about the nutrients themselves, and a lot of people thought that there should be a broader set of nutrients that are included in any definition for healthy. All the nutrients that have a daily value was considered. If it's in the nutrition facts, then it should be included in the definition for healthy.

With that, there was some discussion that the 10 percent daily value level for beneficial nutrients was a little bit too restrictive, and maybe that could get changed.

Ways that other nutrients could get included that maybe weren't in the nutrition facts, they thought that if you can demonstrate a health benefit for this particular substance, then maybe that can get included as a criteria, too.

For example, if there was an FDA-approved health claim about a substance, maybe that could be used as one of the nutrient criteria. Down here you see some examples like calcium, potassium, fiber, bio-actives, things that were brought up as

possible nutrients. Let me speed through a little of these.

Looking at nutrients that would be disqualifying-type nutrients, there was some discussion that there were some nutrients that if there was any of that nutrient at all in a food, then it would not be eligible to bear a healthy claim. If there was any added sugars, for example, then that food would not bear a healthy claim.

Alternatively, there was discussion more of, well, just not get too much of particular nutrients. Set threshold levels for sodium, added sugars, things like that, saturated fat. And one of the discussions about the disqualifying nutrients was, take a look again at serving sizes and see how that affects the disqualifying nutrients because things like the 50-gram rule for small RACCs can affect eligibility for a claim like healthy.

There were mixed views on fortification. Some people mentioned that manufacturers' products couldn't fortify their way to a healthy claim. But

by and large, fortification for foods that bear a healthy claim was thought to be okay, especially for examples of things like vitamin D, where vitamin D is fortified in milk products and things like that that could be healthy. So there's a need to look at the specific nutrients and the product.

Nutrient density, we introduced that concept, and it is a little bit of a challenging concept. The definition that was provided from the dietary guidelines, a lot of people were in agreement that that would be an appropriate nutrient density definition. There was some discussion of how you would define nutrient density, and even if it was an option for being included in healthy. So that was a little bit of a complicated one.

Regarding criteria for different categories, there was some discussion of should there be different sets of criteria for different food categories, fresh produce, for example, versus processed foods; foods directed toward different populations, like young children and infants, or

different groups. In those cases, there were a lot of comments that maybe there should be specific criteria directed toward those sets of categories as long as the criteria is still aligned with our current dietary guidelines.

As I mentioned, the combined approach was an approach that, even though we were focusing on nutrient criteria, everyone was in agreement that this was a more appropriate approach. So everything that we talked about with nutrient criteria was spoken about in the context of possible food group criteria being incorporated. And I think those were the top line points for that session.

I'll turn it over to Claudine now, and she'll talk about the food group session.

DR. KAVANAUGH: Great. Thanks, Vinnie.

So you'll notice we definitely had a lot of overlap in the healthy as a nutrient-based claim and healthy as a food group claim. So I'm not going to go over a lot of the points that Vinnie already covered, but a lot of them were covered in

our section. So I'm just going to give you, really, a high-level overview.

Some of the key themes were very similar, definitely consistency with the Dietary Guidelines for Americans. Again, looking at shortfall nutrients, the group really seemed to think that we needed to consider shortfall nutrients and incorporate that, what's identified in the dietary guidelines, in what our definition of healthy is.

They also recommended having the intakes of -- dietary guidelines are normally -- they're more food-based now, and so the recommendations are more on foods, and the recommendations are not the same as what our serving sizes are on nutrition facts labels.

They definitely said we need to work on that. And there was definitely some concern for the serving sizes for some of our foods, like a bagel, which may have whole grains, and a slice of bread are very different. So you need to consider that as you recommend, if you looked at whole grains in a healthy definition.

Another thing that came up is how to keep the healthy definition in context with the changing science as well as science progresses.

We definitely, our group, had the food-based definition versus nutrient approach, and definitely we hit upon the hybrid approach. It probably had to be a combination of foods as well as nutrients. I think it was challenged to have a single criteria for just one food. There didn't seem to be a one-size-fits-all criteria.

They also thought fortification -- I know Vinnie hit upon this, that for fortification, a lot of the group thought that was okay, and particularly for nutrients that are identified as shortfall nutrients.

We think balancing whole foods and complex foods was one that was another common theme. People thought that if you added, say, strawberries to a food, it needed to still be a strawberry, and when did it not become a strawberry any more. In the afternoon session, we used carrots as the example in that. So I think there was definite

thinking into when it's contributing a fruit or vegetable and then when it's processed so much that maybe it's not that fruit or vegetable.

We also had some discussion about adding sugars or fats or sodium or salt to different foods that maybe would make them more palatable and increase the consumption of some foods, like nuts or some fruits and vegetables. So that was something that the group said to consider.

We also thought consistent messaging and education came up a lot. And I think that's true with the label in general. There's always an education component. So no matter if you have the nutrition facts label information on the label or you have different health claims, specifically healthy, there seems to be the need for an educational component because the label can't be the end-all of everything. So that came out in both sessions quite a bit.

I'm going to hand it off to Dr. Robin McKinnon now, who's going to go over the consumer meaning and understanding.

DR. MCKINNON: Thanks, Claudine.

I'll be presenting the results of the discussion this morning and this afternoon on the consumer meaning and understanding of the use of the term healthy. And we also -- I can see common themes throughout the session that we've discovered also, was also a common theme in our session.

Our first question that we considered was, what is the consumer's understanding of the term healthy? And one very strong theme is that there's a very wide range, that people's perceptions of what healthy means vary extremely widely.

They come from very different places in terms of health literacy, education, other influences. And then there are many different interpretations, and maybe even due to generational differences. We heard a lot about how millennials and Gen Xs and Ys perceive this term in a different way to older consumers, but also by differing levels of education and socioeconomic status.

But overall, the point was made that the term healthy was perceived fairly positively by

consumers. Others noted the rise in the use and seemingly the impact of absence claims, like GMO-free or gluten-free, and also noted that the term organic also, for many consumers, was almost -- conveyed healthy, conveyed healthfulness in a different way. I think somebody described it as being super-healthy. If a product was organic, it was therefore super-healthy.

But people vary in how much information they seek or use. If they decide a product is -- they want to use that product and whether that's healthful for them, some people want a lot of information.

They want all of the information. They want to go to websites beyond what's on the label sometimes. And others want to almost outsource all of that effort and work, and they want something. They want a heuristic device or a term like healthy.

People don't necessarily think in terms of absolute terms of whether a product is healthy or not. They often think in terms of, within a

product category or a food group, whether that is healthy comparatively within a particular health group.

There may be other connotations as well of the term healthy, which was interesting that came up, that people might think of healthy as being less tasty or possibly being higher cost, and therefore might attract different customers.

There was also the thought that was brought up that healthy is, in fact, much broader than just healthy on a food label, that people use the term healthy in a much broader context in terms of healthy lifestyles.

For the second question, would changing the definition of healthy affect consumer behavior and public health, the number of key points that are summarized here. Firstly, healthfulness is only one factor that impacts consumer choices. People noted that purchasing often is much more informed by price and also taste. So healthy is important, but it's one of a mix of inputs for consumers.

It's possible that healthy on a label

may promote reformulation, and that was seen as a positive thing by some of the attendees. At the same time, it might be confusing or carry less meaning and be crowded out by some of the other terms that are on the label.

Certainly changing the term is only part of affecting or changing consumer behavior, as we saw before. Education is also key. That was a constant theme throughout the session, the importance of education.

Because the understanding of the term is so varied among consumers, we should consider not allowing a healthy claim at all. And this is something we heard in the panel session this morning as well.

Others noted then if we went down that road, it may be possible that food manufacturers may then increase their use of other similar-sounding terms that convey healthy in a different way like "wholesome" or "fit" or "smart" or some of those things.

Then the third question, how does healthy

labeling of products affect consuming a healthy dietary pattern? So this is healthy on a food product, but affecting overall dietary pattern.

Thoughts were amongst the participants that products that were labeled healthy need to contribute to a healthy dietary pattern, and for us to consider combining a healthy claim with the MyPlate icon from USDA, which may also, in fact, help with some literacy issues for some consumers.

Other people added that healthy should be allowed on fruits and vegetables and produce or other whole foods. One person noted that starting slow on this process would be important, that we should start slowly, include whole foods, and then add to what might be allowed to bear the claim healthy, and allow that to evolve over time as the science continues to emerge.

At the same time, interestingly, others noted that consumers are impatient, so that if we were to define healthy and people saw that in headlines because people get information from a number of different sources, they might expect the

next day to be seeing healthy on products in their grocery store. But if we're starting slow and adding, that we need to balance that with the considerations that people might expect to see that almost immediately in their stores.

Another thought, another theme, was that a healthy claim may convey that the product contains everything you need in a healthy diet, and so that might skew dietary behavior in terms of people pursuing certain dietary trends, or possibly may lead to over-consumption of calories. And related to this, having the use of healthy on a specific food may, in fact, detract from understanding of an overall healthy dietary pattern.

As people noted, just because a food is healthy doesn't mean you can eat as much of it as you want, which gets to that question of calories. If it's automatically healthy, certainly that does not mean that it's calorie-free.

That's what we had. I'd like to thank all of the people who participated in all of the sessions. It was very informative.

(Applause.)

Open Public Comment/Q&A

MS. BARRETT: All right. I want to again thank our lead facilitators. Nicely done. And as I mentioned earlier, we will have a fuller summary of the breakout sessions that we will put on our website once we have a chance to compile that.

So at this time we're going to switch over in the agenda. We're going to go to our open public comment period. And then following that, we'll have a general Q&A. So I'd like to invite the rest of the FDA panel up to the stage who will be listening to the public comment.

(Pause.)

MS. BARRETT: Okay. So let me just introduce the additions to our panel. Some we had introduced earlier this morning. But again, Susan Mayne, director, FDA Center for Food Safety and Applied Nutrition. Down second from the end is Doug Balentine, our director, Office of Nutrition and Food Labeling, CFSAN.

We also have Conrad Choiniere, who is our

director, Office of Analytics Outreach at CFSAN, down at the very end. And Jill Kevala, who's our supervisory chemist, Office of Nutrition and Food Labeling.

Okay. I've got my order incorrect. Hopefully, you can see their names on the table as well. So sorry, Jill, you were a little hidden between Doug and Conrad there at the end.

We do have a number of folks who have signed up to offer public comment. And so I just want to walk you through that process, and then we'll begin.

For anyone who is offering public comment, if you hopefully are somewhere near an end of a row so it's easy for you to come up to the microphone when I call your name, and maybe even anticipate if you know that -- again, you can see where the microphones are. So that will just be helpful.

I will call each individual up by name, and they will have up to four minutes to present their remarks. And again, I just want to emphasize, when you do come up to the microphone, if you will

repeat your name and your affiliation for the transcriber, that would be appreciated before you give your remarks.

The FDA panel will be listening to remarks, and then I will look occasionally over to see if they have any questions for the panelists.

Typically, there's not a lot of questioning of panelists; it's really not meant to be a back-and-forth. But if there is a need to ask a clarifying question, I just want the panelists to know that, please, that opportunity is there, if that's helpful.

Then at the conclusion of the public comment process, as mentioned, we will open up the floor to general Q&A or observation or other comment that people may have. So with that, we'll begin our process.

Our first person, individual coming to give public comment, is Samantha Watters, National Center for Health Research. And Samantha, I'm sorry if I did not pronounce your last name correctly. I'm going to grab my glasses right now.

Thank you.

MS. WATTERS: That was perfect.

Hi. Thank you so much for the opportunity to speak today. As she mentioned, my name is Samantha Watters. I'm with the National Center for Health Research. I'm their director of communications and outreach.

Our center conducts and scrutinizes medical research to determine what's known and not known about specific treatment and prevention strategies, as well as general health research. We then translate that complicated information into plain language so that patients, consumers, media, and policy-makers will also understand it.

It's challenging work, but obviously incredibly important, given the varying levels of health and scientific literacy across the general population and even in policy as well.

The challenge becomes exceedingly more difficult when we start using a word like "healthy." We know that all studies are not created equal, all scientific studies, and all

health claims are certainly not all backed by solid scientific evidence and can be misleading, as we've already discussed.

Allowing industry to deem a particular food healthy based on a limited set of criteria adds to that confusion. For example, claiming something is healthy based on a certain nutrient like fat content, or a vitamin breakdown, can be misleading as there are many foods that might be low in fat or high in processed or added sugars, things that we've brought up earlier today.

We don't want something to be labeled healthy just because it's low in fat and pumped full of vitamins. You can do that with a lot of different foods, and it might still contain many ingredients that are known to be unhealthy in some way.

We know that the term healthy is a powerful marketing tool, as we've talked about, and that can make it dangerous.

I know that FDA guidances in the past have recommended use of the term healthy with qualifying

statements explaining a distinction, for example, healthy contains 3 grams of fat. All nutrient contents used to substantiate the healthy claim would then need to be clearly defined on the nutrition label. But in practice, this is also confusing. The word healthy is going to jump out at people, but reading nutrition labels isn't necessarily a skill that everyone possesses.

Most people who look at the food labels, as we discussed, when health claims are made are not likely to even look at the food labels, let alone have the health literacy to actually analyze them in a way that would allow them to make an informed decision about the actual health of the particular product. Many people also have limited reading skills, which is why it's so important to communicate that kind of risk information or benefit information at such a low literacy level.

The FDA in general has not done the best job at following this health literacy standard, in our opinion. But industry knows how to talk to consumers well so they will listen. If allowed to

make health claims, companies can communicate the information they want to well with their marketing and downplay nutritional information that they don't necessarily want highlighted.

We feel that the FDA needs to try to do a better job in preventing misleading information and inadequate explanations of risk and benefit in all forms of direct-to-consumer ads, whether the information is about a drug or a food.

It's not necessarily good enough to require nutritional content on a label. We feel it's essential to clearly explain why and how the product is or is not healthy. For example, the FTC requires information in ads to be understandable, not just accurate.

People need to be better informed on how to make healthy eating choices, and that's part of the FDA's responsibility, not only to make the most accurate and up-to-date evidence readily available and easily to understand, which again is something that we try to help do at our center, but also to prevent misleading statements and strive for a more

unified message.

Thank you so much for letting me share.

MS. BARRETT: Thank you very much for your comments.

Marsha, we are going to go to you. But then after Marsha will be Laurie Tansman. So I just wanted to let you know we did have a change in the order. But Marsha Echols?

MS. ECHOLS: Thank you and good afternoon. My name is Marsha Echols. I represent the Specialty Food Association here in Washington, D.C.

The Specialty Food Association is a nonprofit trade association headquartered in New York City. It represents the interests of its 3600 members, who are located throughout the United States. They are the manufacturers, retailers, distributors, brokers, importers, and others who make up the specialty food trade. Those are high-value processed foods.

Many of those foods are part of a healthy diet or are ingredients that are now considered essential to a healthy diet and life. The majority

of the companies involved in the specialty food trade are small or even very small businesses.

The SFA welcomes this opportunity to comment about the meaning and use of healthy, and we'll submit more comments before April. Its position has been initially determined, but certainly there will be details later.

Along with natural, organic, GMO-related labels and local, healthy is one of the words or claims of most interest to today's consumers. So depending on how the word is defined and used, healthy might be the most complex of these popular terms.

With that in mind, SFA hopes that FDA, in defining healthy, will remember that small businesses need to implement the definition, especially if you have a hybrid or a mixed definition combining food and nutrients.

That can become harder with regard to food formulations, more difficult, especially for small companies that often are creating new, novel products. So what will be required for them in

order to use the word healthy or the claim healthy, which is a very good business proposition as well as a nutrition proposition.

The Specialty Food Association favors using healthy in a food and lifestyle context rather than a nutrient-focused context. The word could be a type of dietary guidance about healthy eating patterns and situations rather than only a technical claim, depending on how it is used, the context for it on a food label.

We think that in the minds of U.S. consumers, healthy as it relates to food is more than a statement about nutrient content. What we eat and how we eat and our lifestyle influence whether a food is healthy for a group or even an individual.

This contrasts with the current nutrient focus at FDA, which is reflected in the revised nutrition facts panel and in the guidance about the use of a healthy claim on a food label.

The food, and to some extent lifestyle, approach to healthy foods has been recognized in

the 2015 Dietary Guidelines for Americans, as many people have mentioned today. Those recommended diets have increased amounts of nuts, whole grains, legumes, seeds, fruits, vegetables, and nutrient-dense foods and seafood. All of these foods figure prominently among specialty foods or foods that are produced by members of the Specialty Food Association. They use them in finished products and also as ingredients in the foods.

One of the points that we haven't heard mentioned today is putting the whole definition of healthy and its use in an international or global context, as we are involved more and more with international trade in foods.

Some other countries are shifting to this food-based approach, including in their food or dietary guidelines. You might know that Brazil clearly follows this approach with its food-based dietary guidelines.

Among its 10 recommended steps to healthy diets are that we make natural or minimally processed foods the basis of our diet. That's the

first of their 10. And they recommend that we eat regularly and carefully in appropriate environments, and whenever possible, in company. That's their fifth point. So it is a very different, more holistic approach to what is healthy and one that we think that FDA should bear in mind.

Again, with this possibility of a mixed or hybrid approach, we hope that you will remember the small food companies trying to create novel foods' lead in food manufacturing, and making it possible for them to meet a healthy claim or use the healthy claim without too much cost or expense or added administrative complexity.

Thank you for this opportunity to comment. The Specialty Food Association of course will respond to your questions. We will provide additional information in April. Thank you very much.

MS. BARRETT: Thank you.

Okay. Our next individual coming up is Laurie Tansman. Laurie? Thank you.

MS. TANSMAN: It's nice that there's no red or green lights when I usually talk at the drug hearings, so this is nice.

My name is Laurie Tansman. I am affiliated with the Mount Sinai Hospital and the Icahn School of Medicine at Mount Sinai in New York. But I am speaking on behalf of myself only.

My comments today pertain to the appearance of healthy on the food label rather than how it's defined. And while I'm not opposed to the FDA's move to redefine healthy in the labeling of human food products that will align with the updated nutrition facts label, I want to take this opportunity to recommend what you need to do and for which a public hearing is indicated as it relates to claims being made on food labels.

An expression that I sometimes use and which Marion Nestle, a colleague, was recently quoted using, "You need to pick and choose your battles." The updated nutrition facts label is one of those battles that needed to be waged.

Likewise, the recommendations for sodium

reduction in processed foods is a battle that you should have waged, too, as I do believe it should be mandatory, and there should have been a public hearing for the most recent proposed recommendations.

Moving on to healthy, regardless of how you define the term healthy, I don't think it's going to make a big difference in whether a consumer chooses a particular product or not. Why? Because food companies have gotten out of control when it comes to what they put on food labels to ensure their product is purchased. If the term healthy is going to stand out and have value, then you need to clean up what is currently permitted on food labels.

The biggest food label buzzword of the past few years has been the appearance of gluten-free. I am confident that it is not being done to help those with celiac disease or non-celiac gluten sensitivity. Rather, it's to sell the product because gluten-free has come to imply that a food is healthy. I mean, really. I have my friend here

to show and tell, my show and tell.

I mean, really, just how absurd is it to have gluten-free appearing on this carton of eggs? And what about this package of raw apple slices that has on it, "No added sugar and gluten-free" on the label?

Better yet, how absurd is the unbelievable amount of health-related info that appears on the side of this package of candy, including, "Good food, good life," and that the term "the good stuff" appears further down with the gluten-free claim? This food manufacturer is practically promoting this as their healthy indulgent treat. After all, it can't be unhealthy if it's gluten-free. Right?

If you really want gluten to mean something, then you need to be aggressive in cleaning up what may appear on food labels. And I have no doubt that the FDA would be entangled in quite an uproar with the food industry, but I think this is an important battle to be waged, as consumers are confused by all the info that appears on food

labels.

Again, it's not that I'm against the term healthy, but even if you redefine it, I don't think it's going to have an impact on the consumer any more than other marketing terms. And so, in cleaning up what may appear on food labels, I have another suggestion.

Forget about the term healthy. Why not let the food manufacturer only be permitted to use the "Choose MyPlate" icon on the food package if the product complies with the FDA, how the FDA eventually defines as healthy?

Depending on the food group that the food belongs to, that part of the plate should be highlighted in a particular color while the rest of the plate is black and white. I think that using this icon, especially on processed and minimally processed foods, may be quite a successful strategy that may also cross the literacy barrier.

If you partner with the USDA, you may come up with a great way to help the consumer make the best possible choices in guiding that consumer to

improve the quality of their diet, which is your goal and pertaining to the term healthy on the label.

Finally, since it happens that I have given gluten-free as an example of a buzzword used to market many foods, let me state that the food industry needs to stop making such a mockery over what's important for many to avoid.

Rather, if the FDA is able to do so, I recommend the term "This product contains gluten" or "This product was made on equipment that was used to prepare gluten-containing products" appear on the package where allergy info also appears, and not gluten-free on the front of the package unless the products, such as bread, cereals, crackers, and pasta, for example, are specifically formulated for those who need to avoid gluten. Thank you.

MS. BARRETT: Thank you very much.

We will go back to our original order now. So if Catherine Williamson could come up to the microphone, Virginia Department of Health. Catherine?

(No response.)

MS. BARRETT: Okay. I'm going to move on, then. Albert Lear, International Bottled Water Association?

MR. LEAR: Good afternoon. My name is Al Lear, and I am the director of science and research at the International Bottled Water Association. IBWA was founded in 1958, and our member companies include U.S. and international bottlers, distributors, and suppliers.

The majority of our members are small, locally owned companies. IBWA represents all segments of the bottled water industry, including spring, sparkling, mineral, artesian, and purified water products. We appreciate the opportunity to present oral comments and to have a public dialogue on the meaning of healthy, which is an issue important to both our members and our consumers.

IBWA strongly supports FDA's actions to revisit and update the healthy definition for use in labeling. The term healthy, by its current FDA definition, describes a product that, because of

its nutrient content, may help consumers maintain healthy dietary practices.

Bottled water does just that. If the touchstone for healthy is healthy dietary practices, IBWA believes that the Dietary Guidelines for Americans is the best tool to inform FDA's criteria for a healthy claim.

The dietary guidelines and other government guidelines consistently recommend consumption of water as part of a healthy dietary pattern. The 2015 dietary guidelines state that beverages that are calorie-free, especially water, should be among the primary beverages consumed.

Not only is drinking water strongly encouraged, but public health recommendations widely recognize that water is a preferred source of hydration and contributes to good health. Scientific research shows that drinking water positively influences a number of healthy bodily functions and organs, such as the kidneys.

Water is also a healthy alternative to sugar-sweetened beverages, and its consumption is

encouraged to help prevent obesity. In fact, water is poised to surpass carbonated soda as the number one packed beverage product in the U.S. by volume.

In recognition of the important role that water plays in a healthy diet and to help consumers shape the healthy dietary practices, IBWA believes bottled water should be eligible for a healthy claim. Currently, bottled water does not qualify as healthy under existing regulations because it does not contain sufficient levels of beneficial nutrients like calcium or iron.

FDA has nevertheless recognized that narrow exemptions to the beneficial nutrients criterion are justified where dietary recommendations encourage consumption of the food, and such consumption has been associated with health benefits.

For example, the current regulation exempts raw fruits and vegetables from the beneficial nutrients criterion. FDA recognized that fruits and vegetables, like celery and cucumbers, do not contain 10 percent of the daily value of one of the

nutrients of public health significance, but should still be eligible for a healthy claim because increased consumption of these foods can contribute significantly to a healthy diet.

Bottled water should be eligible for the same exemption. Indeed, water is associated with significant health benefits and is consistently recommended in dietary guidance. Moreover, the fruit and vegetable examples cited by FDA contain mostly water.

For example, cucumbers contain 96 percent water. It would be inconsistent to allow cucumber to bear a healthy claim but not allow water, a cucumber's main component, to do so when the nutritional profile of the two products is so similar.

We therefore request a narrow exemption from the beneficial nutrients criterion for bottled water in recognition of its role in a healthy dietary pattern. Thank you for your consideration. IBWA also plans to submit written comments to the docket.

MS. BARRETT: Thank you.

Our next individual giving public comment is Sarah Reinhardt, Union of Concerned Scientists.

MS. REINHARDT: Good afternoon. My name is Sarah Reinhardt. I'm a registered dietitian with the Union of Concerned Scientists in Washington, D.C., and I'm pleased to present this comment on their behalf.

The 2015-2020 Dietary Guidelines for Americans emphasized the importance of choosing a variety of minimally processed, nutrient-dense foods as part of a healthy eating pattern. The definition of nutrient-dense foods provided by the guidelines reflects current scientific evidence on the health benefits associated with consumption of foods from key food groups, as well as the chronic disease risks associated with consumption of target nutrients.

This definition provides the basis for our recommendations on the use of the term healthy in the labeling of human food. UCS proposes the following modifications to the criteria required to

bear the healthy label.

First, the term healthy should be characterized on the basis of foods, not just nutrients. Health-promoting foods are those recommended by the dietary guidelines as part of a healthy diet, and they include vegetables, fruits, whole grains, seafood, eggs, beans and peas, nuts and seeds, dairy products, and meats and poultry.

Food from one or more of the aforementioned groups should constitute a substantial proportion of a food item to meet standards for use of the term healthy. Some foods may be subject to exception from general healthy labels due to evidence of health risks associated with excess intake, including fruit juices, processed meat, and red meat.

Second, conditions related to total fat, cholesterol, added sugar, and sodium should be evaluated with respect to current scientific evidence. Conditions on total fat content should be revised to provide exception to health-promoting foods with favorable total fat distributions of

predominately mono- and/or polyunsaturated fats.

This reflects current scientific evidence on the health benefits of replacing saturated fats with unsaturated fats, including reduced blood levels of total cholesterol, reduced low density lipoprotein cholesterol, and reduced risk of cardiovascular events and related deaths.

In light of the advancements in the understanding of the role of dietary cholesterol in chronic disease risk, conditions related to cholesterol should be removed. This is consistent with the 2015-2020 dietary guidelines and reflects current nutritional science.

It is critical that updated criteria establish limits on added sugar. Research shows that over 70 percent of the population consumes this nutrient in excess, increasing the risk of obesity, type 2 diabetes, and some types of cancer in adults. Limits should be established to help Americans limit added sugar intake to less than 10 percent of daily calorie intake, as recommended by the dietary guidelines.

Lastly, allowable sodium levels should be further reduced to help protect against chronic disease. Americans consume approximately 3,440 milligrams of sodium per day, 75 percent of which comes from processed foods. Foods labeled as healthy should contain levels of sodium that will help meet daily sodium recommendations of 2,300 milligrams and reduce the risk of high blood pressure, heart disease, and stroke.

In conclusion, it is the recommendation of UCS that the conditions required for food items to bear the healthy label should closely align with the definition of nutrient-dense foods provided by the 2015-2020 dietary guidelines.

Restructuring these criteria in a way that promotes healthy foods and restricts target nutrients will result in an established definition of healthy that provides clear and consistent messaging to consumers and follows evidence-based recommendations to reduce the population risk of diet-related chronic disease. Thank you.

MS. BARRETT: Thank you.

Our next speaker, Sarah Roller?

MS. ROLLER: Good afternoon. My name is Sarah Roller. I'm a partner in the law firm of Kelley, Drye and Warren, and I chair the firm's food and drug practice. My remarks today are made on behalf of the California Walnut Commission, and we appreciate this opportunity to participate in the meeting.

The California walnut industry is made up of more than 4500 walnut growers and over 90 processors. The commission was established in 1987 under California law and is funded by mandatory assessments of California walnut growers.

From the beginning, the commission has been firmly committed to both advancing scientific research concerning the diet and health benefits of walnuts and also to ensuring that the public has access to accurate, well-substantiated information about the benefits of walnuts.

The commission applauds FDA's current initiative to update the regulations governing the implied nutrient content claim healthy, and

believes that significant changes are vital for healthy claims to serve the policy objectives that FDA originally intended.

Specifically, as FDA explained in the original rulemaking record, the healthy claim was intended to assist consumers in selecting foods that are helpful in achieving a total diet that is consistent with current dietary recommendations, and to have confidence that the foods that bear this term will in fact be useful.

Unfortunately, the existing healthy regulation restricts the claim to foods that are low in fat, low in saturated fat, plus a good source of an essential nutrient that is deemed to be significant. And these nutrient criteria stand in the way of healthy claims for walnuts and many other nuts.

In this regard, the existing regulations are at odds with the current Dietary Guidelines for Americans and the current body of relevant scientific evidence. The current dietary guidelines explicitly encourage Americans to

consume nuts as an important source of protein and other essential nutrients as part of a plant-rich, nutrient-dense diet.

The guidelines also encourage increased consumption of poly- and monounsaturated fatty acids, which are concentrated in nuts, to help achieve a healthy balance of fatty acids in the diet.

FDA'S qualified health claims concerning walnuts and other nuts and the reduced risk of heart disease already recognize the contribution nuts make toward achieving a total diet that is nutrient-rich with a healthy balance of fatty acids. In clearing these claims, FDA relied on its enforcement discretion for saturated fat and other disqualifying nutrient levels.

The commission believes that healthy claims for walnuts and other nuts are claims that are accurate, well-substantiated, and consistent with FDA's original purposes for the healthy claim. The commission also believes that the time has come for the FDA to authorize healthy claims for walnuts and

all other nuts as whole foods on a category basis.

The commission also believes that current FDA regulations have an ongoing chilling effect on the use of accurate, well-substantiated healthy claims for walnuts and other nuts, and this raises serious First Amendment concerns.

For this reason, FDA should immediately extend its policy to exercise enforcement discretion to cover healthy claims for all nuts, including, in particular, nuts that are covered by the qualified health claims.

FDA should also use expedited rulemaking procedures to promptly authorize healthy claims for walnuts and other nuts as a category under Section 101.65(d) of FDA regulations.

The commission will be submitting more detailed written comments for the record. Thank you very much.

MS. BARRETT: Thank you for your comments.

Our next speaker, Randall Popelka?

MR. POPELKA: Good afternoon. My name is Randall Popelka. I'm with Herbalife Nutrition. We

appreciate the opportunity to provide our comments today regarding defining the term healthy.

Founded in 1980, Herbalife is a global nutrition company with over 8,000 employees and a presence in over 90 countries. Our nutrition philosophy is based on three key pillars: balanced nutrition, a healthy, active lifestyle, and social support to facilitate healthy behavior change. Our nutrition philosophy is grounded in a personalized and customized approach. We don't believe a one-size-fits-all approach works any more.

We would like to commend the agency for initiating the public process to redefine the term healthy and the timeliness of this exercise, for two major reasons.

First, accurate and meaningful labeling of food products is essential for consumers to make informed choices. In the 2014 FDA Health and Diet Survey conducted by the Center for Food Safety and Applied Nutrition, almost 9 out of 10 U.S. adults reported relying on nutrient content claims such as low in sodium and rich in antioxidants when

purchasing food products.

Secondly, the scope of nutrition science has widened to include the overall nutrition quality of dietary patterns, lifestyle, and behavior.

Nutrition policy and regulations now must evolve beyond the reductionist approach of focusing on single isolated nutrients. We urge the FDA to take great care in defining the term healthy to ensure that current science drives the evolution of this important and influential regulation.

As stated in the 2015 Dietary Guidelines for Americans, we agree that focusing on a variety of nutrient-dense foods within calorie limits contributes to healthy eating patterns more than focusing on a few nutrients. We believe that nutrient-dense foods such as those listed in the guidelines can be considered healthy when prepared with little or no added solid fats, sugar, refined starches, and sodium.

It is important to also note that even foods that are not explicitly listed in the guidelines as being nutrient-dense can contribute to a healthy

eating pattern and therefore can be claimed as healthy.

We propose using techniques such as nutrient profiling, which rates the overall nutrient density of foods. For instance, using the nutrient-rich foods model, the NRF model, which calculates nutrient density determined by the balance between beneficial nutrients and nutrients to limit, one can calculate the content of key nutrients per serving.

If such a nutrient profiling model is established with proper guardrails, the agency can ensure that foods bearing the term healthy based on nutrient density can contribute to a healthy eating pattern.

We also propose that food manufacturers or brand owners include a mandatory dietary guidance statement whenever the claim healthy is used on product labels. Adding such a dietary guideline statement provides context and can inform consumers about the importance of a healthy eating pattern. This could also guard against consumers choosing

and over-consuming a single food item, and we give an example of what we would suggest as a statement in our written testimony, our written comments.

Once again, Herbalife believes that redefining the term healthy in the labeling of food products is critical for consumers, and we pleased to have had the opportunity to provide our comments. Thank you so much.

MS. BARRETT: Thank you for your comment.

We'll move on to Julie Levy or Levy.

MS. LEVY: Good afternoon, everyone. This healthy piece is a summary coming from Jenni Brand Miller and others, PhD, from "The New Glucose Revolution," a permanent weight loss book, solution. Okay.

"Nutritionists have had to rethink and fine-tune the health message, the natural of carbohydrates. The glycemic index, surprisingly, scientists did not study the actual blood glucose response to common foods until the early 1980s. Prior to that, they tested solutions of pure sugars and raw starches and had drawn conclusions that did

not apply to real foods and real meals.

"Since 1981, hundreds of different foods have been tested as single foods and in mixed meals with both healthy people and people with diabetes. Professor David Jenkins and Tom Wolever at the University of Toronto were the first to introduce the term 'glycemic index' to compare the ability of different carbohydrates to raise blood glucose levels.

"The glycemic index is simply a numerical way of describing how the carbohydrates in individual food affect blood glucose levels, while food with low glycemic index value contain carbohydrates with much less impact. Therefore, the glycemic index describes the type of carbohydrate in foods. It indicates the ability to raise your blood glucose levels, and research has turned some widely-held beliefs upside down.

"It truly is a revolution, and in the process, quite understandably caused a lot of controversy. The first surprise was that the starch in foods like bread and potatoes and many

types of rice is digested and is gone very quickly, not slowly, as had always been assumed.

"Secondly, scientists found that the sugar in foods like fruit, ice cream, and candy did not produce more rapid or prolonged rises in blood glucose, as had always been thought. The truth was that most of the sugars in foods, regardless of the source, actually produce quite moderate blood glucose response, lower than most starches.

"We need to forget the old directions that have been made between the starchy foods and sugary foods or simply versus complex carbohydrates. They have no useful application at all when it comes to blood glucose levels. Even experienced scientists with a detailed knowledge of a food's chemical composition find it difficult to predict a food's glycemic index value.

"So forget about the words 'simple' and 'complex' carbohydrate. Think in terms of low in GI values, eating carbohydrates and the right kind you should eat:

"Fruits in every meal. Vegetables with

lunch and dinner, and even snacks. At least one low GI food at each meal. At least the minimum quality [sic] of carbohydrate foods suggested for small eaters. Lots of fiber foods with low energy density or fewer calories per gram.

"You will find that if you are choosy about your carbohydrate, your insulin levels will be lower and will automatically burn more fat. You may not feel this change as it's happening, but you will see the results. You will lose weight over time. Eating high-fiber foods will also help fill you up and prevent you from overeating.

"If you are looking for ways to improve your own diet, and you can take this back to your patients, that there are two important things to remember: One, identify your source of carbohydrate in your diet and reduce your high GI foods. Don't go to extremes because there is room for your favorite high GI foods." Thank you.

MS. BARRETT: Thank you for your comments.

We'll go to our next speaker, Maureen Ternus, International Tree Nut Council Nutrition

Research and Education Foundation.

MS. TERNUS: Thank you. I'm Maureen Ternus with the International Tree Nut Council Nutrition Research and Education Foundation, or INC NREF, as we call it. And on behalf of INC NREF, I'd like to thank you for the opportunity to present comments today regarding the term healthy in the labeling of human food products.

INC NREF is a nonprofit organization that represents nine tree nuts, including almonds, Brazils, cashew, hazelnuts, pecans, pistachios, pine nuts, macadamias, and walnuts. INC NREF believes that any labeling on food products should reflect current nutrition science and should agree with other federal recommendations, policies, and regulations, such as the U.S. dietary guidelines and health claims.

INC NREF is requesting that FDA exercise enforcement discretion to permit those tree nuts -- almonds, hazelnuts, pecans, pine nuts, pistachios, and walnuts -- included in the qualified health claim for nuts and heart disease

to bear healthy claims in product labeling. INC NREF is also requesting consideration of enforcement discretion for Brazils, cashews, and macadamias since the body of research has increased for these nuts over the last decade.

INC NREF further supports the FDA's guidance on the use of the term healthy, which states, "Foods that use the term healthy on their labels that are not low in total fat should have a fat profile makeup of predominately mono- and polyunsaturated fats." All nuts already meet these criteria.

Additionally, foods such as nuts, which provide a wide array of health benefits, should not be precluded from usage of the claim healthy due to their potential lack of a prescribed beneficial nutrient at 10 percent daily value or more.

In 2003, FDA announced one of the first qualified health claims, a claim for nuts in heart disease. The claim states, "Scientific evidence suggests, but does not prove, that eating 1.5 ounces per day of most nuts as part of a diet

low in saturated fat and cholesterol may reduce the risk of heart disease."

FDA used enforcement discretion for saturated fat and disqualifying nutrient levels when it approved this health claim. We recommend that FDA apply the same logic and enforcement discretion to the healthy definition as well.

With regard to the dietary guidelines, FDA has stated that they are the foundation of federal nutrition guidance and are fundamental in shaping federal policies and programs related to food, nutrition, and health.

Specific recommendations in the dietary guidelines have evolved over time as nutrition science has advanced. For example, in the 2015-2020 U.S. dietary guidelines, nuts are recommended in each of the three healthy eating patterns.

No longer do the dietary guidelines characterize healthy dietary patterns as low in fat or recommend that Americans limit their overall fat intake. Instead, the focus is on choosing foods with more unsaturated fat, such as nuts.

In addition, the new guidelines recommend a shift to increased variety in protein food choices and to make more nutrient-dense choices. More plant protein sources are encouraged despite the fact that foods such as nuts don't always reach the FDA'S current 10 percent daily value per RACC requirement for healthy claims.

When it comes to nuts and health, there has been a dramatic increase in the last decade in the number of studies showing the positive impact of nuts on cardiometabolic health and on weight and satiety.

Finally, all the evidence to date continues to support the recommendation that nuts (1) can and should play an important role in the American diet, (2) help to improve overall health, and (3) reduce the risk for various chronic diseases.

We believe that current FDA regulations governing healthy claims are outdated and do not align with the current U.S. dietary guidelines or the latest scientific research supporting the contributions made by nuts in achieving an overall

healthy dietary pattern.

As mentioned earlier, the International Tree Nut Council Nutrition Research and Education Foundation feels strongly that FDA should use the same enforcement discretion for saturated fat in disqualifying nutrient levels for the term healthy as it did when it approved the qualified health claim for nuts in heart disease. Thank you.

MS. BARRETT: Thank you for your comment.

Pamela Schoenfeld?

MS. SCHOENFELD: I have a little visual aid here. I'm sorry, everybody won't be able to see it.

MS. BARRETT: As you're setting that up, I will mention I know it has gotten warm in the room. I think it's getting a little cooler, so I hope that everyone will be comfortable as we move forward.

MS. SCHOENFELD: Thank you. Okay. I'm Pam Schoenfeld, registered dietitian, and I represent the 12,000 members of the Weston Price Foundation, a nonprofit nutrition advocacy group working to

restore the knowledge of ancestral dietary practices to all the American public.

We strongly recommend that the FDA no longer permit the use of the term healthy on all food labels and any similar terms such as healthy, and abandon their efforts to redefine the word "healthy," despite any legal challenge of eliminating this, as the FDA has said.

Since you've developed the current definition, it has become increasingly clear that important questions have arisen regarding what we thought we knew to be true in the field of human nutrition.

New discoveries are continually expanding our knowledge base. Any attempt to capture all the foods that offer health benefits with a regulatory definition is an exercise in futility and in all likelihood will be out of date before it even takes effect.

Today we've heard a lot about nutrient-dense foods. On this poster, I have four nutrient-dense foods that the Weston A. Price Foundation members

value, along with other foods such as plant foods. And you'll see why I don't have plant foods up here in a moment.

These are necessary -- we feel they are very important to support our health and our children's health. They're all either high or good sources of nutrients that are often insufficient in the diets of Americans. So we have chicken livers, hard aged cheese, whole eggs, and red meat beefsteak.

You'll see that chicken livers have a tremendous amount of vitamin A, 250 percent of daily value. Vitamin B-12. That's just a couple of things. The Jarlsberg cheese, for example, is very high in vitamin K-2 and calcium. The eggs are good sources of vitamin A and B-12 and excellent sources of choline. And beef is an excellent source of iron and zinc. And these are all just normal serving sizes.

Now, if you'll look at the Dietary Guidelines Advisory Committee report, they included vitamin A, folate, calcium, and iron in their list of under-consumed nutrients relative to the EAR.

Vitamin A still is an under-consumed nutrient. I'm not sure why they FDA took it off the label.

But anyway, 40 percent of Americans are flirting with marginal vitamin B-12 status. As I said before, 90 percent of Americans don't meet the adequate intake of choline. For the zinc, the at-risk groups include pregnant women, teens, elderly, vegetarians, and low-income people. And vitamin K-2, and up-and-coming nutrient, in the Rotterdam study we saw a 50 percent drop in arterial calcification and cardiovascular mortality in the highest intake groups. But none of these four foods would fit in the current definition because they're either too high in cholesterol or saturated fat, as I've illustrated.

Although we recommend against it, should the FDA in fact proceed with a new definition of healthy on food, we urge they first make a careful reevaluation of any potential restrictions on saturated fat and cholesterol.

Two questions should be asked. One, are saturated fat and cholesterol truly nutrients of

public health concern for over-consumption? And two, should the presence of either of these two nutrients in amounts over the current regulation continue to disqualify a food from being labeled as healthy?

An unbiased review of the evidence will lead to these two conclusions: one, that saturated fat and cholesterol and not nutrients of concern for the majority of Americans; and specifically about saturated fat, more and more scientists, dietitians, and physicians are challenging the long-held belief that it's a primary risk factor for cardiovascular disease.

In fact, in the most recent position paper on dietary facts, the Academy of Nutrition and Dietetics stated, and I quote, "Despite documented influence of saturated fat on surrogate disease markers, the effect of saturated fat intake on disease endpoints is not clear."

According to the 2015 DGAC Dietary Guidelines Advisory Committee, cholesterol is no longer a nutrient of concern for over-consumption,

or it's not a nutrient of concern, but actually, it was never a nutrient of concern. "Therefore, levels of saturated fat and cholesterol should not be used to disqualify food that contains important, essential nutrients."

It is clear that those foods -- egg yolks, red meat, hard cheese, and what was the last one? Chicken livers, my favorite -- and foods like these make meaningful contributions to a healthy, nutritionally balanced diet, as the Weston Price Foundation has taught since 1999.

This is really important. This is something I'd like all the agencies to hear that have anything to do with dietary guidance. "Meeting essential nutrient requirements must be reinstated as the primary objective of all federal nutrition guidance and policy," including the FDA and the HHS, as well as the USDA.

So if the FDA decides to continue their effort to redefine healthy, it must be done so that nutrient-dense foods such as these are not purposely or even inadvertently excluded. And if

the FDA cannot guarantee this outcome, we urge that they follow our strong recommendation that the use of the term healthy or terms like it be permanently discontinued.

We can no longer afford to nutritionally shortchange our nation with incomplete or misleading dietary guidance. Thank you for your time, and we'll be submitting written commentary.

MS. BARRETT: Thank you for your comments.

Our last speaker offering public comment is Diane Welland, National Pasta Association.

MS. WELLAND: Thank you for this opportunity to deliver these oral comments. My name is Diane Welland, and I am a registered dietitian working with the National Pasta Association.

NPA is a national trade association representing companies that manufacture, market, and distribute pasta throughout the United States, as well as those who support the industry such as millers, wheat growers, and equipment makers.

First, NPA commends the agency for reviewing the use of the term healthy and supports the

existing criteria for healthy claims that appropriately recognize that both whole grain and enriched pasta have an important place in a healthy diet.

The ability of whole grain and enriched pasta to bear a healthy claim is strongly supported by the current 2015-2020 Dietary Guidelines for Americans, which encourage consumers to choose whole and enriched grains.

NPA also encourages FDA to continue to allow products that contain at least 10 percent of the daily value of a beneficial nutrient, such as dietary fiber or iron, to qualify for a healthy claim when the product meets this criteria via fortification.

Second, NPA requests that FDA expand the current definition of healthy to provide a new beneficial nutrient criterion for whole grains. This criterion would allow a food to qualify as healthy if the food, first, meets the fat, saturated fat, cholesterol, and sodium criteria required to qualify as healthy, set by the FDA; and

second, qualifies as a whole grain-rich food, as defined by the USDA's Smart Snacks in School rule.

This would allow gluten-free pastas that may fall short of the 10 percent daily value for fiber, but provide a meaningful amount of whole grains per serving to qualify as healthy. This would also be consistent with current dietary guidance and previous FDA precedent on whole grains.

Third, NPA supports FDA's exercise of enforcement discretion for certain products to bear healthy claims related to specific fat and nutrient content. In particular, we recommend FDA revise the regulation defining healthy to reflect the importance of vitamin D and potassium, as well as the recognition that the type of fat and not the total amount of fat is relevant in crafting a healthy diet.

Finally, NPA agrees with the flexibility issued by the FDA in the May 2016 Constituent Update regarding the labeling of KIND, LLC products and supports more flexibility as to when the term healthy is considered a nutrient content claim.

To conclude, a clear definition of the term healthy will not only help consumers identify products that contribute to a healthy diet and increase their general knowledge about good food choices, it will also ensure consumers are provided with accurate, up-to-date information grounded in sound science. Thank you.

MS. BARRETT: Thank you for your comment. And I just generally want to give a round of applause for everyone who offered comments. We do appreciate you taking the time to do that.

(Applause.)

MS. BARRETT: We do want to encourage everyone, as mentioned by a number of presenters, to submit written comments to the docket in April, and again, appreciate the remarks this afternoon.

We do have some time now on the agenda to take some questions from the audience. I won't forget our webcast audience, so if there are folks who would like to submit a question through the webcast, please do so.

We have two microphones in the meeting room.

What I would ask is if you have a question, to please come to the microphone and again give your name and affiliation before asking the question so we capture it in the transcript.

Then, if possible, if you would like to direct your question to one of the panelists, feel free to do that. You may not know who to direct it to; that's totally fine, but just either option. And depending on the number of questions, I'll move back and forth between the microphones and webcast questions.

So with that, we'll actually check in and see. Do we have any webcast questions at this time? Not at this time.

Okay. Anyone in the room like to ask a question? Again, please come to a microphone.

MS. SCHOENFELD: I've actually already asked this question, but since we're all assembled here, I asked it in one of the breakouts.

MS. BARRETT: Again, say your name and affiliation.

MS. SCHOENFELD: Yes. I'm sorry. Pam

Schoenfeld, registered dietitian, with the Weston Price Foundation.

I hear a lot of consensus here that the FDA should be modeling or following the dietary guidelines advisory -- sorry, Dietary Guidelines for Americans recommendations with their nutrition labeling, especially for the word healthy, so even the idea of using the logo for the MyPlate image, which sounds like pretty good advice -- sounds like it would be pretty simple.

My concern is the dietary guidelines are actually out of date themselves. The evidence against cholesterol is certainly not there, and the saturated fat is being called into question whether that is a problem or a problematic nutrient of concern for most Americans.

So we're going to have to wait till 2020 to see how the USDA/HHS address this with their new dietary guidelines. And at that time, they're going to be adding the births to '24 cohort, if I'm not mistaken. Yes. So it's really going to be critical that they get it right for our children.

But since we're working on what I think is old information, and you all are starting a new definition, how are we going to make sure this definition doesn't time out or is not even obsolete before it even goes into effect? And in essence, what is the anticipated duration of this new definition?

Because my presentation indicated that there are valuable nutrients in foods that the American public would not think of as healthy. However, I live in the South, and I can tell you they love their chicken livers down there.

So I'm just wondering, what are we thinking about? How many years will this definition -- is this definition anticipated to last for?

MS. BARRETT: To the panel?

DR. MAYNE: Well, I'll just jump in. Susan Mayne. What I would say in terms of today's hearing, we're here to get your input. I think we've heard your input. The nutrition facts label, we're not here to talk about that science. We've put all of that science out in the rule that

finalized the nutrition facts label. So we're here to get your input.

Obviously, our goal is to get your input on how do we help consumers use this term, the most useful to consumers. So we're anxious to hear everybody's input. If you have specific recommendations, we'd love to see those and have those included in the docket. We want to hear from all stakeholders on this issue.

MS. SCHOENFELD: And do you really think it's useful to the public to be listing cholesterol and saturated fat and not listing other essential nutrients such as vitamin A and B-12 and perhaps zinc that are critical to human health, and a number of the population subgroups don't consume adequate amounts of?

You don't have to answer that. I'm just saying, I don't think we're really doing the American public the service that we should. And I do think this is part of the reason we're seeing extremely high health care costs.

A number of these nutrients -- vitamin A is

very important for immunity. So is zinc. And vitamin B-12 I think would have a huge impact; the more B-12 that people took on the epidemic of dementia and possibly Alzheimer's disease.

So I really think we need to think long and hard about how we're informing the American public about what their nutrient needs are. I'm all for the total diet, but the total diet has to include foods that our ancestors valued, and they're for good reason. Thank you.

MS. BARRETT: Thank you for the perspective.

Do we have another question? Yes, please.

MS. THORSTEN: Lisa Thorsten from the Campbell's Soup Company.

My question is about protein. We've talked a lot today about a total dietary approach, and the inclusion or exclusion of particular individual nutrients. But as you know, protein presents a unique situation in that currently, as a nutrient content claim, the protein quality needs to be considered.

I guess my question is, in the course of

re-looking at healthy, would the basis for a protein nutrient content claim be reconsidered on the total dietary approach, where it may not be appropriate, especially for some of the newer plant proteins that are being looked at, to hold an individual food accountable, I guess you could say, for a complete amino acid profile?

It's kind of a question of scope. Would the definition of a nutrient content claim for protein be encompassed in the work that the agency is doing on healthy?

MS. BARRETT: Doug, or if any --

DR. BALENTINE: Well, I think that I recommend you also submit that comment to the docket.

MS. THORSTEN: Sure.

DR. BALENTINE: I think that we may need to think about how protein plays a role in the term healthy and diet patterns as opposed to the role that it's playing in nutrient content claims. And I think we may need to think about whether they're the same or whether they're different.

But I think input into that area is quite -- and I think the whole area of protein quality is something that's quite dynamic now. And I think we might need a bit more information in order to be able to make a good decision on that space.

MS. THORSTEN: Okay. In a number of foods where protein might be the qualifying nutrient, if it needed to be eligible for a good source in a single nutrient, at least one nutrient that was either naturally occurring or added, I'm thinking of something like bone broth, where we do see a lot of products in the market now making statements about protein.

As we know, it's really all about collagen, which is not a complete protein. And so those products would not be eligible for healthy even if they otherwise met. So it's kind of a special case, but I thought we would bring that to the table. Thank you.

MS. BARRETT: Thank you for your comment.

Okay. Other questions in the room?

(No response.)

MS. BARRETT: How about on the webcast?
Janesia? No? Okay.

All right. Looking down at this side,
questions? Okay. On this side?

(No response.)

MS. BARRETT: Won't hold out forever.

(Laughter.)

MS. BARRETT: Okay. I know it's been a long
day. I think at this point, then, we will go ahead
to look to wrap up. I have not heard anyone yet
complain about wrapping up early.

So with that, I'm going to hand the podium
over to Doug Balentine to provide some closing
remarks.

Wrap-Up and Next Steps

DR. BALENTINE: Thank you, Kari.

First I want to just thank all for you for
being here today. I think the public comment
period and getting input from all of you through
your comments, through the presentations, through
your engagement in the breakout sessions, has been

really valuable. And your participation today is really what I think made today a very successful and useful day for us because we've heard lots of views from lots of different points of view.

There is some leaning towards some consensus in some areas, and clearly there's areas where there's disagreement, which is a good thing. And I think it's good that we heard from those different viewpoints. And we really encourage you to continue to put those positions into the docket because that will really help us as we move forward.

It's been a long day, so I don't really need to spend a lot of time summarizing because I think our colleagues did a really good job earlier of summarizing the key themes from the breakout sessions. So what I'd really like to just do is in closing just say what our plans may or may not be.

I think our plan going forward is we've put out this request for information. The docket is still open, and we encourage, as I said, people to continue to provide comments into that docket.

We'll go away and take away the input we got from this meeting. We'll look at all of the comments we get into the docket. And after review of that information, we'll then step back and give some really good thought on how and when and should we go ahead and redefine the definition, and what way would best help consumers from a public health perspective?

I really can't give any timing on when things would happen and how that will move forward, but what I would encourage is that we will continue a dialogue as we move forward in the process.

So thank you all for the time you spent today, your engagement, and safe travels wherever you are.

(Applause.)

(Whereupon, at 5:00 p.m., the meeting was adjourned.)