

FDA's Comprehensive, Multi-Year Nutrition Innovation Strategy 7/26/18

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FDA's COMPREHENSIVE
MULTI-YEAR NUTRITION INNOVATION STRATEGY

Docket No. FDA-2018-N 2381

Thursday, July 26, 2018

Hilton Washington DC/Rockville Hotel
1750 Rockville Pike
Rockville, Maryland 20852

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P R O C E E D I N G S

MS. BARRETT: Good morning, if we can go ahead and take a seat. I feel like the microphone is working really well, so, I will try not to talk too loud.

Okay. You guys are really responsive. Thank you.

All right. Well, I just want to welcome everyone to today's public meeting. We're focused on FDA's Comprehensive, Multi-Year Nutrition Innovation Strategy.

My name is Kari Barrett and I work in our Office of Foods and Veterinary Medicine, on the Public Engagement Communication Team. And we'll be moderating today's meeting.

I know today that there's a great deal of interest in the issues that we're going to be covering, and I just want to thank everyone in the room for being here. I also want to note, our very large webcast group that's also participating, and thank them for their time today as well.

Before we jump in, there's always a housekeeping. I've tried over time to make this as brief as I can, but let me mention a couple of things.

You should know that today we are webcasting live. And when this meeting is over, we will have a transcript that we will publish to our website on the meeting page. We will have -- later, when we have the breakout sessions, the breakout sessions in this room will be webcast. The others will not. And for those -- for all the breakout sessions, we'll be taking some notes we go along and we plan to put those notes into the docket as well since there won't be a full transcript for the Breakout.

I do want to note that everyone here should have a folder that you got at the registration desk. It does have the agenda. It notes for the breakouts the various rooms that they're in. We also have short bios for everybody, so today, as we move through the agenda, we're just going to note speakers by name and title, and not give that background.

For media, if you haven't checked in with Jen Dorren, I'm looking around for Jen, she may be out, ah,

in the back, Okay. Please do check-in with her if you haven't already.

I also want to note, here again, -- if you're signed up to give public comment this afternoon, if you can see Juanita Yates, you can always check-in at the registration desk, just so she knows you are here and you still intend to give that comment.

I think many of you have found that we don't have Wi-Fi in this room. I'm sorry about that, but it is available if you go out into the restaurant area and the public spaces of the hotel.

Also, in regard to parking, if you parked here today, you do need to pay your parking at the hotel desk. Excuse me. There isn't the ability to pay in the garage, so you just need to be aware of that.

Also, I want to say for lunch, if you plan to eat here in the restaurant, they will be offering a buffet. And as well as the -- the regular menus so you might want to keep that in mind as an option.

Restrooms are right across the hall. Exit signs just are in the back of the room. Phones, please, everybody, silence them. We always appreciate that. And if you have any general questions or need assistance, please go to the registration desk and they'll be happy to help you.

So, with that, let's jump into the program. I have the pleasure this morning of introducing our first two speakers. We're very pleased to have our FDA Commissioner Scott Gottlieb with us this morning. As well as, Susan Mayne, who is our director of our FDA Center for Food Safety and Applied Nutrition. So, Dr. Gottlieb, I'll hand this over to you.

DR. GOTTLIEB: Thanks a lot. And thanks for joining us here today. I want to welcome all of you to FDA's Nutrition Innovation Strategy Public Meeting. I'm really pleased to see how many people have joined us today, not just in person, but we have hundreds of people as you've heard on the webcast, so it's -- it's good to see the interest in what we're doing and we appreciate it very much.

In March, I announced this strategy as a way

to reduce the burden of chronic disease by improving the nutritional status of Americans. I described how consumers want more information about the foods they eat, and that these trends provide a unique opportunity to empower individuals who are using nutrition to improve their health and the health of their families.

The food industry is innovating to give people more of what they want, and we need to encourage this trend. I believe that FDA can help advance the public health by empowering consumers with information and facilitating industry innovation towards healthier foods that consumers want.

As a person who cares about his health and as a parent who wants his children to have long, healthy lives, I have a deep personal interest in these issues and this strategy. And I think we all do here today. Whether in government or the food industry, we're all consumers. We all have families and we all have a stake in the success of this strategy and it hits us all in our homes.

That's what this public meeting is about. We want to hear your ideas about how we can advance the proposals that we've talked about to modernize our approach to better protect public health while removing barriers to innovation that can lead to better products and more choices for consumers. Leveraging nutrition to advance public health is one of my top priorities as Commissioner. We work very hard on a lot of new ideas. Nutrition Innovation Strategy provides us with tremendous opportunity to take a fresh look at what can be done to reduce preventable disease and disease related to poor nutrition.

We can't change all the factors that contribute to chronic diseases, but improved nutrition is one that we can change if we work together. The fact that FDA regulates 80 percent of America's food supply highlights the potential impact of our efforts to take a fresh look at our nutrition-related responsibilities.

FDA has a long history of working to provide the American public with tools to make informed dietary choices. Most recently, we've been working to implement the first major overhaul of the Nutrition Facts Label

in more than 20 years and to provide consumers with calorie and other nutrition information to certain eating establishments, such as restaurants.

We also continue to have a strong interest in voluntary efforts to reduce sodium in the food supply. This is one of the most effective public health actions we can take, and we're awaiting the results of the National Academy of Medicine's Dietary Reference Intake study to inform our next steps. These activities will continue to be high priorities of mine and of the agency.

Today, I'm delighted that this meeting will be taking a close look at three elements of our strategy: Modernizing our approach to claims, modernizing standards of identity, and modernizing ingredient information. These three new elements have the potential to help the many consumers that are seeking healthier options and are more interested in learning about the foods they eat.

We've also heard requests from many in the food industry to modernize claims, ingredient information, and standards of identity. Many in the food industry want to provide consumers with the foods they seek, more nutritious offerings and clearer labeling for greater transparency. But I know that food producers sometimes find that the FDA's historical approach in these areas creates barriers to innovation.

We see a market that's actively trying to respond to consumer expectations, and FDA, we believe, can help by providing a framework for encouraging industry to compete on the nutritional attributes of their products. We need a policy framework that allows consumers to readily identify healthier options. We need a framework that inspires the marketplace to reformulate foods at an affordable cost with science driving these reformulation decisions. The Nutrition Innovation Strategy is aimed at providing such a framework. It's designed to empower consumers with modernized food labels. And it's designed to empower manufacturers to innovate to meet consumer demand.

In a moment, I'll turn to Dr. Mayne to provide more detail on some of the new areas of our focus. And

given my recent interview with Politico last week and all of the social media comments on almonds and lactation, Susan -- Susan volunteered to me that she'd cover the standards of identity issue -- so I'm done, for now, talking about the physical attributes of almonds and what they're capable of doing. I'll just say they -- they taste very good.

Calls for FDA to take a closer look at the standards of identity for dairy products are one of the many reasons we're interested in modernizing our standards of identity. And we'll be putting out a statement later today that speaks in more detail to some of the things that we're proposing to do with respect to the milk standard of identity. This is also one of the first areas we're going to have an active public process for reviewing our standard and how consumers understand and use terms like "milk" in both animal-derived and plant-based products.

We want to see if inherent nutritional characteristics and other differences between these products are well-understood by consumers when making dietary choices for themselves and their families. We must better understand if consumers are being misled as a result of the way the term "milk" is being applied. We've seen a proliferation of products like soy and almond beverages calling themselves milk, and we've seen -- we've been questioned on whether we have been enforcing our Act with respect to standard of identity for these food names.

The challenge for us is, as a regulatory agency, we can't unilaterally change our regulatory approach if we have a history of enforcing our provisions in a certain way. We must go through a public process, and that's what I'm committed to initiating.

We've already encouraged a number of stakeholders that have met with us on this issue to submit comments to the docket for this public meeting, and we continue to encourage interested stakeholders to do so. In the late summer or early fall, we'll be reviewing the information gathered and posting additional request for information with a specific set

of questions pertaining to consumer awareness and understanding of the use of the term "milk" and other dairy terms on plant-based alternatives. The feedback we receive will help inform a revisiting of our enforcement policies in these -- in these and with respect to these terms.

And over the next year, we'll be looking at next steps which could include issuing guidance for industry and new compliance policies outlining our enforcement approach. In the meantime, we'll continue to take actions to address situations when we become aware of products with misleading labels that have a high likelihood of consumer misunderstanding as to the basic nature of the product. And this is especially true when we think nutrition and therefore public health may be at risk.

While dairy has received a lot of attention of late, I also want to recognize that there are many standards of identity that need to be revisited. Today, we're here to discuss more broadly the framework for standard of identity. After all, there is nearly 300 of these standards on our books. And some of them were created when my grandparents were my age or younger.

We want to hear feedback on how the agency should assess whether a standard of identity reflects consumer expectations about that food. We also want to hear about changes in food technology, nutritional science, fortification practices, and marketing trends that we should be aware of when reviewing and updating these standards.

We've heard concerns that standards of identity can sometimes cause industry to avoid reformulating products to reduce things like fat or sodium content because of the limitations in these standards. So, we want to hear about how modifications in our standards can facilitate the production of more healthful foods. And we want to gather input from a wide range of stakeholders, and we encourage out-of-the-box ideas.

Dr. Mayne is up next, and she'll be talking to you more about our other two areas of focus in this

modernization effort. Dr. Mayne is director of the Center for Food Safety and Applied Nutrition and a recognized expert on nutrition and chronic disease prevention with years of policy experience in this area. And I look forward to continue to work very closely with her and her team as we move these things forward.

With the diversity of stakeholders attending today, I'm sure that today's dialogue will be lively and informative. And we need diverse opinions to help inform our decisions on how we improve our policy framework in a way that allows consumers to identify healthier options and provides incentives to manufacturers to develop what consumers want.

So, we appreciate very much your partnership as we begin this dialogue. And I can assure you that this dialogue will continue as we make progress in developing our proposals. Thanks a lot.

DR. MAYNE: Good morning. Welcome to everyone here in the room. And thank you to Dr. Gottlieb for your informative remarks and a special thanks for addressing standard of identity.

We are here today to begin an important dialogue on the new elements of our Nutrition Innovation Strategy. Public engagement is critical to the success of this initiative, and today's public meeting is an important part of that effort. But the opportunity for input doesn't end today. We have established a docket to receive comments, and we are committed to continuing public engagement as we further develop and fine-tune our Nutrition Innovation Strategy.

As Dr. Gottlieb said, The Nutrition Innovation Strategy provides us with a tremendous opportunity to take a fresh look at what can be done to reduce preventable death and disease related to poor nutrition. Today, chronic diseases are the leading causes of death and disability in the United States, and we need to reduce the burden of chronic diseases stemming from poor nutrition, including obesity, diabetes, heart disease and certain cancers.

The prevalence of obesity in adults increased

from 33.7 percent in 2007 to 2008 to 39.6 percent in 2015 to 2016, and it increased in children from 16.8 percent to 18.5 percent over that same time period. Chronic diseases and obesity-related conditions raise health care costs, reduce productivity and shorten lifespans. It's also important to recognize that disparities in diet and nutrition are exacerbating disparities in health and continuing to -- contributing to growing gaps in our society, including those related to longevity.

I'd like to take a few minutes to provide a bit more detail about two of the three new elements of our Nutrition Innovation Strategy and about our Nutrition Facts Label educational campaign.

First, modernizing label claims. Modernizing labeling claims is a key element of our Nutrition Innovation Strategy. We know that claims are quick signals that provide consumers with important information about the nutritional benefits of the foods and beverages they are choosing. We -- we also know that they can provide incentives for industry to innovate and offer products with more healthful attributes. It's time to reexamine claims to make sure they are still relevant, aligned with current science, and that they foster innovation as well.

So today, we will be asking you questions such as: How and why do manufacturers choose to use claims on food packages? How do claims, and what types of claims, best stimulate innovation by the food industry to create products with better health attributes? What types of claims and other information are most helpful to consumers in selecting healthful foods?

We also will explore the concept of a standard icon or symbol for the word "healthy." We will not be discussing the definition of healthy, because FDA has already held a public meeting on that issue. If I recall correctly, it was in this room. We are reviewing comments (I recognize many faces from that meeting).

UNIDENTIFIED MALE SPEAKER: Do you have Wi-Fi?

Dr. MAYNE: I don't know if we have Wi-Fi. We are reviewing comments on "healthy" and we're

developing a proposed rule as a result of all the feedback we have -- we have heard on that issue.

Modernizing ingredient labels. Modernizing ingredient labels is another part of the Nutrition Innovation Strategy. We will discuss possible changes that could make ingredient information more consumer friendly.

One aspect is readability of the ingredient information. Another is whether simpler alternative names can be used for certain ingredients. We will ask for input on whether there are particular features of the ingredient label that could be improved to enhance consumer comprehension. Also, what changes could be made to increase clarity, and better support consumers who want to make more informed choices about the nutritional attributes of the products they are considering purchasing.

Next, Nutrition Facts Label Consumer Educational Campaign. We will also discuss our new educational campaign for consumers on the Nutrition Facts Label. We know you are likely already seeing the new label when you buy packaged food. Around 30,000 products in the marketplace are now carrying the revised Nutrition Facts Panel. Educating consumers is a big part of making information on nutrition more relevant and usable. We will be using a variety of tools to help consumers understand how the choices they make impact their health and the health of their families. Our efforts will focus on areas where we recognize that there are gaps in consumer understanding and the use of nutrition information.

We can't do all of this alone. We are very interested in working with groups that educate consumers, especially those consumers who are at greatest risk for chronic diseases related to nutrition. During our breakout session, we will be asking about any educational partnerships you have been involved with, what has worked and what hasn't. Your experience will help guide us as we move forward with our campaign.

So, in closing, I join the commissioner in thanking you for giving us your time and your

collective thinking today. Meetings such as this one are incredibly valuable in enabling us to hear the broad array of thinking on various topics.

I want to remind you that while this meeting is focusing on the new elements of the Nutrition Innovation Strategy, we've also had -- held public meetings on other aspects of the strategy. As I mentioned that we held a meeting on the definition of "healthy." We also held a public meeting on sodium. All of the information we receive, in total, will be considered. So, thank you again for participating today. I look forward to some lively discussions on these very complex and interesting issues. Thank you.

MS. BARRETT: Thank you both. And now, actually, I'd like to have David Portalatin come up. David is the vice president and food industry advisor for the NPD Group. David is here to speak about Consumer Trends in the marketplace around these issues. So, welcome, David.

MR. PORTALATIN: Good morning. Honored to be here. I am not a food scientist. I am not a nutritionist. I am not a dietitian. But I do have the privilege of having access to vast data assets that for 30 or more years, have monitored what people eat, where they eat it, how they consume it, and as a part of that, a significant amount of information, specifically around sort of this overarching term of "health and wellness" and the role that food and our diet plays in that.

So, before I get started, let me just say one thing about that. I -- I believe that the American consumer is, more than in the past, really focused on this idea of health and wellness. We see it not just in our food industry research but in the research that we're doing across a wide range of consumer goods. Everything from our apparel to our technology to the kinds of things that we're purchasing for our home. They all sort of are connected in some way or another to this overall pursuit of health and wellness. So, I -- I do think that the consumer today is -- is more intensely focused on food and its role and that objective than in the past.

But, with that said, I think what sets the American consumer apart in this regard is that their pursuit of health and wellness as it pertains to food and beverages is really underpinned by two key pillars. And one is this idea of food as function; in other words, what are the attributes, the nutrients in foods, the things that the food can actually do for me. You know, is it heart healthy, can I avoid cancer, does it help me build muscle? All these other things that consumers obsess over in the functionality of foods. And -- and, I think we're unique -- you know, we're passionately committed to this idea of functionality in our food. But at the same time, as I look in this data, I'm also seeing the American Consumer increasingly embrace this other notion of how to live well. And that is: Food is part of how we enjoy life.

And so, I believe the consumer today is more committed than ever to balancing out these two pillars. Yes, I'm concerned about the nutritional value of the functional elements of food, but I'm also committed to the idea that food is part of how I feel good and how I indulge and how I receive comfort and how I receive joy, and how I experience life.

And so, with that regard, some of the aspects around diet, exercise, and nutrition in our data are sort of waning a little bit. So, that's just a -- I just want to offer that as backdrop because -- because I'm about to hit you over the head with a whole bunch of charts. So -- so keep that in mind, as -- as sort of the backdrop, and I'm going to talk about three key areas right now.

One, we're going to talk about diet and exercise and some trend data on that. Then we're going to examine specifically the Nutrition Facts Label and how consumers tell us they engage with that label. And then specifically, what they're looking for from a nutrient standpoint.

And then we'll also address a variety of special labels because as it's been addressed already, there are more ways consumers receive information about the healthfulness or lack thereof, of their food, and so we'll talk about a lot of these "better for you"

labels.

So, diet and exercise, quickly. I don't think that there has been a whole lot of change here. As -- as we measure it, about 82 percent of people report that they moderately exercise at least once a month. 44 percent of those report that they work out two to five times a week. And these numbers are really, really stable over time. A few years ago, we were somewhat hopeful that the intensity of exercise was increasing, but if you look at that 12th percent that's in the chart there, roughly, that report that they exercise vigorously, it -- it really is sort of a flatline over time. It just doesn't change a whole lot. And I think this also is due in part to the fact that the consumer is starting to approach health and wellness in terms that are beyond diet and exercise.

When we ask consumers just to describe their life style, that orange bar down at the bottom is -- is somewhat interesting. We would argue that over the last decade, there has been a slight increase in the percentage of people that report living an active lifestyle. While, you know, the moderate lifestyle in the light blue is also up a little bit. And the sedentary lifestyle is maybe down slightly. It -- thank goodness, it's only about 25 percent. I know we'd all like to see that number change somewhat. But again, not a whole lot of change here.

And when it comes to the - the notion of dieting, in it of itself, the percentage of people that actually report following a specific diet continues to decline as we move beyond these parameters of diet and exercise to -- to define our pursuit of healthy. And when we do diet -- so you can see the percentage that say they've been on a diet has declined from 31 percent to 25 percent over the last several years. When we do diet, it's increasingly one of our design. Among people who say they're following a diet, which, remember, is only what, 25 percent, the single most popular diet, 36 percent of people say it's -- it's one of my own making.

And so, in this idea where we're trying to balance out my functional foods pillar and my feel-good

foods pillar, what the American consumer is really saying is, "I get to decide what works for me." And it doesn't have to be what works for you. It doesn't have to be what the doctor on television said. It doesn't have to be -- be what my real doctor says. It just has to work for me, and that's -- that's really where we are as a customer base today. Increasingly, this idea of what works is being informed by social media in ever more fragmented, diverse sources, some of which are credible. And -- and those of you in this room know, some of which are garbage, right? But this is how we're making choices today.

So, here are the list of diets. This is a busy chart. I apologize if the type is too small for you to read in the back. But, you know, number one on the list there that we've already seen is, "My own diet." Number two at 19 percent are people that follow Weight Watchers and then you can see Slim Fast. Atkins is still around at 19 percent. Number five is an interesting one, appetite suppressants or diet pills. And then we get down to number six, a diet prescribed by a doctor, only about 10 percent say they're following that. And you can see all the other forms of diets on there, whether it's some form of shakes, or whether it's a branded thing like, a Nutrisystem. You see South Beach, you see paleo on there. All relatively small. In general, participation rates in all of these is declining as we really don't prescribe to a diet as our pathway to health and wellness.

Part of the reason for this, I think, is our society is embracing this "You be you." You know, I get to be me, you get to be you, I get to be a little bit heavier, you get to be a little bit skinnier, and that's just how it is. Here's an interesting statement. This is the percentage of people who agree that people who aren't overweight look a lot more attractive. And that's declining. We're becoming much more accepting of a variety of body types overtime, and that's not necessarily a bad thing, but in terms of being willing, perhaps, to carry a few extra pounds, maybe people are getting a little more comfortable with that. So, in general, moving beyond the parameters of

diet and exercise to provide health and wellness.

Now, let's talk specifically about the Nutrition Facts Panel and -- my apologies, I think our graphic there is the Legacy panel, is it not? It's not the revised one? Is that correct? So, when -- when you do 30-plus years of research, you're very hesitant to change your questionnaire, and our questionnaire currently follows that panel. We're going to have to revisit that at some point. But with that said, let's move forward.

One of the interesting things that's happening, and I'm sorry we render the chart this way so it's -- it's -- I'm -- it's -- the chart is the inverse of what I'm going to say. Over the past three years, people are starting to read the Nutrition Facts Label more again. This is the percentage of people who don't check the label. And you can see, it had been increasing up until about, I don't know what happened to my dates down there. We go from 2010 to 2182. So, this is a very forward-looking data chart. The -- the proper timescale, there is 2010 to 2018. So, you can see through 2016, fewer people were looking at the label. Now, all of a sudden perhaps with the proposed changes and with the manufacturers that are adopting the new label and putting added sugars on the label, I think that's creating some renewed interest, and so people are starting to look at the label. Only 17 percent now tell us that they don't look at it.

When they look at it -- now this is in order of the items as they appear on the label. The number one thing that we're checking the label for now, and this may be a surprise, is protein. Now, you have to go all the way down, near the bottom, there. Forty-nine percent of consumers are checking the label for protein.

UNIDENTIFIED FEMALE SPEAKER: Sugar.

UNIDENTIFIED FEMALE SPEAKER: Sugar.

MR. PORTALATIN: Sugars, I'm sorry. I, I am going to talk about protein in a minute, I really do know what I'm talking about, folks. Trust me. I totally misspoke. It is sugars. Thank you very much. We are -- we're going to get to protein in a minute.

But that -- that's -- that is the national dialogue right now, is sugar. And of course, as was mentioned, sodium, which we're starting to talk about sodium at 38 percent. But then number two on the label is calories. We're still looking at that calories. We're still looking at serving size. We're looking at fat content. We're looking at cholesterol. But sugar has become the number one thing that we check. Thirty percent is protein, which we'll get to in a minute.

When you trend this overtime, what you find is sugar is the only thing on that label, really, that we're looking at among the main items there, that we're looking at the label for more than we did a decade ago. The other top items have all declined over the last decade. Historically, calories was the number one thing that we looked at that label for. I think that calories are being listed in a lot of cases elsewhere on the package today, sometimes in a little callout right on the front of the package; that may be why calories is falling off some. But, clearly, the national dialogue on sugar has been somewhat effective because it is increasing in terms of people checking the label.

The other thing further down the list that people are checking the label for now is protein. And that continues to increase. And the primary reason more people are checking the label for protein is that, when we ask consumers what nutrients they are trying to get more of, protein is at the top of the list. Sixty-one percent of American consumers say, "We need more protein." Now, I don't think, and -- and many of you in the room are experts on this and could instruct me here, but I don't think we're malnourished on protein, as a nation. But again, remember where we're getting our nutritional information from. We've got social media, we've got the latest trend, we've got, you know, our -- our CrossFit trainer. We've got all these other people that are telling us all these reasons why you need more protein in your diet, and, so, it is the number one thing we want to add. Followed by whole grain. Dietary fiber, comes in after that, a little more than half. Vitamin C at 54 percent of people that

say they're trying to get more in their diet.

And when we look at the trend on this, the desire to increase these -- these nutrients had been declining for a few years, but they've all been increasing again for the last three years.

So, again, a little bit of background here, the general context is, the -- the American desire to define, "healthy" in terms of the nutrients that I'm intaking, have generally been declining. So, pretty much anything that we ask people, "Are you trying to get more of this? Or are you trying to reduce or avoid that?" All of those trend lines were declining in favor of this more "pursuit of clean eating" as an umbrella term. I like to call it the pursuit of purity or authenticity in our food. So, we are really more focused on, you know, is it a clean label? Is it natural? Is it real? All those kinds of things, rather than what the nutrient content was. But that seems to be changing over the last couple of years. Is all of those top four things that we wanted to add, are all now increasing again in terms of the percentage who say, "We are trying to get more."

When we look at the things that people, you know, a few -- a few of these other items on down the list, you can see what I was talking about before. For the most part, even though there has been a little rebound over the last year or so, for the most part, the percentage of people trying to get calcium or antioxidants or iron or vitamin A has been declining for the better part of a decade. You know, not withstanding the -- the little rebound there over the last year.

And then, there are some other attributes that are sort of interesting, that people say they are trying to get more of and increasingly so. If you look at something, like, Omega 3 fatty acids, it had sort of peaked around 2010 or so, maybe a little renewed interest, recently. But then the idea of pro-biotics or prebiotics in our food supply seems to have some momentum around it over the last few years.

Now, these are the things that people say that -- that they want to get more of. When we ask

people, you know, what are you trying to cut back on or avoid completely, number one on the list is sugar. It's now 72 percent of consumers say that they're trying to reduce or cut back on sugar. So, this conversation that we've been having nationally over the last several years on sugar is being heard. It is resonating. In a moment, we'll talk about the degree to which it's actually changing behavior which is a different story all together. But in -- in terms of the consumer mindset, they get it. They understand that we probably are -- have too much sugar in our diet.

Historically on this chart, fat was always the number one thing, number one thing we said we're trying to cut back. Attitudes around fat are changing a little bit. There's still 65 percent that want to avoid fat, but it has been surpassed by sugar, and it's soon to be surpassed by sodium. So, all of the attention and effort that has gone on over the last couple of years around sodium is starting to resonate and be heard by the consumer.

Here's the trend line on some of these things. So, again, historically, our national dialogue revolved around caloric intake, or cholesterol, or fat, or those kinds of things. The desire to cutback or avoid some of those things had declined over time.

Now, there could be a couple of things going on here, right? With cholesterol, for example, we -- we've dealt with cholesterol for a long, long time. And a lot of people may have gotten to the point where they feel like they've got that managed in their diet, so they're no longer trying to cut back. We also have different understandings about cholesterol over time and good cholesterol versus the bad, and that's the ratio, and that is the role of dietary cholesterol versus your DNA. And so, I think that, maybe there's even still confusion on that that makes cholesterol less of an emphasis in the consumer mindset in terms of their desire to reduce or cut back.

Same thing with fats. You know, I can show -- show you relatively small, but there is some small percentage of consumers that tell us now, "Oh, I'm

trying to get more fat in my diet." Because it depends on the source of the fat. If the fat is coming from certain nuts or seeds or natural oils or -- things of that nature -- and again, informed by all these very diverse information sources that they get, many people feel like this is something they need more of. So, different attitudes around fat is why I think you've seen some of these things sort of decline over time.

The things that we are persisting on and even increasing in our desire to avoid, of course, sugar, sodium, and then really, I know high-fructose corn syrup is sugar but we often call that out separately because consumers have a pretty high level of concern about high fructose corn syrup in their diet. And then gluten. Now we all know that it's maybe only one percent of the population that by medical necessity, must avoid gluten. But again, this is a perfect illustration, of, if I'm following this fad, or this trend, or this social media group, or -- or this exercise regimen, or whatever the case may be, we've got a lot of people convinced that there are health benefits to avoiding gluten. So, gluten avoidance is still increasing in terms of what consumers tell us they're trying to avoid.

Now, let's talk a little bit about sugar. And we do have some -- there are all kinds of labels on packages about sugar content, right? So, even though sugar is the number one thing we're checking the label for, it's the number one thing we say we're trying to avoid, when we look at actual food consumption occasions, the percentage of occasions that have some kind of sugar identifying label has not really increased. So, the -- the dark blue there is a package that was labeled as sugar-free, sugarless, or unsweetened, the green is low sugar, or reduced sugar, and then the light blue would be a label identifying some kind of sugar substitute or artificial sweetener. And you would think, if we're trying to avoid sugar, that we might be seeking out foods that are labeled as sugar-free or sugarless. Not so much.

And when we do decide to have something that's sweetened, this path to purity that the American

consumer is on seems to trump our stated desire to avoid sugar. So, if we're going to have something sweet, it better have real sugar in it not something artificial. It's the artificial sweeteners that we're really avoiding most. Now, you can see other natural sweeteners, like, honey, stevia, raw sugar, agave nectar, those kinds of things are starting to get a little bit of momentum, but in terms of the sweetener hierarchy, they're number three on the list. But they're -- they are growing in adoption.

And I think in terms of behavior, if you look at actual consumption occasions (this is the percentage of meals prepared and eaten in home or carried from home, but our -- our home-sourced foods, the percentage of actual eating occasions), if we aggregate together all the sweet foods, we really have not reduced our consumption of sweet foods. Now, you can argue that our sugar avoidances all manifesting itself in the avoidance of sweet beverages, and our consumption of regular carbonated soft drinks and other sugary beverages, is declining. So, I really think that that's where the American consumer is really turning to work out their sugar problem, is elimination of the sugary beverages. We're not so concerned about natural -- naturally occurring sugars, such as in fruit. In fact, consumption of fresh food is actually up slightly. It's hard to see it in the scale that this chart has rendered, but, you know we are returning to the perimeter of the store, and we are consuming more fresh fruit than in the past.

And as I said, our path to purity is really what trumps all. This is the percentage of people who say they're trying to cut down or avoid completely artificial colors or preservatives. So, our -- our desire really overall is for authenticity in the food, purity in the food, natural food. We're must more inclined to define that as healthy, even if it has naturally occurring fat, or cholesterol, or sugar, or some of these other things that we're, you know, would typically want to try to avoid. If it's found in its natural state, we're more inclined today, I think, to call that a healthy food.

So, now let's talk about a variety of these other labels, and how consumers are engaging with them on a path to health and wellness.

We track a lot of labels. I'll just put them all up here for you. Again, this is too many to read, but I just want you to see sort of the universes that we're dealing with. Number one, on the list, in terms of consumption, and this is not purchase, I maybe should have clarified this earlier. We don't measure the -- a sale in dollar terms, we actually measure it an eating occasion. So, in terms of what people actually consume, the number one special label on a product is all-natural or natural ingredients.

Now, I know this is a bit of a conundrum for folks in the room when -- when the definition of natural includes the word "natural," yeah, that's a little bit of a challenge. But, what this is really saying more than anything else and to underscore this once again, I've already said it once, the -- the overarching desire for consumers is really this quest for purity or authenticity in the food. Give me real food, give me minimally processed food, give me food in its natural state, and we're going to consider that to be healthy.

Now, we -- a comment was earlier that the American consumer probably needs better, more transparent information on a couple of -- in a couple of areas. I could not agree more. And if you look at the next two highest in consumption special labels, organic, or made with organic ingredients, or non-GMO project verified. And I would argue that the American consumer has no idea what either one of those really means. I think they desire to know. So, I think more information is always a good thing. I think there is a great quest for information, but, you know, if you take something like non-GMO, and we've done a lot of research around this. Awareness of genetic modifications in the food supply is rising among consumers. As it rises, so does consumers reported concern about it in the food supply. But if you go one step below that, there's also a rising awareness that, wait a minute, food science is not necessarily a bad

thing. So, yeah, we can reverse farming practices by 150 years and people around the world probably will starve to death.

So, you know, if we're concerned about soil and water conservation and feeling starving populations and all of those things, we need modern food science. So, what -- what we really -- what the consumer really needs is just to be educated, to be equipped to make an informed decision about their food supply, about genetic modification, where it exists, and -- and those kinds of things.

Gluten free is another one. You guys have probably all seen the little Jimmy Kimmel man on the street thing, about gluten. Anybody seen this? That shows -- a few of you have. If you haven't seen it, Google it. It's pretty funny. He goes out on the street with a camera. He interviews people, "Are you trying to avoid gluten?" "Oh, yes, I've got to avoid gluten" "Well, what is gluten?" "Oh, man, it's this stuff. It's not good. It's not good for you." "But what is it?" "Well, it's this thing you've got to avoid." Nobody knows what gluten is, which by the way, you all can tell me gluten is a protein, which is the number one thing that we want to add in our diet. So -- suffice it to say, yes, we need to educate and equip the American consumer to really understand all of these choices that are being made.

Now, I'm going to show you some trend lines on some of this stuff. I think these -- this slide will be available after the show if you want to see the -- the whole comprehensive list of special labels, that we're tracking. But as I said, number one is natural -- or -- or all-natural ingredients. That has been increasing slightly over time, over the last few years. It's now a little bit more than 35 percent. The -- the next two are also increasing, organic or non-GMO. So the way to read this chart, 24 percent of all in-home eating occasions included at least one item, not -- maybe not the whole meal, but at least one item, that was labeled as organic or made with organic ingredients. And then 18 percent labeled as non-GMO.

Here are the other items that are growing.

And these things are all really, really small right now, in terms of share of total consumption occasions. And you know, we can slice all of this demographically and in other ways to show you the constituencies that are really driving the needle on this. But, these are all increasing pretty significantly. Antibiotic free, grass fed, cage-free, dairy alternative which was mentioned before.

I -- I should say -- I should say a word or two about plant-based protein, since it's the number one thing we want to add. I didn't prepare slides on it today. Our data would suggest that plant-based protein alternatives are increasing very, very rapidly in our consumption. Our data would also at the very same time say, that the percentage of the population that is vegan or vegetarian is not increasing. So, what gives? And I think it's -- and I think it's as simple as this. When protein is the number one thing that we want to add to our diet, and we innovate and proliferate the market with all kinds of new ways to add protein to your diet, the American consumer almost always says, "Yes, I'll try that." And this is true, I mean we -- we're in the apparel business, the electronics business, the toy business, and I don't care what industry it is, when there's investment and innovation and new stuff, we buy it. That's what's going on with -- we're, we're not a meat-avoidance society, in general. We are still consuming animal protein. We -- we are less likely today to consume animal protein as a center-of-the-plate protein with a couple of side dishes. We are much more likely to consume that animal protein as an ingredient to another dish.

How many of you have bought an Instant Pot multi-cooker in the last year? That's what I thought. And it's anything that you can throw in that multi-cooker and walk away from it and come back and have what is ultimately a very authentic, healthful meal with real ingredients in it, but you didn't have a pork chop, necessarily, you had an ingredient to another dish. And so -- I think it's not either/or animal or plant based, it's and, for consumers right now. It's

and. In fact, 84 percent of the people that report consuming plant-based alternatives are specifically not vegan or vegetarian. So, there are lot of us trying plant-based alternatives.

All right. Sorry for getting sidetracked there. But, you can also see that these labels -- again, these are also the things that are indicative of this movement towards purity or authenticity in the foods. Antibiotic-free, grass fed. And again, antibiotic free, is maybe another one where we need more information because it pertains directly to food safety and -- you know, we -- we may not be perfect, but I -- I think we have the safest, most abundant food supply in the history of humanity. So, you know, maybe some good conversations to have with the consumer around things like antibiotic free or hormone free, those kinds of things.

We are also consuming more items that have a gluten-free label. It goes without saying that a lot of stuff with a gluten-free label on it right now, never had gluten to begin with. But we're going to take advantage of this rising percentage of consumers that want to avoid gluten, to remind them, that this doesn't have gluten in it.

And then, this desire for the -- for authenticity or purity in our foods is driving us to avoid a lot of things that the label might imply that it was processed in some way to remove something that was naturally occurring. So, you know, even though we say we want to pursue a healthy life and -- and, you know, a lot of us say we're trying to lose weight, and you've heard the obesity numbers, the consumption of foods that are labeled as low-fat, or reduced fat, or light, or diet, or low calorie, or fat-free or non-fat, are all declining. Because even if we're trying to avoid fat, we'd rather deal with the fat in some other way, than have a food that was processed in some way to take the fat out, if it was a naturally occurring fat. I think the consumer today is committed to the idea of, now, give me the food as it is, and then I'll deal with it either through portion size or, or frequency of consumption or, or whatever the case may be. But we

are generally not going after some of these traditionally healthier labels in food.

So, I would just summarize quickly the three ways the American consumer's quest for health and wellness is moving beyond the realm of diet and exercise today. It's really a more holistic view that includes the notion that to live well, I need to enjoy the foods that I'm eating. In fact, I have a chart I didn't show you that says, it shows the percentage of consumers that say the nutritional content of food is the most important thing is actually declining slightly. And the percentage of people that say, how food tastes is more important than how nutritious it is is actually increasing slightly. Now these -- this is not a volumetric thing, or a purchase thing, this is just an attitudinal thing. They're also not mutually exclusive. They're just two of, you know, dozens of attributes that we ask questions about. But I think it does illustrate this idea that I mentioned up front about the American consumer being firmly anchored to these two pillars, the functional pillar and the feel-good pillar, and we're going to curate a diet for ourselves that satisfies both requirements. And again, we're going to do it in a very personalized way. It just has to work for me.

When it comes to our nutrient focus, our desire to avoid sugar and sodium and -- and with our -- coupled with our desire to add protein, I think is part of what's driving some renewed interest in reading the Nutrition Facts Label. Forgive me for the typo there. But, we do see label reading on the rise again and those -- those are probably the key reasons why along with the fact that the label's been redesigned, people are talking about the label a little bit more. And then overall, when it comes to special labels, we really have this quest for purity in our foods. So, those labels that indicate that something is natural or in its authentic state, or is organic, or has been minimally processed or minimally altered in some way, I think is where the momentum is, as opposed to some of the traditional better-for-you labels, like lower fat, or reduced fat, or those kinds of things.

We have so much more that we can talk about or say, in the interest in time I've limited my remarks to this. If we have time for questions --

MS. BARRETT: We do. We do.

MR. PORTALAATIN: -- I'd be happy to -- to take them.

MS. BARRETT: David mentioned, yeah, that he would be amenable to taking some questions, so if folks have a question, there are a couple of microphones in the aisle. I'm sorry, I don't think there's a microphone in that aisle, but there is one here and one over here. Please feel free to come up and -- and ask a question. We do have a little time.

Okay. Great. I think I'll start here and then I'll go down to the next aisle. So, yes, sir, and if you could say your name and organization.

MR. HUBBARD: Van Hubbard, Retired. My question is, really, it's a part of the methodology. How did you select the consumers that you asked these questions. Some of them were attitudinal questions, that don't really allow them to be about -- answered by a questionnaire as -- as much. You made a lot of comments on that. So, how was that data selected?

MR. PORTALATIN: So, two main data sources that I used today. One is called National Leading Trends, which for more than 30 years has measured on a monthly basis actual consumption, both in-home and away from home, among a nationally representative sample of consumers. If you're really interested, I can follow up with you on sample size and those kinds of things. I don't have that number off the top of my head, but it's a -- it's a rep sample. A very consistent methodology over time. So, for example, if I were to tell you that 72 percent of people are avoiding sugar, and you were to say, "No, no, no, I really think it's 75 percent." Fine. I wouldn't argue with that. But if I tell you it's increased over the last five years, I'd take that to the bank because if there is any bias in the data, it's a consistent bias over time and our methodology is very consistent over time. So, the trend ability is -- is I think very, very reliable. Does -- is that helpful, sir?

MS. BARRETT: Yes.

MR. PORTALATIN: Thank you. Yes, sir. Oh, I'm sorry, I should mention the other source that I referenced, is a similar methodology. It's a service called Dieting Monitor, that really measures nutrition intake, you know, self-reported dieting behavior, and all of those kinds of things. Yes, sir.

MR. KANTOR: Mark Kantor, FDA. My question is probably very similar to the previous one, but we've been hearing so much about how we're such a polarized country these days, in terms of attitudes, beliefs and so forth. So, I was wondering if -- if your -- if you just sample people on the two coasts, east coast, west coast, do you think you have a sense of how that -- your results might be different --

MR. PORTALATIN: Yeah. I --

MR. KANTOR: -- compared to the rest of the country.

MR. PORTALATIN: I'll tell you what -- I'll tell you what I believe is the more important differentiator, and it's a generational cohort. So, we see -- many of these trends that we've talked about are absolutely generationally driven. We've done some cohort analysis and done some forecasting on these things. So, for example, let's take the consumption of foods labeled as organic or organic ingredients. Does anybody know what age-cohort has the absolute highest rate of consumption of organic? By age range? Any guesses? I heard a lot of numbers out there. Zero to nine years old. Who is making those decisions? Mom is. And how old is mom? She's -- she's in her 30s to early 40s right now. She's that millennial mom. And it goes like this -- and we've -- we've done some in-depth work on it, but to put it narrative against it: Mom has a baby. Mom gets militantly passionate about the purity of foods that that baby eats, right down to buying organic carrots, steaming them, pureeing them, and making homemade baby food. And then one day a lightbulb goes off and they say, "You know, if I'm so passionate about what little darling eats, maybe I should care more about what I eat." So, number two highest rated consumption for organic is that

millennial mom. And then in -- here's another -- do you know who number three is? Millennial mom's dad.

So, we have this multi-generational conversation where she says, "You know, dad, you just got back from the cardiologist, and here's what we're doing in our house, and I think this could help you too." So, it's this multi-tiered conversation. It's teenagers and generation Xers like myself that still eat like crap.

Now, with your, with regard to your comment about on the coasts, you know, the millennial generation is migrating out of the suburbs, back into urban core, so there probably is some of that correlation as well. But I believe that the generational cohort is one of the bigger drivers of change that we see.

MS. BARRETT: Thank you.

MR. PORTALATIN: Yes, sir. Good morning.

MR. MISTER: I'm Steven Mister with the Council for Responsible Nutrition. I couldn't help but notice on a number of your slides, there seemed to be an inflection point in 2015 in terms of things people had been eating and now they're looking to avoid.

MR. PORTALATIN: Right.

MR. MISTER: They weren't looking for things, now they are looking for things on their label.

MR. PORTALATIN: Yeah.

MR. MISTER: Things -- healthy ingredients that they're now looking for. So, my question is, what do you think happened in 2015 that might have caused that shift?

MR. PORTALATIN: Yeah. Great question. So, prior -- prior to 2015, you know, my message was really that our avoidance mindset for healthy eating was -- was on the wing. So, our -- in other words, the -- avoid fat, avoid cholesterol, avoid this, avoid that, or even add this or add that. So kind of, really the whole nutrient based definition of healthy, was declining, declining, declining, declining, in favor of this pursuit of just clean eating, natural, whatever. Right?

But along about 2015 is when we started really

talking more about, let's put added sugars on the label. Let's do this, let's -- and so we've reignited a more robust dialogue on sugar, followed up with a more robust dialogue around sodium. It also corresponded with this renewed interest in diets, like, keto or other high protein diets where people are really interested in adding protein. And so I -- I really think the combination of those things, has sort of caused people to go back and look at the nutrient information again and start to track these things.

And also, 2015 was interesting in that that was one of the years that had the -- the absolute -- that's the year that every single person in this year bought a Fitbit. And we all started doing MyFitnessPal and we all started doing all these other things where we were logging this information all of a sudden. So, there's -- so I think some of the technology that we got into right around that time, caused us to start taking a more granular look at the various nutrients and -- and ingredients and things like that again. So, I think it's probably a combination of factors, but those would -- those would be the big ones.

DR. REIMERS: Hi. Thank you for your -- your presentation. Kristi Reimers, I'm with ConAgra brand. And your data certainly resonates with our sales data showing that consumers have drifted away from nutrient content claims and other health claims, and more for that food authenticity and purity.

You've talked a little bit how the Nutrition Facts panel might help bring them back. I don't think we'll ever completely leave that pursuit of the authentic pure food idea. So, do you have any ideas about how we can -- can continue to bring that consumer back to foods that really will relate to positive health outcomes?

MR. PORTALATIN: And I -- yeah, that's -- that's a great question. You know, I think that it's -- it's hard because, not only do you have your Nutrition Facts Label but there is information being delivered all over that package and then beyond the package. One of the things that I think holds great interest is that the food industry is going digital

pretty fast. So, for -- let me give -- tell you what I mean. If we looked at the consumer electronics space right now, 31 percent of every dollar spent in consumer electronics is spent online.

Now, for a variety of a reasons in the grocery store, it's probably never going to get to 31 percent because we like to see and smell the produce, and we like to see the fish and the meat and those kinds of things, right? But it's already, our -- our data tells us 16 percent of consumers have bought groceries online in the past 30 days. And it's growing very rapidly. So, I think the more we engage the consumer digitally, it opens up a tremendous avenue for a technological solution to deliver information and insights and analysis, beyond the limitations of a package, right?

In the physical store, you're limited to what somebody can see on a shelf or hold on a package. But in the digital world, we have all kinds of different -- different possibilities. You know, we're seeing manufacturers look at the entire path to consumption now, so everything from meal planning, to recipe development to, you know, we already talked about apps like MyFitnessPal that are monitoring your nutrient intake for you.

So, there are all kinds of ways, I think, in the future, where we can really help the consumer understand what's coming in? What am I missing? What have I got too much of? And where is the more robust information? It could be just a click away now, not -- no longer constrained by the limitations of a specific package. So, maybe there's a solution in there somewhere.

MS. THORNDIKE: Hi. My name is Ann Thorndike. I'm a physician from Boston Mass. And -- I've -- your data is so interesting to me because I work with people every day trying to make changes. And so the one -- when you were talking about the diets and that people -- the most popular diet is what -- what works for me. And then we hear about what's happening with the prevalence of obesity and clearly it's not --

MR. PORTALATIN: It's not working.

MS. THORNDIKE: -- working. And so I'm just --

number one, wondering if you have any data about how people feel about how this is all working for them. And just make the point that people see what they want to see. And I think this is really important as we think about labeling. Like, people are going to look for what makes them feel better about what they're doing and not sometimes for changing -- making a better change for themselves.

MR. PORTALATIN: Yeah. And I -- and I think sometimes you know, the data that I just showed you today is -- is national high-level, and sometimes the answer to those questions requires a little more in-depth insight and analysis.

You know, for example, we don't -- we don't purport to have the official obesity statistics. However, we do ask everybody that's in our panel what their BMI is, and at least in terms of people that are answering our question, we -- we can identify certain cohorts, specifically among younger women, that millennial mom, for example, obesity rates, at least among those in our panel, are not going up. So, maybe it is working for some of them. But you -- you bring up a great point, but I think it requires a little more in -depth study than you know, just the high level numbers that I've brought today.

MS. BARRETT: And I think -- so there, our last question. Please.

MS. CAMPBELL: Thank you. My name is Jessica Campbell from General Mills. Thank you for your presentation. I really appreciated the way you looked at both nutrients to limit as well as nutrients to encourage in -- in the diets of -- of our consumers. Were you able to look at say, food group consumption at all? You know, trying to think a little bit more from a holistic lens rather than a one, single-nutrient approach. So, I don't know if you were able to look at food groups, you know, servings of dairy, servings of fruits and veg.

MR. PORTALATIN: Right. Mm-hmm.

MS. CAMPBELL: Or another way to kind of more complimentary look across, you know, people's individual food choices because as we know, it's not

just about one nutrient --

MR. PORTALATIN: That's right.

MS. CAMPBELL: -- or another, but maybe more of a nutrient dense approach.

MR. PORTALATIN: Yeah. And we -- we do look at that, as a matter of fact. And I -- and I can just say, in general, the interesting thing to me is that we -- we were on a trajectory for 25 years or so in this country where, what you might call perimeter of the store, so meats, fish, poultry, you know, the dairy, those kinds of things, consumption of those foods was declining, in part because we had a massive revolution in convenience-oriented foods, and that's what the consumer demanded. So, we shifted into the center of the store and into the freezer case and into the restaurant space and other prepared foods. That pendulum is actually shifting back the other way now. We actually see the consumption of those perimeter of the store foods increasing again.

I will say that we ate more fresh perimeter of the store foods in 1980 than we eat today, but that pendulum is gradually tilting back the other direction. So, yeah, we -- we do look at things of that --

MS. CAMPBELL: What was the time -- what was the timepoint for that? Was it around that 2015, 2016, or was it actually earlier? Just, just curious.

MR. PORTALATIN: Maybe a little bit earlier, but, yeah, but over the past few years, and by the way, also, very tied to generational cohort. It is very much a millennial, generation Z driven return to this idea of purity and authenticity in our -- in our foods.

MS. BARRETT: All right. Well, let's give David a round of applause.

MR. PORTALATIN: Thank you all very much.

MS. BARRETT: Thank you so much. All right. That was super. Thank you. We are now going to have a panel of external folks offer their perspective. This panel is going to be moderated by Chris Waldrop. So, I'm going to ask Chris and the panel members to come up.

I will introduce Chris as he's coming up. He is the Senior Public Health Educator at our FDA Center

for Food Safety and Applied Nutrition. He is in the Office of Analytics and Outreach. So, Chris will be moderating this session. I'm going to hand you the podium. Thank you. And the other panelists, please come up.

MR. WALDROP: Okay. Good morning, everyone. Thank you again on -- for being here this morning. This next session is going to provide an opportunity for us to hear a few perspectives from some of our stakeholders. They're going to be speaking about the role that innovation can play and developing and improving healthy and nutritious food products, as well as touching on some of the issues that we'll be -- that you've already heard about and that we'll be talking about later today.

So, I'm going to just very briefly introduce them. There are bios in your packets, so if you want to learn more about them and -- and the -- their backgrounds, you can turn to those bios.

But first we'll be hearing from Dr. Neal Hooker, who is a professor of food policy at John Glenn College of Public Affairs at Ohio State University. Then we'll be hearing from Rob Post, who is senior director for Health and Wellness and Corporate Affairs at Chobani. And then we will hear from Laura MacCleery, who is policy director for the Center for Science and the Public Interest.

So, we've asked each panelist to take about 10 minutes to provide their perspective and then if there's some time remaining, we'll open up the panel like we did just previously, to get some questions for the panelist from the audience. So, I will turn the panel -- the podium over to Dr. Neal Hooker. Dr. Hooker?

DR. HOOKER: Thanks, Chris. Pleasure to be here. This is a real honor and I'm very happy to be in the room to listen. I really enjoyed that last presentation.

So, I'm going to use three case studies on some of our recent academic research. I'm going to kind of give you a 30,000-foot view of three different example products. Not meant to be exhaustive, but they

each of them, I think, fit within the three rooms that you'll have discussions and the broad discussion of what -- what I understand FDA's intent for the meeting is. And I tried to pick up some different types of product categories that explored different aspects of food and nutrition innovation. So, prepared meals and some other work on front-of-pack claims, trans fats with cookies or biscuits, depending on which one you want me to say.

Nice interesting policy-led discussion, and then the third one, yogurt, or yogurt, again Bob will probably say it in a slightly different way. Not policy driven but presenting the challenge of if we want to track public health gains from food innovation, from whether it's industry led, public-private partnership, or -- or policy driven, then what sort of nutrition surveillance information can we have and what's the level of disaggregation, and we'll provide an example of that.

My bio doesn't say it, but, in -- in training I'm an economist, so I would be remiss if I were not to say everything is demand and supply driven. We just had a great presentation of consumer insight. I'm going to give a little bit of some trends from firm use, and then I'm going to combine demand and supply; in other words, what are firms doing and then how do we weight consumption and to try to understand what a societal level impact might be.

So, these are going to be busy and -- and lots of data-driven slides, and I apologize, I'm going to not -- I'm going to give you some of the highlights of each one.

So, the first -- this is based on 1,000 prepared meals over this five-year period. And what we're looking at here in the three bars, the green is which firms are actually using the healthy claim on this prepared meals category. Maybe or maybe not, it's a category that you think of as particularly healthful. There is, obviously, diversity in this category and this could -- you know, this -- as a prior speaker said, this is spanning the time of interest of looking at frozen categories, you know, frozen pizza, for

example, or lasagna.

So, the middle bar, we go in and using Nutrition Facts information, based off of these 1,000 real products in the marketplace, solely firm supply. This isn't weighted by sales that this -- this data that you're looking at. Which of those are eligible to make a healthy stand -- a healthy claim?

Again, your own perspective of what this category is, I would ask you to think: If the standard can be met by the majority in, you know, 60 percent of the category, it -- what is the job of that standard? Is that standard too lax? Is it challenging? Should it be dynamic?

So, that led us to then say, well, and -- and the 60 percent are eligible and yet, only two or three percent are claiming. What can we find out about these products that better describe why the firms are choosing to make a healthy claim? And that's the third bar, which what we've done, the healthy claim, requires a sodium threshold. We've strengthened that sodium threshold to make the low sodium claim that has FDA -- or use of this period, and we then closely mirror the use.

So, in other words, here's the front of claim -- front-of-pack claim, healthy, and we're trying to understand when a firm chooses to use this. Again, in the spirit of demand and supply, if you're a consumer seeking a healthy product and you're using this front-of-pack heuristic, what sorts -- where are you seeing it? Right? Until you're actually seeing it on products, the firms are only going to put it on products that are already well ahead of the standard as far as sodium goes.

So, that's something to think about when we -- when we generally talk, talk about standards, you know, front-of-pack claim or a, a low, or free, or reduced. What is the industry doing and what's our job with our standard if we go and are regulating it? Should we -- should we push industry further or are we already just catching up with industry?

Okay. So, what we wanted -- what our research group wanted to do is then try and weight that sort of

insight with nationally represented consumption trends. And our group has chosen to go along the route of NHANES. NHANES is the state of the art we argued for nutrition surveillance and other things. We use it in other ways. But we do not -- and I'm not presenting here any scanner data, any sales-based data. And part of the issue is, if we want to explore subpopulation dynamics. So, we want to know not did a household buy a particular food, but who in that household consumed, so that's why we use NHANES. NHANES -- and I'm getting policy wonk-ish here and throwing out lots of acronyms. NHANES uses a standard nutritional characteristic of a food group or -- or a food code, to say, a cookie is a cookie. A chocolate chip cookie are all identical. We know they're not. You know the cookies you make at home are very different than -- than Chips Ahoy or other -- other brands, that I wouldn't call out.

So, there's diversity in the market place, and we want to try to characterize that diversity. What we also wanted to do is extend some of our earlier work on trans fat surveillance, and I apologize, it's really, really small. What -- what the -- so let's go to the -- what the title is saying. So, what we're able to do through this process is merge in food label information with NHANES consumption patterns. And then what we're able to do is provide something that NHANES can't -- can't -- cannot do, yet, and talk about trans fats.

So, the story is -- I'm sure everybody in the room knows, and label innovation, we label trans fat, we saw a great reduction in trans fat levels. Although, not to zero. Over the study period, we still saw diversity of cookies and biscuits that had different levels of trans fat. But generally, we're able to say as a category, .03 of a gram for consumers per day if you're consuming of trans fat. So, we're able to get a point estimate of trans fat consumption, using just label information and then weighting it to a nationally representative consumption part.

So, that's interesting, but what I wanted to pull or -- pull out from this slide is this continued diversity in the marketplace from zero to four. So, in other words, how you shop the supermarket, the aisles,

the products in -- in those aisles, can still have incredible diversity. And whether you're shopping on Amazon.com or shopping in Safeway's aisles, there's different, as a prior speaker said, there's different amounts of information, but we shouldn't forget that there is information that is on trans fat on the label on the product. So, that information, perhaps, needs to -- we still need to recognize that information can be then a point of comparison. If I pick three different types of cookies off of the shelf I can do a comparison like this and see a continued diversity.

So, a dynamic version of this story says the right thing. The trans fat levels are going down and trans fat consumption is going down, but those that got really much better eyes than I have might see in the line above, saturated fat consumption has increased. And then this -- we knew that from earlier studies, you know, the food scientists take out one lipid and they have to replace it with another. Those lipids play multiple functional roles, so you cannot simply negate the need for a lipid of one form. And we already knew that as the trans fat reduction was happening, so a saturated fat content increased.

What -- what this data, this version of data suggested how much behind the market is our nutrition surveillance? And similar version I'm going to use, yogurt as a story, and again, I apologize if these are coming out so, so small. What we're looking at here is two-year versions of NHANES data, or those of you who know, it's collected on two-year basis, 10,000 -- an n (ph) of 10,000 over each two-year period of -- of respondents.

What we -- so we looked at yogurt, and like many in the room, here we were interested about protein, and we were interested in saying, well, the role of Greek style Yogurts, surely we're going to be increasing our consumption of protein through yogurt.

No, we didn't see that. That's the bottom right panel. Not dramatically different. And although there are some differences in what the label-based data suggests, we're fairly close in our approximation to our traditional ways of estimating nutrition and table

dietary intakes that we do for NHANES. So, we're not too far off. But where we go a little bit askew is with fat. So, over the same period we're actually eating more fat; or, based on the food label information of the more innovative products, we are having a higher level of fat intake through yogurts, than -- than we think if we solely rely upon traditional estimates of NHANES consumption. So, those numbers are increasing and -- and the gap in between what our traditional nutrition surveillance says and this market-based surveillance says, has also increased.

So, we didn't see the story we expected with protein, but we saw this other story with fat, and that was a similar story that we saw with trans fat, right? So, we saw trans fat reductions, but then we also saw saturated fat increase.

So, what's the take home? What -- what can we take from this? Yes, absolutely, firms do have, and do respond to market-based incentives. They lead some of this demand with push-and-pull marketing, but they also respond to interest in -- in certain market trends and diet trends that we've heard about. Then -- it's not that every firm is going to do that for all products. Firms are very, very sadly marketed. Food firms are very, very sadly marketed, and they may add a better-for-you version of a product whilst maintaining a -- a product portfolio that has points of -- other products of other types of nutritional quality.

A prior speaker said it -- and -- and -- and without the slide, but, you know -- while we think this stuff is the most important for consumers, it's not it's taste, it's convenience, and it's price. Any survey that you look at, those are going to be the top three items, as far as product choice. Nutrition wellness comes in fourth, if we're lucky, after that.

There's an adoption and diffusion process, both by firms on the supply side and consumers. So, yes, we may be very interested in buying the latest and greatest electronics, and we choose to purchase that and be an early adopter. The difference with food as opposed to electronics, or the big-ticket items, is our

repeat purchase. So, it's the second and third time going to buy that product. And we are very fickle, right? So, we see a lot of those foods -- food industry folks in the room know this well -- we see a high failure rate of novel foods. It could be as much as 90 percent of new foods are not available a year after launch.

So, they think this is going to be a good product, they invest, we don't buy it. We buy it once, but we don't go back and buy it. So, keep in mind, a label as a point of communication for those interested in the education policy, a label is a repeat-exposure issue. And it's repeat exposure - we keep going back and we may get that message in the grocery store. But if we have the breakfast cereal box in front of us as we have breakfast, we're still receiving information from that -- from the nutritional facts panel, from the front-of-pack claims, from the ingredients list. So, we're -- we're -- we have multiple exposure to that information that goes on differently to the purchaser, the millennial mom, and the consumer, the -- the kid, right? And they are exposed to that information at different points of times. So, keep that in mind.

We do respond to heuristics. There is -- there is gut reaction, there's this sort of natural, but not knowing what natural -- gluten, not knowing what gluten is. So, heuristics absolutely play a role, which is where our behavioral psychologists colleagues are incredibly useful in understanding that.

So, I apologize for the -- that the slides were so small. These -- these are taken from these three papers, which I -- which I'd be more than happy to follow up with if you have interest and my e-mail address is there. Oh, there goes the time. Yup. Thanks.

DR. POST: Well, thank you. I'm very glad for the invitation to speak at today's panel on behalf of Chobani. At Chobani, we believe that business can be a force for good. And -- Okay. So, where are my slides?

MR. WALDROP: Can we -- can we bring up the slides for Dr. Post? Nope. Not those. There we go.

DR. POST: There we go.

MR. WALDROP: Thank you.

DR. POST: Thank you. Thank you. So, at Chobani, we do believe that business can be a force for good, and it's our goal to accelerate universal wellness. And to accomplish this requires a collaboration between the food sector and the policy sector to support a culture of innovation. And I'd like to briefly describe the approach to innovation for wellness-focused companies and the challenges and opportunities that exist in the areas of standards of identify, defining healthy, defining nutrient dense, and the best practices for nutritional labeling education, in the experiences we've had.

So, as we know, today's consumer has evolving demands for their food purchases. We heard that this morning. And these are shaped by a new set of food values. Health is important to consumers, but so are safety, naturalness, and lifestyle beliefs. This can't be minimized. This is very real today. And as you see, taste, convenience, and price has been mentioned, but so are these other values drivers.

So, as a food-focused wellness company, Chobani has been on a mission to provide better food for more people through our food philosophy and standards that really take consumer values into account. This means developing nutrient-dense products that provide the good nutrition that people need.

Additionally, we're working to extend our reach to ensure that better food, or better foods, are more assessable in all channels, and that's by leveraging partnerships and programs through the communities in which we serve. We want to have a large-scale impact. And this multi-dimensional approach is the signature of today's business that's built on the belief that health means business.

And so today I'll share a food-sector perspective on the role innovation plays in developing and improving healthy and nutritious project -- products and how lifting limits on innovation that policies may pose may help to deliver healthy products that relate to consumer values, consumer value drivers, which are very much real today.

Chobani is not alone in our quest to improve the food environment. Companies that are building the future toward healthier communities through a culture of innovation are keeping up with consumer demands and health science, and therefore, we believe the FDA should take a similar approach.

So, I'd like to begin by addressing standards of identity. There are some challenges here. Standards of identity have not kept pace with the market place and, in some instances, prevent the development and recognition of nutritious products that align with the Dietary Guidelines for Americans. For example, the standard of identity for certain cheeses, prevents the use of salt substitutes which could, in fact, lead to lower sodium content, a public health benefit.

And meanwhile, the current standard for yogurt, in the 2009 proposed revision, don't reflect the array of yogurt products available in the U.S. market place, particularly, strained high-protein yogurt, or Greek yogurt, which is -- which now accounts for more than half of yogurt sales.

There are some opportunities here. There's a need to create standards in an efficient, timely mechanism for recognizing new product innovations, or new product categories, like strained high-protein yogurt, to ensure uniformity and nutritional quality of these newer but now prominent products in the marketplace to promote public health.

And there's a need to adhere to standards. Standards assure consumers of the authenticity of foods and the nutrition they provide and expect. And the terms established and standards should be reserved for these products. For example, use of dairy terms like milk.

You know, it's not an anti-dairy or anti-plant-based thing. It's important to have options and both products have an important place on the shelf. But, words matter to consumers and for a great deal of time, for example, "dairy" has come to mean something very specific through standards, a nutrient-dense option with minimal processing. And it's important

that this meaning is preserved because the important -- of the important contributions to meeting dietary guidelines recommendations.

So, there's an opportunity among the approaches that FDA could use to support innovation through standards of identity. It could be leveraging public-private partnerships to help reduce federal resources and keep faster pace with the marketplace and consumer purchase trends. Another option, perhaps, is to consider adopting the product specifications that USDA's Agricultural Marketing Service has established for federal programs, such as the National School Meals Programs.

So, regarding standards of identity, there's also a need for all federal agencies to be aligned. And here's a case where -- a case study where agencies aren't working towards the same public health goals, because standards don't reflect the marketplace. While USDA's Agricultural and Marketing Service for school purchasing recognizes strained high-protein yogurt as different from other yogurts because of its protein -- protein content, the lack of an FDA standard of identity prevents equal crediting in USDA's school meals program.

So, child nutrition program operators have recognized the nutritional benefits of these products; yet, they struggle to incorporate such options because they're not recognized in the existing crediting system. So, agencies have to work together in a unified way to support healthier foods in the market place by setting and applying standard of identity, uniformly.

A second area I'd like to address as it relates to using innovation to create positive impacts on public health and more specifically, consumer habits, is the meaning in the use of claims and the first being the -- the healthy claim. When it comes to the policy on healthy, there are some challenges. Consumers benefit from guiding -- guidance that's out there towards healthier choices. However, foods that are recognized in guidance on adopting the dietary guidelines are not eligible to be labeled healthy

because the FDA definition is outdated and hasn't evolved to relate to a larger dimension of health.

The foods shown here are examples of this contradiction; however, there are some opportunities. "Healthy" should be used in the context of the Dietary Guidelines for Americans, as it relates to healthy eating patterns. That's not just defined in the context of -- of nutrients, but defined more broadly in the context of the total diet with meaningful amount of food group contributions not just nutrients. And this will help encourage the development of products that align with the federal dietary guidance and the latest science.

Associated with "healthy," is the term "natural." It's a consumer value, which needs a unified definition. Now, every day USDA applies a definition of "natural" to labeling they review and approve which can be recognized by FDA with the ultimate goal to harmonize across agencies to prevent inconsistencies that may lead to consumer confusion and misleading interpretations.

Similar arguments can be made as it relates to "nutrient dense" as -- as a term or a claim. Regarding nutrient dense, there are some challenges. Shifting towards nutrient-dense choices is a core message of the Dietary Guidelines for Americans, but manufacturers do not have a clear "nutrient dense" definition to guide product development. Without a definition, there's no assurance for consumers that their food choices are contributing to healthy eating patterns. But there are some opportunities. Defining nutrient density, being -- using unified criteria for food categories could be a means to give manufacturers a guide for consistently developing and communicating about nutrient-dense options.

And then the last area I'd like to address is the Nutrition Facts Label and consumer education. Some of the challenges here are that consumers are focusing on one or two nutrients or ingredients to make their food choices. It's not based necessarily on the full nutrition package in a dietary pattern. And that's according to research that's cited here. The new label

may present further challenges. With the new Nutrition Facts Label, it's welcome for the updated science behind it, for sure. It still, though, isn't a one-stop shop to move consumers in the right direction towards making more helpful informed food and -- and beverage choices.

Consumers need multiple tools to help overcome these barriers. And further, the Nutrition Facts Label on -- on one food does not present information in the context of the total diet. For life stage dietary needs, which as we know, as -- as consumers are looking for more customized and personalized information, life-stage dietary needs become important, and they're looking for those recommendations. And that makes it incomplete as a dietary guidance, incomplete as dietary guidance towards meeting the Dietary Guidelines for Americans. So, there's an opportunity here. And that is to encourage FDA to broaden nutritional labeling education to include tools like MyPlate, to help consumers better evaluate a food in the context of a total diet, rather than focusing on single or individual nutrients and ingredients to make their choices.

So, in summary, the opportunities for improved policies in the areas of standard of identity, defining "healthy," defining "nutrient dense," and the best practices for nutritional labeling education can foster innovation for companies that are invested in improving public health. And we believe these insights will help guide FDA in their efforts to update and improve policies that support nutrition innovation. Thank you.

MS. MACCLEERY: Hi. What a pleasure to be here today with you. I apologize in advance because I have a nasty cold, so to the extent that I sound flatter than usual, I hope you'll give me credit.

We certainly applaud the FDA and the Commissioner's interest in using labeling strategies to guide Americans to more healthful diets. As the Dietary Guidelines makes clear, Americans under-consume healthful foods, in particular fruits, vegetables, and wholegrains and over-consume salts, sugars, and saturated fats. So, that's the problem we all have,

right?

I'll start with some general observations on labeling and then move to some more particular solutions that we might propose.

CSPI, Center for Science in the Public Interest, has worked on labeling for decades. We also regularly analyze the marketplace for our nutrition action health letter. We have filed many citizen petitions over the years requesting improvements in labeling on everything from added sugars and food dyes, to trans fat, and wholegrains, and we've had some success.

We believe that labeling transparency is a valuable tool to assist consumers in making helpful choices. We certainly pay attention to the same data we saw earlier, presented this morning, that shows that consumers use the labels, that they read them, and that when we take the time to update them, as we have -- as FDA did with the Nutrition Facts Panel -- that they become even more part of what information that consumers rely upon.

Labeling also can spur companies to market more healthful products and reformulate existing ones. Yet, we think consumers today face the marketplace that is too noisy to make consistently useful choices. We're working with Congress to address some of these needs in the Food Labeling Modernization Act which was introduced this past spring, again, in both the House and the Senate. But we also welcome FDA's interest in fixing labeling and believe there is much the FDA can accomplish under its current authority.

The bill we proposed directs rule-makings by the agencies on areas that I'll touch on today, including front-of-package interpretive labels, made with claims, caffeine labeling, and fortification of junk food.

The stakes are high, as we all know. Seventy-percent of adults and 33 percent of children and teens are now overweight or obese. Half of adults have high blood pressure. As context for this, we very much appreciate FDA's focus on health disparities as we seek to understand how to address these factors.

Conflicting information in the marketplace does contribute to consumer confusion. Data from the International Food Information Council shows that many consumers who dutifully try to follow dietary advice struggle with confusing information. IFIC indicates that 80 percent of consumers say that they come across conflicting information about food and nutrition. The same survey indicates that consumers trust food companies and manufacturers less than any other source. For which foods to eat or avoid, nearly 20 percent of consumers say they don't trust the food industry at all.

On the bright side, the same survey reports that confidence grows after FDA acts. They found that consumers are more confident in purchasing meat and poultry in the wake of new regulations on antibiotics than they were in 2017. And the consumers pay attention to labels, as we saw earlier.

Alongside what we know is the decision fatigue and cognitive overload that a company is shopping, this lack of clarity can drive cynicism and frustration about the links between health and food choices, fueling trends that encourage wishful or even magical thinking by consumers rather than scientific thinking and undermining the government's dietary advice, leaving space for profiteers having diet fads and shoddy science in lieu of nutrition education.

For their part, food companies seek -- seeking to meet consumer demand for more healthful foods, or more authentic foods, or more pure foods, as we saw this morning face a forbidding marketplace. They must overcome uncertainty that they will be able to effectively communicate to consumers when they do invest in creating a more healthful food and that can -- that lack of confidence can stymie innovation. Aligning labeling with the truth about health is a place to start.

Here's an advertisement from the Institute of Food Technology's conference I just attended this year. As you can see, suppliers are eager to add food or vegetable powders, concentrates, purees, paste, and juices, sometimes in minimal amounts, to everything

from chips and fruit snacks to bars, cookies, and crackers. "Make nutrition claims that consumers love," says one supplier. For us, that gets it exactly backwards. We would certainly like to essentially improve nutrition on the front end and drive consumers towards healthier choices rather than adding paste and powders that promise unrewarding nutrition benefits.

So, it is most critical that as FDA designs its program, the agency consider whether it's labeling strategy will create more clarity on what's in products and not in them, thereby helping to encourage consumers to fill up most of their grocery carts with fresh fruits and vegetables that bare no labels at all. FDA can address these problems by restricting harmful and misleading claims and by wielding a clear and powerful vision of a better market place for consumers and companies alike.

So, I'll next turn to some of the specific questions posed by FDA on modernizing claims. The Commissioner indicated a concern that food companies wait too long to secure FDA approval of health claims and that this impedes innovation. Yet, in our review, the problem is not a paucity of claims, but instead is that packages sometimes include meaningless and taken on the whole, misleading and deceptive claims.

We would therefore urge FDA to review the most frequently employed labeling claims with implications for public health, including the use of misleading images of whole fruits and vegetables when they are used only for flavoring, the misleading titles for categories of food that are actually fairly unhealthy or are minimally nutritious, like veggie sticks or fruit snacks and so on. FDA should consider whether taken as a whole, such labels, images, or claims are misleading or deceptive, and use its full range of regularly options including enforcement (and I was happy to hear the Commissioner mention that this morning) as well as developing new clarifying guidance or rules.

For example, FDA could require foods that make fruit and vegetables claims to disclose the quantity of each fruit and vegetable pictured or named on the label

per serving in household measures. For example, contains two teaspoons of berry puree and a half a teaspoon of cherry puree per pouch.

In industry, self regulatory body run by the Council of Better Business Bureaus administers the children's advertising review unit and evaluates child directed advertising to advance truthfulness. In 2016, CARU recommended that Kellogg remove "made with real fruit" claims from its fruit-flavored snacks and make other changes. The box on the right -- on the right, yes, is the result of that action, indicating that it is fruity snacks and made with fruit puree instead. A small change, but we think it actually provides more information to consumers and makes these look less like a substitute for real fruit. We think FDA could follow CARU's lead on this and also include the amount of fruit in a serving.

As a housekeeping matter and keeping with promises made in the Nutrition Fact Panel rule, FDA should also update the disqualifying levels on health claims to include limits on added sugars which we do see high in many foods.

We're also specifically concerned with the opportunity for increasing consumption of high value ingredients, like, whole grains. Virtually everyone eats packaged bread, cereals, and alike, rather than preparing them at home. And so, grain labeling on processed foods is an important or promising area for clear clarity for consumers. The DGA indicates that at least half of grains should be consumed whole. Yet, we under-consume whole grains, and overconsume refined grains. Currently, labels fail to make clear how much of grain in a product is whole. While companies may be innovating to create products with whole grains that appeal to consumers, these innovations are blunted by the fact that consumers can't tell how much of the grain is whole or refined.

We looked into wholegrain white breads, as a recent example. We have six very gifted interns who are going to indulge me by letting me embarrass them publicly. They are public policy and law interns and we asked them to order a group of six bread products to

see among the wholegrains claims, whether they could tell how much had the most or least whole grain or refine grain content. And they couldn't tell. They got it wrong. So, I would think the ordinary consumer would also probably make a similar mistake. There's also problems with serving differences, so in some breads, the serving size is two slices, whereas another bread, it is one.

In an online 2011 survey that we did, we found the majority of consumers who were shown the front of packages with wholegrain claims believe that more than half the grain in the product was whole, even when refined grain was the first ingredient. Terms like, "wheat", "multigrain" or "stoneground", also led more than half of consumers think that products were mostly whole grains.

So, we would propose that for any product that make an implied or overclaim about whole-grain content, multi-grain, et cetera, the FDA require a declaration of grains in an explicitly explained serving size, including the number of servings in a slice, to indicate both the amounts of whole and refined grains in a serving, so that consumers can readily compare them and choose the wholegrain content that they desire.

We also think FDA could revise nutrient content claim disclosure so they're more informed at a glance. So, rather than saying in tiny type on the box, as you can see here, "see nutrition information" for example, as this product does, the disclosure would indicate outright that a food is high in saturated fat.

Relatedly, FDA could require a disclosure if a product boasted has zero grams or no trans fat but it is above a certain threshold for saturated fat, added sugars or sodium, as most artificial trans fat is now gone from foods, and this is a nutrient content claim that likely indicates, and misleadingly, in some cases, that a product is healthful, when they actually have high levels of saturated fats, such as this margarine, in which tablespoon -- in which one tablespoon supplies 25 percent of the daily value for saturated fat.

In addition, FDA should define terms, like,

"lightly sweetened," "low sugar," "sort of sweet," "tad sweet," or the like. A reasonable consumer would likely believe that a product label with any variation of this term "lightly sweetened," contains a small amount of sugar, but it has 40 percent of the daily value.

FDA should also further develop enforcement and regulatory strategies limiting fortification of unhealthful foods.

And I should say, you know, we appreciate that these companies that we're showing are operating within the bounds of the law. We're showing these examples to provide examples of where we think consumer confusion might derive from their products.

There's also a plethora of claims on energy which can refer either to calories or caffeine and can be confusing. FDA should require caffeine-containing foods and beverages to disclose caffeine content. And foods that make energy claims, should be required to disclose that "energy" is another word for calories.

Last, we appreciate FDA's interest in using labeling, including a contemplated symbol for healthy foods, to indicate more clearly to consumers which foods are better for them. We support a system for front-of-package labeling and believe that FDA and researchers should conduct testing of a range of labeling system, including the Healthy Stars rating system, used in Australian and New Zealand, which is in the top left corner, and looks similar to Facts Up Front by providing sort of objective cross-category information but also having an interpretive symbol that allows consumers to know within a category, for example, cookies or crackers, what is a more healthful choice.

Front-of-package labeling is particularly important for those we know that use the Nutrition Facts panel less often, including lower social and economic consumers, those with lower numeracy and literacy skills, non-English speakers, harried parents, et cetera.

There's much we can explore over the conversation, including natural and voluntary sodium

guidance, standard of identity, and ingredient list. As CSPI has worked on labeling for so long, it's tremendously exciting to have FDA engaging stakeholders in this way. It's worth noting the enormous educational success of past labeling efforts by FDA, which have become nothing short of cultural icons.

Overall, there's a huge opportunity for greater clarity on foods to impact health. We are grateful that FDA is convening this dialogue and look forward to working with all of you.

MR. WALDROP: Thank you very much to our panelists. I think we need to figure out where we can get some of those dresses for people that are interested. That was -- that was pretty cool.

But thank you again to our panelists for -- for your perspectives. We do have some time now, so I wanted to open it up to the audience. You have -- if you have questions for the panelist, please come to the mics in the aisle and -- and they'd be happy to answer any questions you might have.

All right. Maybe while people are thinking, I'll start off with one. We heard from our first panel, from the NPD Group, about the interest of consumers in nutritious foods and -- and sort of this path to -- pathway to purity, but we also, Neal, you also mentioned that price, taste, convenience are still very important.

So, I was wondering if the panelists might have any thoughts on that -- that balance, and -- and how that, you know, kind of, does that -- is that shifting? Does that balance still exist and -- and how do -- how do food companies then kind of navigate that balance? Any thoughts on that issue?

DR. POST: Yeah. Well, obviously accessibility and affordability are part of the formula. And it -- it is a balance when it comes to sourcing ingredients and -- and staying within your -- the food philosophy that you establish. So, if in fact, you're -- you're a company that produces products -- products or -- with all-natural ingredients, obviously you're going to look for what will fit, how you can formulate at the point of ideation so that

ultimately you can have a product that's going to be scaled for success that still is affordable. And it -- it is a very -- it's a puzzle. And it starts at the point of innovation and ultimately knowing also at the end of it all, who your consumer is. And -- and -- and -- and ultimately, too, where you're marketing.

DR. HOOKER: Can I add just one -- so, that was answered from a brand's perspective. The other player, who isn't presented on this panel, is the retailer, right? So, certainly, it's a cliché to say private label products are always going to be cheaper. They aren't. We're moving, increasingly more, if you want to call it European in style for our private labels strategies, where there are multiple tiers. But retailers can be highly innovative in this space. I think back to a functionable food IFT meeting I was at, where the largest cohort of presenters and active -- active folks in the room were from -- from Target. Right? And Target is 100 percent contract manufacturing player, so they don't have their own facilities. So, -- so I'd encourage you to think through the other player, retailers. So you know, what Kroger does with its private level entry into a particular category could be hugely impactful at various socioeconomical points, right? And certainly -- certainly the value consumer may be much better -- much more impacted if Kroger is choosing its value product to be low sodium.

MR. SILVERGLADE: Yes. All right. Thanks, Chris. I'm Bruce Silverglade from Olsson Frank Weeda --, Terman, Matz for the last eight years. And as Laura knows, I was with the Center for Science and the Public Interest for the past 28 years before that and covered many of the same issues that she covered, uh, this -- this morning.

Over -- over my time in the field, when I first got to CSPI in 1982, I was told to work on -- on sugar, but from the standpoint of dental caries. And at that point, dental caries related to consumption of sugary beverages was a problem, and the dental profession has found other ways to prevent cavities now, and sugar-free is not a major health priority, in

terms of preventing cavities.

Then in the mid-80s, cholesterol -- the definition of low cholesterol became the priority of the public health to consumer communities. And yet, the latest dietary guidelines de-emphasizes the role of dietary cholesterol some 20 years later.

Then in -- around 1985, the commissioner of the FDA was Commissioner Hayes and he had a campaign on sodium. And a few years after that, palm oil became a villain, and companies replaced palm oil with partially hydrogenated oil or trans fats. Then trans fats became the villain and some trans -- partially hydrogenated oils are now banned, but, for the most part, but some companies have replaced them with palm oil, going backwards. Taking a step forward, a step backwards, depending on your perspective. And most recently added sugars is the villain.

And I was wondering if each of the panelists could just briefly comment on -- how -- how do we get away from this approach of -- of the nutrient villain of the day? Which -- which in my opinion, confuses consumers as to what the real dietary message should be. Thank you.

MS. MACCLEERY: Thanks, Bruce. I do think we're operating a place from -- in which consumers have significant confusion and it is an unfortunate context because you often see, you know, man bites -- bites dog, coverage of scientificities (ph) that may or not -- may not be keeping with the robust body of evidence.

But for us, at CSPI, our North Star is the Dietary Guidelines for Americans, and when you look at the long-term trends over the DGA's history, you find that the -- the core recommendations actually don't shift very much. It's -- you know, we -- we need to eat more fruits and vegetables and more wholegrains, less refined grains, and less sodium, sugar, and saturated fat.

And so -- and to some degree, we do see that consumers take up this message. I mean, I was actually encouraged by the NPD presentation this morning because it shows that consumers are getting the message, and probably are getting asked the wrong questions on fats.

They -- they might understand that total fats is actually something that can include a healthy version of fat and that they should be thinking about saturated fats. So, I would encourage pollsters and folks to keep -- keep pace with the science, which I think consumers are actually paying reasonable amounts of attention to in terms of how they evolve their understanding.

I do think, though, that there a number of places where there -- the trendiness of food labels results in them being kind of misled as -- as a marketing strategy. And again, this is within -- I'll leave it to FDA, actually, to determine whether it's within the bounds of the law -- but, you know, things like gluten free on packages that never went anywhere near gluten -- gluten free juices or gluten free seltzers or something like that. Non-GMO labeling on -- the companies know that these things contribute to a health halo for foods, even when they're not scientifically relevant. And I think at the level of just sheer noise from a consumer perspective, those things are not helpful in creating a scientific dialogue with consumers that's actually going to be necessary for the food industry to continue to innovate and to have consumer trust.

So, you know, I -- I just think having some kind of voluntary disarmament agreement, amongst the food industry where -- you know, the claims that go on foods actually have a scientific relevance to the food in the box would be a huge advance. And that FDA should look at data on what's misleading and deceptive from a consumer perspective and think about what enforcement strategies it has at -- at its disposal.

DR. POST: And from -- from our perspective, you know, it's about simple shifts to nutrient-dense foods. And it's really putting a product, one product, in the context of a total diet. And -- and this gets back to shifting away from that single ingredient, single nutrient focus, which is not aligning with the Dietary Guidelines and Dietary Guidelines talk about shifting to eating patterns that are healthy.

And so, really, the full nutrition package

should drive the purchase. And that actually should be a default. It should be a simple way of thinking, and perhaps through nutrition labeling education, the nutrition facts plus the other information about food group contributions, about foods in the context of a diet, and -- and bridging more closely to the dietary guidelines will -- will result. It's just not the label anymore. There are many channels and multi-channel approach to giving information that's helpful to consumers. And so -- you know, other media or channels should be considered as well in that consumers are getting information in a variety of ways. So, there is an opportunity beyond the label, beyond the package, to provide this information as well.

But to answer the question about that focus on one nutrient, it really needs to bring back the messaging and the education to judge the product in a full context of diet, as well as the full nutritional profile.

MR. WALDROP: I think we have time for one, one more question.

MS. SCHNEEMAN: Yes, I'd be -- I'm Barbara Schneeman. And I'd be interested on comment on two aspects of the standards. One is that there's a regulation that does allow modification of the standard to meet a nutrient content claim or a nutrient claim. And I'm -- I'm just curious, how you see that fitting in with where we are with standards and re-thinking standards.

And the other, and maybe this is more to Rob, the -- as I recall, I think the USDA definition of natural contains the "minimally processed" concept and so it would be interesting to hear comments about how that might apply in an FDA context and how that is actually defined in a way that's meaningful.

MS. MACCLEERY: So, on standards of identity, and -- you can imagine the system has had quite a robust conversation at CSPI. One the one hand, obviously, these provide a certain kind of anchoring effect for consumers in terms of knowing what's in a food, and they shouldn't be abolished without a consideration to how -- they provide those concrete

definitions. On the other hand, where they are stifling innovation, where we might see modest incremental benefits in lowered saturated fat or sodium from the full fat version of, say, cheese, to -- in between that and what is the current standard for low-fat cheese, we think that there's an opportunity there.

And so where we land, is that we think FDA could abolish the milk fat minimums for major cheese varieties and the sodium requirement, and then consider on a petition basis as it has for added fibers whether or not additional ingredients compensate for the loss of those things challenge the standard of identity versus say, cheddar or something like that.

Again, it's a balance of -- of not wanting to create consumer confusion and have transparency for consumers and predictability. But also knowing that, you know, milk fat minimums in the context of cheese may not need to stay at 50 percent for cheddar or what have you, it could be 35 or 42, or something, and that company should be able to innovate in that way.

On the question of natural, we also look to the USDA definition. There are -- we think there are some flaws in it. We -- we favor a disclaimer so that it -- consumers can have a -- clear understanding of what that means. But it should say that it contains no artificial ingredients and it's only minimally processed. And further, that the term "natural" does not refer to whether crops or animals were raised, using pesticides, insecticides, hormones, or antibiotics. You know, and sort of, a long explanation because we see in the consumer data that people are badly misled by this term and yet it is a driver for consumer preferences as we saw from the data this morning.

MS. SCHNEEMAN: It was on the label?

MS. MACCLEERY: On the label as an asterisk.

MS. SCHNEEMAN: Okay.

MS. MACCLEERY: Yeah.

DR. HOOKER: So, a concern I would have with this, sorry, the concern I would have with that is more generally around the same with traffic lights and issues there. Is it going to be category specific or

is it going to be uniform? So, does what defines minimally processed from an FDA's perspective, is it going to be the same for cheese as it is for a cheese pizza. I mean, there are two philosophies, right? One if you're going to use it as a category, guiding towards a category, then you want to have a heuristic that is -- that allows these cross-category comparisons. But then the concern with that is certain categories stand out as having more of a health halo, right? And whether we necessarily want to suggest that is more consistent with DGA approach that is diet based. So, it's --

MS. MACCLEERY: I mean, I'll just state --

DR. HOOKER: -- complicated.

MS. MACCLEERY: Often times "natural" is modifying some component of a more packaged food. So it would say "natural cheese," or something and then you have the -- the same heuristic applying to the cheese in both cases. Mostly, it's not pizza being described as natural.

MR. HOOKER: It's 60 to 70 percent of new packaged products are making a natural claim so, yeah, it's everywhere, I mean, it's all across.

DR. POST: But -- but it --

MS. MACCLEERY: But, it's usually about something ...

DR. POST: I think you need to look closely and it's usually about ingredients and not the entire food. And so that's the judgement, by the way. I mean, so going to the second part of your question, the USDA definition. First of all, I would say that USDA applies it every day. They make judgements in a preapproval mode, so there's something to be learned in preapproval, so obviously you can apply their criteria and have labels approved by USDA. And that's a requirement.

Health Canada has a little bit more of a rigorous aspect as well. It's not only no -- no artificial, no synthetic, no preservatives, those types of ingredients, but it's also, not more than minimally processed. And Health Canada goes a little further in the listing of what is minimal processing as opposed to

more than minimal processing. So that kind of categorization is totally possible. And that's the kind of food philosophy that can be built in to using - - at a company -- in using that term when you source ingredients. And looking through a lot of the information about ingredients, you can make those judgements. It's not - it's not difficult to do. And on the 130.10, the 21 CFR 130.10, which is -- was put in place to allow for more healthful versions, as you recall, as we recall. You know, standardized terms and nutrient content claims.

So, you know, the point there, I think, is that obviously, you know, putting into a regulatory structure, the allowance for some variability exists. I think that shows there's hopefully a path forward that might be similar for new products that are entering the market place.

I -- I think probably an improvement of thought since then is the idea that it could be public-private partnerships that actually get together to look at newer products that are promoting public health, that do fit the dietary guidelines and get them into the market place -- well, that they are in the marketplace, they are prominent, that they are now part of that standard structure in a more nimble and effective way. And -- and hopefully, that's what my remarks had -- had proposed.

MS. SCHNEEMAN: Great. Thank you.

DR. POST: Sure.

MS. MACCLEERY: I'll just make one other comment, which -- since we have so much -- so many folks in the food industry in the room. I do think there's a missed opportunity around this other push, which is driving some of the standard of identity concerns and some of the ingredient labeling concerns around the clean label or notion of purity and authenticity. And companies have responded to those with clean label programs that are largely disconnected from the nutrition programs within the company. We think that's a flaw in the clean label design. We would encourage some kind of cross collaboration between the thinking about food as, you know, pure,

authentic and the thinking of food as healthy.

We think consumers think about them in interchangeable ways. And we also would call -- you know, issue an invitation to the food industry to try to collaborate with potentially the NGO sector among yourselves, on what -- what's a meaningful clean label program and how should that be driven by public health considerations foreground. So, you know, there's only a handful of additives I would say and contaminants that are actually real -- a real concern from a public health perspective. Some of these are addressed by clean label programs and some of them are not. It would be nice to have some kind of industry initiative that actually identifies ongoing systematic efforts to address public health concerns in a coordinated way and to be in dialogue with the public in a way that actually might engender trust as opposed to just kind of thinking about what names sound chemically and having that be the consumer anxiety around the ingredient list. And so, you know, that's something that we're very interested in working -- working on and trying to develop from a public health perspective.

MR. WALDROP: So, we are out of time for this panel, but I think we've primed the discussion quite well for the breakouts later this afternoon, so thank you very much for our panelists. Let's give them a round of applause.

MR. WALDROP: And we'll turn it back over to Kari for our instructions on next steps.

MS. BARRETT: All right. As Chris mentioned, we're actually going to be transitioning now into our first set of breakout sessions. We have three sessions that will be occurring at the same time. What we're going to do is I'm going to give you a little guidance in that regard, then we're going to take a break. And then you're going into that breakout session, and we're going to start right on time at 11:15, okay? Because we're not going to have a lot of time in those sessions and we have a lot of ground to cover. So, please, be in your breakout session room at 11:15.

They will be repeated this afternoon from 2:00 to 3:15, and so if you start this morning and you go

into a room and it's completely full, maybe you can make a different choice this morning and perhaps get that session this afternoon. So, we just ask for some assistance, too, in -- in trying to help with the numbers in the different rooms.

The sessions are, "Claims and Statements used on Food Labels, the Icon for Health." That is in this room, in the Plaza room. That will -- session will be webcast.

Then we have, "The Nutrition Facts Label Consumer Education Campaign" which is in the Regency room, which is down the hall to your right. So, when you exit this room, you will go to the left and then to the right down the hall. If I don't have that -- I'm looking at Juanita, if that's not absolutely correct, I know there's signage to help you get there.

MS. BARRETT: Okay. Thank you. And then we have -- "The Modernizing --" I -- I stumble over this word -- "Standards of Identity, Ingredients Lists on Labels" which is in the Eisenhower room, which is located, I understand, in the restaurant area of the hotel. And again, there will be signage. I just want to note for that session, it's addressing two topics, we're going to start with the "Ingredients Lists on Labels" first and then we're going to move into "The Standards of Identity."

During the breakout sessions, you'll get some instruction as you begin in each room, but I really want to encourage good dialogue among the participants. We have put out some questions, they're in your folder. We'll move through these questions in the sessions. We really want to solicit your ideas, your input, your comments. It's for the benefit of the agency; it's also for your benefit to hear from others, as all of you consider the comments that we hope that you'll be submitting to the docket.

I do want to mention, too, again, in the sequencing, we'll have the break. We'll start the breakout session at 11:15. They will end. Then we have a long lunch period, and then directly after lunch you will go into the next breakout session. So just look at the agenda for where the afternoon sessions will be

held. And, again, a reminder, that we do have the discussion questions in your package. If you're webcasting in, they are posted on our website. And I think with that, we can go ahead and break. So, again, we'll start up the sessions at 11:15. Thank you.

(session break)

MS. BARRETT: All right. Again, if everyone could take seats. All right. We're going to jump in. It's 3:30, and I want to welcome everybody to our open public comment session. We have a number of folks who have signed up to offer public comment this afternoon. And so, now is the -- the opportunity for that. We're here to further listen to comments on the Nutrition Innovation Strategy and the various elements of that.

We have a panel of FDA folks who are up here with me who will be listening to the comments. I'd just like to note who they are. So, next to me we have Doug Balentine, who is our director of the CFSAN Office of Nutrition and Food Labeling. Felicia Billingslea, who is our director of CFSAN Food Labeling Standard Staff, Office of Nutrition and Food Labeling. Steve Bradbard, who is our director of Consumer Studies branch at CFSAN and the Office of Analytics and Outreach. Blakeley Fitzpatrick, who is an interdisciplinary nutrition scientist in the Nutrition Assessment and Evaluation Team, which is part of our Nutrition Program Staff, also in the Office of Nutrition and Food Labeling. And Chris Waldrop, who is our senior Public Health educator in the CFSAN Office of Analytics and Outreach.

And I really want to welcome all of the people, again, who have signed up to give public comment. I thank you in advance for the remarks that you've prepared. I am going to ask folks, and I know you've been given guidance, to keep your remarks to the three minutes. I realize it's not a lot of time, but we do have a large number of people offering public comment and in fairness to the larger group, I know that some people had to cut back on their comments to -- to meet that three-minute mark and so, I really want to be respectful of -- of people's time and their effort to, again, stay within that time frame.

So, with that in mind, I also know sometimes when you're talking and it's not a lot of time, when we get to three minutes, if you've not finished your comments, I would just ask you to wrap up. And at that point if -- if you could just -- just really go ahead and close and certainly put your full comments into the docket. So, I just want to forewarn folks, that there really is attention paid here to the three-minute timeframe.

We will go through basically the list that you have in your packet, but there's always some changes that are made, and so I -- I want folks who are giving public comment to have some sense of where they are in the lineup. What we've did traditionally is we'd sort of have everybody line up and, I mean, how uncomfortable is that? So, we're not going to have people do that. We're going to call you by name and just one-by-one. If this microphone is closest to you, you're welcome to come to this one. If -- if the one that's further to my left is -- is closer, you're welcome to go to that one. But, please, if you are giving public comment, if you can try to be maybe near the end of the row just in a place where it might be easier for you to get up and -- and get to the microphone.

And again, it's not going to be exactly as written, so do listen for the name as we call it out. When you come to the microphone, if you will restate your name and your organization, that is always appreciated.

And I think with that, we can jump in. One other thing I wanted to mention is the panel here really is taking in what you're saying. If there is a need to ask a clarifying remark, just so that they have certainty of what you're saying, there is that opportunity, but, typically there's -- there's not too much dialogue in that regard, but I do want the panelists to know that that is certainly an option for you. And if that's the case, if you'll just press your microphone and -- and give me an indication that there is something you would like to ask.

So, why don't we go ahead and begin and our

first commenter is Jeanne Blankenship, the Academy of Nutrition and Dietetics.

MS. BLANKENSHIP: Good afternoon. Again, my name is Jeanne Blankenship and I'm a registered dietician/nutritionist and the vice president of Policy Initiatives and Advocacy, with the Academy of Nutrition and Dietetics. We represent over 100,000 credentialed dietician nutritionists and nutrition professionals.

We see our role in this strategy as two-fold. First, to contribute to the science and rigor behind food labeling. And second, to help consumers use labels to improve their diets and overall health. We believe consumer education is the cornerstone to the translation of label information into achieved health outcomes and are encouraged by the dialogue on the consumer education campaign.

Consumers must be readily able to understand what label claims mean. There is often a disconnect or lack of understanding on the meaning of terms. Individuals with food allergies and intolerances use food labels in a different manner than other consumers. Ingredients, and even the lack of an ingredient, such as gluten, must be easily identified. It is erroneous to think that those who suffer from these conditions know which foods indigenously contain them and can decipher ingredients without education.

The Academy applauds HHS and FDA's work protecting consumers and improving American's health, notably with the work done in conjunction with USDA on the dietary guideline. One size does not fit all when it comes to foods that are "healthy." With nearly two-thirds of Americans living with overweight and obesity and others facing chronic disease, there is a need for the context of any claim to be within appropriate dietary patterns as suggested by the DGA. But also, meaningful for prescribed therapeutic diets.

We encourage FDA to continue advancing the joint efforts of industry, public health, consumers, and registered dietitian nutritionists that have occurred over the past decade. Again, the potential for label claims to improve health exist to the extent that they effectuate the Dietary Guidelines for

Americans.

We advocate for focus on food -- foods and food patterns, rather than specific nutrients. The Academy recognizes the potential for improved health through reformulated products resulting from the alignment of incentives that improve health and that contribute to product success. The Academy has been a long-time partner of the FDA and is committed to assisting with the dissemination and implementation of the Nutrition Facts Panel and any labeling.

We know that our members play a critical role in helping consumers understand clear, concise, and meaningful labels. Thank you.

MS. BARRETT: Thank you. Thank you for your comment. Next, we have Joe Reardon, North Carolina Department of Agriculture and Consumer Services.

MR. REARDON: Thank you very much. Again, my name is Joe Reardon. I am the Assistant Commissioner for consumer protection with the North Carolina Department of Agriculture and Consumer Services.

On behalf of North Carolina, I appreciate the opportunity to speak and support Commissioner Gottlieb's recent comments regarding the standard of identity for milk. "Milk" is defined by the Pasteurized Milk Ordinance and the standard of identity as established by Regulation 21 CFR 131.110. In both of these, milk is defined as "the lacteal secretion." This, of course, refers to milk that can only be produced by mammary glands. Plant based beverages do not meet the definition of milk. It's just that simple. Milk has a clear definition and FDA has a clear duty to enforce this standard of identity. It's the law.

Consumers expect, and the law requires accurate labeling. If there is "milk" on the label, there should be legally milk in the product. FDA should do no less than enforce the law as it is currently written now. FDA has upheld the standard of identity for milk through warning letters at least three times since 2008, and we applaud them for their regulatory actions. Obviously, the FDA recognizes mislabeling is simply against the law.

Without enforcement of the law and what's written, the validity of all promulgated standard of identity is compromised. Uniformity and consistency of enforcement are hallmarks of any effective regulatory program at the federal government, at the state as well.

Let's be clear here. We are not advocating for the removal of plant-based products from the market. I'll say it again. We are not advocating for the removal of plant-based products from the market. We recognize that these plant-based beverages are a vital option for many consumers due to how they metabolize. However, they should be labeled correctly without the term, "milk," thus allowing consumers to make an informed and educated choice.

We are asking FDA to enforce the law as, again, as it -- as it is already written. I encourage FDA with the support of many others to enforce the standard of identity to milk and require proper labeling of plant-based beverages. North Carolina and other states stand ready and willing to assist FDA in enforcing the current law and assisting industry in coming into compliance.

In summary, if there's "milk" on the label, there must be milk in the product. Standards of identity assure consumers they get what they pay for. But, this is not only true for milk; it would be true for honey, maple syrup, you heard olive oi, earlier, spring water, and it's no less true for milk.

We heard all day the importance of labels and consumer needs and consumer health. It also centers around one thing, and that's truth in labeling. Without truth in labeling, none of the other matters. It doesn't matter what's in the Nutritional Panel, it doesn't matter what's on the label, it doesn't matter what's in the ingredients. Consumers must know that truth in labeling is the foundation of all things to come from. It applies to milk, and it applies to the standard of identify for milk. Thank you very much.

MS. BARRETT: Thank you for your comments. We're now going to have Kim Bremmer, American Dairy Coalition.

MS. BREMMER: Thank you. Hi, my name is Kim Bremmer, and I'm from Wisconsin, and I'm here today representing the American Dairy Coalition and its 30,000 national members.

I'm passionate about debunking farm and food myths. As a tireless advocate and educator for agriculture, I can tell you we all need to do a better job combatting misinformation marketing that's continually bombarding consumers today, especially as they become farther removed from a farm.

Our role in truthful marking becomes more important than ever and it's never too late to do the right thing. Use of the term "milk" on plant-based beverages easily misleads consumers into believing all these drinks are equal in content and nutrition.

Worldwide, there's over 200 countries that do not allow plant-based beverages to be called milk on their labels, including our neighbors to the north in Canada and the EU, where they're called "beverages" or "drinks." You, the FDA, play a critical role in promoting public health by ensuring that food labeling provides consumers with reliable evidence-based information so they can make informed choices about the healthfulness of the foods they purchase.

Following your current standard of identity, used to divide -- used to define the word "milk," specifying from lactating animals, while restricting its use on plant-based beverages is important. But not only to dairy farmers, more so to consumers. Nutrition matters.

I speak to tens of thousands of consumers in my travels every year as a professional speaker. The vast majority believe that plant-based beverages using the term "milk" have cows milk in them and carry the same or better nutrition. When this couldn't be further from the truth. There's absolutely no product on the market that can complete nutritionally with cows' milk. Even though they've all been able to brand themselves as equivalent through this play on words. This has made it confusing and misleading for consumers.

Cows' milk is a powerhouse of nutrition with

eight grams of complete protein per serving compared to one gram in almond milk, zero in coconut, and the list can go on and on. It also contains nine essential nutrients. Those crucial nutrients that your body requires for cellular function that you need to consume every day. There's no other drink available packed with as much nutrition as one eight-ounce glass of cows' milk. None.

There's a national education program called, "Food for America" where fourth graders visit farms to learn about where their food comes from. I have volunteered for 17 years presenting a nutritional, "Think your Drink" breakout for thousands of kids. When I asked them how many glasses of milk they should be drinking every day for optimum health according to the USDA MyPlate nutritional recommendations, this is the first year I had to specify milk from a cow.

The majority of kids referenced the almond, coconut, pea, oat milks they drink instead. After our session of reading labels and talking through the nutrition, I love to watch all the kids connect the dots, ask the right questions, and come to the same conclusion by the end of our discussion each and every time. There is no comparison.

Do we all need to a better job for consumers? Absolutely. My beloved dairy industry shares in the blame. We need to better educate and connect our consumers. We need to do a better job in innovation and packaging. We need to get what we produce to the people who need it most. One in five kids in our country is food insecure. Five out of six adolescent girls are deficient in calcium. Shame on all of us.

Ultimately, we need to do a better job on nutrition education, but we need your help. Stop the misleading labeling, follow your current standards to help protect the integrity and identity of milk, because nutrition matters. Thank you.

MS. BARRETT: Thank you. Kristen Scott, Grocery Manufacturers Association.

MS. SCOTT: Good afternoon. My name is Kristen Scott. I'm the director of health and nutrition policy at GMA.

The Grocery Manufacturers Association is the leading trade association for food and beverage and consumer products manufacturers. Our member companies are committed to providing tools, information and options to help consumers develop a health diet.

We look forward to working with FDA on our shared committed to developing and implementing a policy framework that facilitates the choice of healthier options and incentivizes innovation in -- in manufacturing. We are pleased to see that the strategy will modernize the framework of labeling claims, strengthen food standards of identity, and help consumers better understand labels and ingredient information.

As the FDA considers new or enhanced labeling claims that could facilitate innovation and promote healthy eating patterns, GMA looks forward to working with the agency to develop a robust claims framework in light of involving nutrition science and dietary guidelines. Working with industry on such a framework, would not only facilitate innovation but would also assist FDA with the development of future definitions of claims while identifying feasible compliance time frames to limit regulatory burden.

GMA encourages the agency to develop a standard mechanism to help streamline the regulatory process, including establishing a standard response time for the review of qualified health claims and enabling more consumer-friendly language to increase utilization of these claims in the market place.

GMA knows the FDA is considering using a standard icon to denote the claim "healthy" on food and beverage labels. GMA urges FDA to consider testing proposed icons with consumers to ensure they understand the icon's meaning and trust that it provides useful information.

GMA encourages FDA to rapidly advance work on an updated science-based definition of "healthy." A definition based both on nutrients and food groups has a potential to -- to spur innovation and provide broader access to foods aligned with healthier dietary patterns. GMA urges FDA to initiate the rule-making

process to update this criteria.

Consumers are increasingly basing purchasing decisions on length and wording of ingredient statements on food and beverages. GMA is supportive of efforts simplifying nomenclature and ingredients statements and adopt language that is easily understandable and does not negatively impact consumer's food and beverage choices.

GMA looks forward to working with the agency on their efforts to modernize food standards of identify. The dated and inflexible nature of food standards often is an impediment to innovation because of the notice-and-comment rulemaking required to change each standard. GMA encourages FDA to consider an approach for modernizing food standards that operates the tandem with current standards but allows for flexibility within agreed upon parameters, such as non-characterizing ingredients.

GMA believes it is imperative that FDA develops a robust consumer education campaign to encompass all aspects and changes to the Nutrition Facts Label and provide consumers with appropriate nutritional guidance based on an overall quality of diet while supporting education on calories and portion sizes. GMA represents a large number of food manufacturers with access to market research and understanding a consumer's needs across a broad array of foods and would be happy to offer this expertise to the agency throughout the development.

We applaud the agency's plan for their multi-year international -- excuse me -- Nutrition Innovation Strategy. We are grateful for the opportunity to provide these remarks today and we look forward to working with the agency throughout the process. Thank you.

MS. BARRETT: Okay. Thank you. Our next speaker is Anne Thorndike, American Heart Association.

MS. THORNDIKE: Good afternoon. Thank you for the opportunity to present the views of the American Heart Association. My name is Anne Thorndike. I'm a general internist at Mass General Hospital and an assistant professor of medicine at Harvard Medical

School. I am also the vice chair of the AHA's Nutrition Committee.

Proper nutrition is essential to cardiovascular and overall health, and therefore, helping Americans to make healthy eating choices is a top priority of the AHA. We look forward to working with the FDA to find new ways to reduce the burden of chronic disease through improved nutrition. The good news is that consumer demand for healthier choices -- healthier food choices is on the rise. A recent consumer survey found that health and nutrition is now only second to taste as the most important attribute when selecting foods and beverages, now, surpassing value for money. However, the data also shows that consumers are confused about what is healthy. And this is a major barrier to making healthy choices.

A standard healthy icon will not only help consumers more easily identify those products, but also encourage the food industry to make a wide -- wider variety of healthy options available. But the FDA must first update the strength in the "healthy" definition.

The "healthy" claim or icon should only appear on foods and beverages emphasized in a healthy eating pattern, as recommended by the dietary guidelines. Food should also be required to meet limits for saturated fat, sodium, and added sugars, and contain a minimum amount of beneficial nutrients. A combined food and nutrient-based approach will ensure that foods cannot qualify for the icon simply because they have been fortified or enriched.

Consumer education about the new icon will also be needed. AHA is conducting a short survey with the International Food Information Council Foundation to gauge consumer knowledge in this area, and we look forward to sharing insights with the FDA as soon as it's available.

We understand the FDA is also looking at the review process for qualified health claims. We agree that the process could be streamlined. We support prioritizing health claims based on their public health significance, impact on health outcomes, and the science base. But FDA must ensure that changes to the

process do not weaken the science or result in false, misleading, or confusing claims. This is especially important because research shows that the majority of consumers believe a health claim if it appears on the package label.

We also update -- support updating the standard of identity. Current standards are outdated and do not reflect current technology or new and novel ingredients designed to improve the nutritional value of foods. Updated standards will provide the food industry flexibility to incorporate new ingredients and, in some cases, reduce less desirable ones, such as sodium and saturated fats. Updated standards could also allow for an increase in positive attributes, such as more fruits and vegetables in a wider variety of foods.

Finally, we thank the FDA for calling sodium reduction the single-most effective health action related to nutrition. We agree. And we urge the agency to finalize the voluntary sodium targets as soon as possible. Reducing sodium in the food supply will improve the health of all Americans.

Thank you for the opportunity to present the view of the American Heart Association.

MS. BARRETT: Thank you. Next speaker is Kristin Reimers, ConAgra.

DR. REIMERS: Hello. I'm Dr. Kristin Reimers, director of health and wellness at ConAgra brands, a leading manufacturing company in North America and proud owner and originator of the Healthy Choice brand.

Our commitment to the healthy definition traces back 30 years when Healthy Choice frozen meals first appeared in the market place. Healthy Choice remains the leading brand of frozen meals today through a continuing effort by our company to keep the meals relevant for consumers.

My comment today centers around our ambition for even great relevance and demand by consumers for healthy foods, that could be unleashed through an updated definition of "healthy." ConAgra commends and supports FDA's efforts to update the definition of "healthy" to reflect certain science. An updated

definition has the potential to help motivate the introduction of more healthy food into the marketplace and allow easier identification of these foods by consumers. This is an important step toward improving the dietary patterns of Americans by making healthy foods more appealing and accessible to all.

FDA has proposed the use of an icon to identify healthy foods. This is a laudable idea that may help differentiate those foods that meet the healthy criteria in a way that is more noticeable and distinctive than use of the word alone. While we would support and even assist with exploration of consumer response to an icon, we feel strongly that the agency needs to prioritize completion of its review and update of the current definition of "healthy" ahead of an icon concept being pursued.

Our vision for the "healthy" definition is to focus more squarely on the beneficial food groups and components paired with flexibility and nutrients to limit. The rationale for this approach is to bring in line the definition of healthy to reflect current science suggesting the dietary patterns, more than individual nutrients, are related to positive health outcomes.

Updating the definition of "healthy" will open the door for innovation that will allow more Americans to identify, purchase, and consume foods that will improve their diet patterns. This is a small, but significant step towards success of FDA's Nutrition Innovation Strategy.

We look forward to continuing to work with FDA on the implementation of the Nutrition Innovation Strategy and specifically on the "healthy" definition and icon exploration. Thank you.

MS. BARRETT: Thank you. Our next speaker is John Hoffman, Food Allergy Research and Education.

MR. HOFFMAN: Hello.

MS. BARRETT: Hi.

MR. HOFFMAN: John Hoffman, associate director of advocacy for food allergy research and education.

The recently published Nutrition Innovation Strategy is a welcome step towards increased

transparency about ingredients and enabling better consumer education and awareness about the food that they eat. As this country's largest patient advocacy organization representing the 15 million Americans with life-threatening food allergies, food allergy research and education is focused on finding a food labeling structure that allows families to have the clear and precise information they need to consume products safely.

The Food Allergy Labeling and Consumer Protection Act of 2004 improved the labeling requirements for the top eight allergens: milk, egg, peanut, tree nuts, soy, wheat, fish, and crustacean shellfish. The law required that those allergens are addressed either in the ingredient list by their common name, or by using a contained statement nearby. This rubric has been very helpful to our community, yet, there is room for improvement, and here -- here are three ways.

First, in keeping with Commissioner Gottlieb's stated interest in ingredient disclosure and consumer awareness, there is concern about the use of the term "non-dairy." Under current regulations, the FDA's non-dairy definition permits inclusion of milk protein which can cause anaphylaxis for a person with milk allergies. In the food allergy community, calling a product "non-dairy" can lead a milk-allergic consumer to mistakenly believe the product is safe for consumption. Although the law requires a plain English inclusion of the allergen on the label, a layman reading of "non-dairy" would infer that the product contains no dairy, or dairy derivatives. In alignment with the stated goals of the FDA to empower consumers to be more aware about the food that they eat, FARE believes that any food containing milk protein should not be allowed to be labeled as non-dairy.

Secondly, closely related to this issue is allergen-free labeling. Product packaging sometimes bears iconography or text conveying that an item is free from a particular allergen. For example, think of a peanut with the universal ban sign through it and the phrase, "peanut free." Yet, some products bearing this

very image also include the warning that the product may contain peanut. Applying some regulatory standards to the phrase "allergen free" could ensure that the products cannot call themselves "peanut free" if there is a risk of allergen, cross-contact conveyed on that same package.

Lastly, FARE asserts with the large number of different cautionary labeling statements presently used is confusing to the food allergy community and therefore misleading. FARE urges FDA to use its authority under the misbranding provisions of Section 403 of the Food Drug and Cosmetic Act to publish regulations that protect food allergic consumers from confusing and misleading statements about allergens on food labeling.

Data shows that significant consumer confusion about allergic cross-contact risk, which is understandable, considering that some companies choose to use "may contain" statements, while others warn of "shared facilities" or products that are "processed using same equipment" as other products that contain allergens. The FDA should specify a small number of cautionary statements with clearly defined, consistently applied meanings to indicate whether a processed food that is not intended to contain major food allergens, may contain them due to manufacturing process.

FARE would be pleased to work with the FDA to develop specific language suggestions because accurate labeling is critical to allow consumers managing food allergies to make an informed and safe choice about the products they purchase and feed to their families.

Thank you for your -- your time and the opportunity to speak about this issue.

MS. BARRETT: Thank you. Next, we have Kristi Muldoon-Jacobs, the United States Pharmacopeia.

MS. JACOBS: Good afternoon. My name is Kristi Muldoon-Jacobs and I'm a director in the external affairs division at the United States Pharmacopeia. I'm also a food scientist and toxicologist with first-hand experience evaluating critical issues associated with ensuring that food is

safe and healthful for consumers.

USP's mission aligns closely with that of FDA, ensuring that safe quality food ingredients are available along with adequate information for informed decision making by manufacturers, suppliers, and consumers. We are an independent scientific non-profit public health organization devoted to improving health through the development of public quality standards for medicines, foods, and dietary supplements. These standards are developed through an open, transparent process that relies on the strong collaboration and commitment of FDA industry and the public.

All elements of food safety are essential to public health as demonstrated by the recent food outbreaks. Consumers deserve access to authentic, safe, quality foods, free from microbial contamination and access to reliable information that enables health choices.

Our comments today focus on FDA's interest and standard of identity. Specifically, their role in helping establish that food ingredients are, in fact, what they are represented to be, thereby, enabling consumers and manufacturers to make informed choices. In an increasingly global supply chain, standards serve as benchmarks for quality and purity that apply to food ingredients, regardless of their origin. USP shares FDA's dedication to innovation and sound scientific decision making to advance public health in the food space. Standards of identity and quality that are relevant and continually maintained, help support industry advances by reflecting the latest developments in science and industry. We commit to working with FDA industry and the public to help achieve this important objective.

Standardization also provides benefits in the naming context. The ingredient name and label are connected components in achieving quality. Monographs, such as those in the Foods Chemicals Codex, link the standardized claim language name with key identity and quality attributes. The basic principle behind this system is the ingredients that share the same identity also share the same standard name. In the absence of a

commonly accepted name and standard, it is difficult to ensure that an ingredient is what it claims to be. For example, ingredients, such as sugar, honey, and olive oil can vary in identity causing confusion for consumers.

Thank you for this opportunity to comment. Consistent with our shared public health mission, USP stands ready to continue this dialogue with FDA and industry and seeks to do this in a way that will have the greatest impact.

MS. BARRETT: Okay. Thank you. Kris Sollid, IFIC.

MR. SOLLID: Good afternoon. On behalf of the International Food Information Council Foundation, I'm Kris Sollid, IFIC's senior director of nutrition communications.

One of the objectives of the IFIC Foundation is to elevate the understanding of American eating habits through consumer research, which we've been conducting for three decades. IFIC Foundation commends FDA's renewed efforts to convey clear and accurate health and nutrition information to the public. We believe our consumer research findings can be valuable to the agency as it develops innovative strategies to help consumers better understand food labels and the importance of their food choices.

The agency, as you've heard, will be interested to know that we are conducting an upcoming survey in collaboration with the American Heart Association on how consumers use food labels to define "healthy." And also, next month, we expect to make public our survey on parents understanding and attitudes about feeding the 6 to 24-month age group.

Several of our studies underscore the broad idea of consumer confusion. In our 2018 Food and Health survey, 80 percent of people reported noticing a lot of conflicting information about what they should - - about what they should eat or avoid, causing about 60 percent to doubt their food choices. The updating of food labels provides an opportunity to share objective, fact-based information that empowers Americans to have more confidence in their food choices.

IFIC Foundation surveys have repeatedly shown that most people regularly consult Nutrition Facts Labels, mostly to compare between products or determine whether a product is a healthy choice. But the definition of "healthy" is personal and consumers use more than nutrition facts, often their food values, to evaluate healthfulness of foods. For example, our Food and Health Survey presented all participants with the same Nutrition Facts Label, while burying other factors. This exercise revealed that even when Nutrition Facts Labels are identical, most people say that a fresh product is healthier than a canned one; a shorter ingredients list is healthier than a longer one; and non-GMO is healthier than GMO. Variables like cost and purchase location impact perceived healthfulness as well.

These perceptions and more could be addressed as part of broad communication and education campaigns. We're happy to hear that the agency is looking for feedback on simplifying the terminology used in an ingredients list to make labels clear and easier to understand.

Our 2018 survey shows that a top factor in food purchasing decisions is whether or not people can recognize ingredients. An example of a potential benefit to simplifying food label technology comes from our 2016 survey where 83 percent of consumers describe Vitamin C as healthy, while only 21 percent said the same about ascorbic acid.

Consumer education efforts about food and nutrition are a large undertaking, and we recognize that the agency will need many partners to make their successes -- their campaigns a success. The IFIC Foundation is excited to hear FDA's plans and welcomes any opportunity to support the agency in achieving its goals. Thank you.

MS. BARRETT: Thank you. Our next speaker, Keith Nelson, SmartyPants.

MR. NELSON: Hi. My name is Keith Nelson. I'm the vice president of Quality Assurance and Regulatory Affairs at SmartyPants Vitamins. On behalf of SmartyPants Vitamins, I'd like to thank you for the

opportunity to participate in this meeting and provide public comment on the Nutrition Innovation Strategy.

SmartyPants is a leading preventative health nutrition startup focused on providing premium, all-in-one supplements for kids and adults. We support the FDA's commitment to finding new ways to reduce the burden of chronic disease to improve nutrition. And we agree with the agency that improvements in diet and nutrition is one of our greatest opportunities to have a profound, generational impact on health -- human health and on reducing health disparity.

We are an industry ally developing innovative products and strategies to achieve these ends and, as such, we are acutely aware of the need to implement this strategy thoughtfully and with the upmost transparency. As a result, we're concerned that the proposal to change ingredient labels will be detrimental to consumer transparency and our industries, specifically, with regards to dietary supplement labels, and believe it will negatively impact consumers' ability to make informed decisions about their health. For example, if companies only list B9 in their labels, versus listing folic acid or methyl folate, this could lead to uniformed health decisions and consumer distrust as these two versions of B9 impact populations must differently.

We understand that the scope of FDA's mission goes well beyond dietary supplements; however, we urge the agency to consider the unintended and adverse consequences that may result if dietary supplements continue to be included in the scope of this policy change.

Dietary supplements, in particular, serve a population that seeks specific ingredients to round out their nutritional profile. These are informed consumers who rely on detailed information to make their decisions about what supplements to take in order to ensure that nutrition is optimal, working towards an improved diet and improved health. In addition, our industry has worked extremely hard to overcome the public's distrust of supplement products through our collective commitment to transparency.

We believe that any change that may limit the information shared with consumers would be a huge step backwards and would offset any potential benefits that the label simplification would provide. Recognizing the uniqueness of the supplement industry, FDA regulates dietary supplements under a different set of regulations than those covering conventional foods. We are requesting that the agency continue to honor this distinction in this instance and carve out dietary supplements from the proposed changes regarding ingredient labels.

We believe the best way to work towards shared goals and improve health outcomes is to continue providing the upmost transparency regarding dietary supplement ingredients so that consumers are able to supplement their diet with the specific nutrients they need.

Thank you, and we look forward to working with the agency as this policy is developed and refined to best protect and advance public health.

MS. BARRETT: All right. Thank you. Our next speaker is Cecilia Richardson, National WIC Association.

MS. RICHARDSON: Good afternoon. Cecilia Richardson from the National WIC Association. I'm the vice president of Nutrition Programs and Administration with the organization.

The National WIC Association, NWA, is the non-profit education arm and advocacy voice of the Special Supplemental Nutrition Program for Woman, Infants, and Children, WIC. WIC serves over 7 million mothers and young children to 10,000 clinics a month. Nutrition education is a cornerstone of WIC.

FDA's Nutrition Innovation Strategy presents a critical opportunity to help with participants understand what is in the food that they eat. NWA supports: (1) Updating the definition of the term "healthy" as an implied nutrient content claim on food packages. The definition of the term, "healthy" must be revised to reflect dietary guidelines, recommendations, and nutrients on the new -- new Nutrition Facts Panel. The most concerning gaps in the

current definition of the lack of the limitation on added sugars, the lack of requirements that grains in grain-containing foods be wholegrain, and a lack of clarity on foods that exceed the total fat limit. FDA should address these gaps and strengthen the healthy definition so that the claims steers consumers towards more wholesome foods; (2) NWA supports the FDA's Consumer Education Campaign about the updated Nutrition Facts Panel. Education and food labeling are particular -- is of particular importance to WIC. FDA's education campaign about the Nutrition Facts Panel when they both program participants to make informed decisions when purchasing packaged foods are a step towards WIC's mission to safeguard the health of the participating families; (3) NWA supports FDA's interest in developing a front-of-package labeling system. In 2011, the National Academy of Sciences Engineering and Medicine, formally known as the IOM, recommended that FDA develop, test, and implement a standard front-of-package label system for foods and beverages. They conclude that that specific subpopulations, including low-income groups, minorities, and parents, all of whom comprise of the WIC population, might benefit from a system that is specifically designed to capture the attention and address their health needs.

In closing, NWA greatly appreciates opportunity to weigh in on the commissioner's Nutrition Innovation Strategy and applauds FDA's effort to make healthy eating an easier choice for the nutritionally at-risk population that WIC serves. Thank you.

MS. BARRETT: Thank you. Our next speaker Eli Briggs, National Association of County and City Health official.

MS. BRIGGS: Good afternoon. I'm Eli Briggs, senior government affairs director at the National Association of County and City Health Officials, or NACCHO. NACCHO is the voice of the nearly 3,000 local health departments across the country and our members create and promote conditions that make it easier for people to be healthy. Many local health departments have been leaders in making sure that people in their

communities have the information they need to make healthy choices.

As we've been talking about today, about half of all American adults have one or more preventable chronic diseases, including cardiovascular disease, high blood pressure, type 2 diabetes and cancer. Many of these are related to poor diet and eating patterns and food environments likely contribute to the increasing epidemic of obesity and chronic diseases.

In order to protect the public's health, NACCHO supports full disclosure of nutritional content of all manufactured and processed food, and the implementation of the new Nutrition Facts labeling. The new proposed labels are easier for consumers to understand and use and provide critical information that they need to make healthy food choices. However, consumers will need help to understand the new labels and how to use them to make healthy choices. In addition, FDA should swiftly finalize its draft guidance on disclosing added sugars to assist companies in adopting the new Nutrition Facts Label.

Thank you for implementing the new -- the menu labeling regulations earlier this year. NACCHO and local health departments have long supported menu labeling as a tool for consumers to take control of their health. Our members are working to enhance menu labeling by conducting campaigns to educate consumers on nutritional content of foods and how to make healthy decisions. The information provided by menu labeling will not have the intended effect without a health literacy campaign. NACCHO is glad that the FDA is planning an awareness and education campaign for menu labeling and looks forward to working together to disseminate this information.

And finally, on the issue of sodium, as Commission Gottlieb has said, reducing sodium in the diet is the single-most effective health action related to nutrition. NACCHO agrees that reducing levels of sodium consumed by the American public would have significant health benefits and calls on the agency to finalize the two-year sodium reduction targets by the end of 2019 given the urgent need to reduce the harm

from excessive sodium in foods. The FDA should include reduced sodium products in its baseline calculations for determining the two-year targets to better represent the current sodium concentration and the food supply.

The upper bounds for categories should be maintained because they provide specific guidance on individual products and because they ensure that all foods do not contain unsafe levels of sodium. The maximums also enable consumers and health officials to identify foods with excessive sodium and to determine whether companies are complying with this element of the program. And the FDA should maintain the existing timeframe for the short-term targets, given that the targets were based on existing products in the marketplace in 2010 with the lowest sodium concentrations in each category. And the FDA should finalize its ten-year sodium reduction targets as soon as possible.

Thank you for your attention to these comments on behalf of local communities.

MS. BARRETT: Thank you. Our next speaker, Lee Sanders, American Baking Association.

MS. SANDERS: Good afternoon. My name is Lee Sanders. I'm the Senior Vice President for Government Relations and Public Affairs for the American Bakers Association representing wholesale bakers and our suppliers.

Thank you for the opportunity to speak briefly today to share ABA's comments on FDA's Nutrition Innovation Strategy and to highlight three key priorities of interest for bakers.

First, ABA agrees with FDA that there is a tremendous opportunity to positively advance public health through consumer education with clear, concise messaging. As industry and FDA proceed with implementation of the Nutrition Facts Label, we would be happy to partner with FDA on its efforts to engage and educate a broad variety of consumers.

One example of a successful partnership is the USDA MyPlate National Strategic Partnership where USDA created a platform for trade organizations, food

companies, and retailers, to participate with USDA in creative and interactive messaging for consumers. This ongoing effort has bolstered online and social media channels with attractive and creative approaches to make nutrition learning fun and easy. ABA encourages the FDA to establish a similar partnership model. Also, the Food and Beverage Issue Alliance, which ABA co-leads with American Frozen Food Institute, has one of its guiding principles to serve as a resource and partner with FDA on consumer education on Nutrition Facts Label consumer messaging.

Second, as FDA considers a more efficient review strategy for evaluating qualified health claims, ABA encourages the agency to consider simplifying and shortening the cumbersome language required, currently required, to make a claim or linking claims to an icon. Claims to be utilized by food manufacturers on the package, a simpler, shorter, easier to understand packaging communications strategy is needed. As an example, in 1998 ABA recommended that for the folic acid health claim, FDA used a healthy baby symbol, coupled with a shorter, simpler, concise statement. The existing mandatory folic acid health claim language is not used on food labels because it may appear overly technical to the average consumer, and it takes up significant space on packaging and as a result, bakers don't use this claim on their packaging which is a lost opportunity to positively educate. Bakers support Commissioner Gottlieb's initiative to use clear, concise messages. And we encourage use of positive voluntary symbols for health claims to assist consumers and assist food manufacturers in communicating.

Lastly, ABA voices are support for standard of identity modernization. Historically, ABA has been supportive of repealing outdated -- outdated standards, such as the frozen cherry pie standard, and modernizing bread standards to allow for innovation for bakers. The ABA has on more than one occasion petitioned the FDA to take such actions in 1997 and then again in 2005. ABA's petition sought to simplify the standards by deleting extemporaneous language and requiring that only characterizing ingredients be listed in the

standard. ABA appreciates FDA issuing the request for information to prioritize which potential standard of identity should be modernized on their public health value. It's important for the standards not to stifle innovation and to provide opportunities to develop new products with optimal nutritional benefits for consumers.

In closing, ABA, again, thanks FDA for the opportunity to comment today and looks forward to partnering with FDA, moving forward, to take action on the elements of this key initiative. Thank you.

MS. BARRETT: Thank you. Our next speaker is Gabby Rothschild, Consumer Reports, Consumers Union.

MS. ROTHSCHILD: Good afternoon. I'm Gabby Rothschild on behalf of Consumers Union.

Consumers Union, the advocacy division of the independent non-profit member organization Consumers Reports, welcomes the opportunity to provide input on the FDA's Nutrition Innovation Strategy. Since 1936, Consumer Reports has worked side-by-side with consumers for truth, transparency, and fairness in the marketplace. Providing consumers with clearer, more accurate, and more useful information about their food, has been a core part of this mission since our founding.

Just within the past year, CR helped consumers decipher the meaning of various food labels, identify healthier foods in the supermarket, learn about ways to cut back on added sugar and sodium and understand the latest scientific research and a variety of nutrients. We've advocated for mandatory menu labeling by chained food outlets which we are very glad the FDA is now implementing. We've also sought revisions to the Nutrition Facts Panel and other health-related labeling as well as new food policies to reduce sodium.

The Nutrition Innovation Strategy is an opportunity to make meaningful, lasting change in the lives of consumers. It can help ensure that Americans have plenty of affordable and healthy food options, including fruits and vegetables, wholegrains, and dairy products low in saturated fat. It can also help consumers better understand through simple and

straightforward information the nutritional value of different foods.

As food companies compete on the basis of nutrition, the marketing and other information presented to consumers can help drive a virtuous cycle, that both improves consumer's health and the corporate bottom line. But this is only possible if reasonable, responsible guardrails are in place in the form of strong standards and diligent enforcement.

Today, however, consumers who want to make healthy choices must -- must often grapple with confusing, deceptive, and meaningless nutrition claims. Foods that are falsely or misleadingly presented as nutritious, or those whose poor nutritional value isn't disclosed, can lead to preventable, weight-related and diet-related diseases.

If standards and enforcement are weak, and food companies are permitted to betray consumers trust, companies may profit, but consumers and our country end up paying the price both in terms of health outcomes and medical costs.

As the Nutrition Innovation Strategy moves forward, the FDA, industry and other stakeholders will have numerous important decisions to make. We urge the agency and everyone in the room to be guided in their decisions at the promise of a food marketplace in which Americans can far more easily make healthy choices for themselves and their families.

At Consumer Reports, we look forward to working with you to advance this goal. Thank you.

MS. BARRETT: Thank you. Our next speaker is Guy Johnson, McCormick Science Institute.

MR. JOHNSON: I hope everybody in the panel writes this word down: Flavor.

MS. BARRETT: All right.

MR. JOHNSON: Hi, everybody. I'm Guy Johnson from the McCormick Science Institute, and really today's meeting is all about helping people eat healthier. And there's clearly work to be done because I don't know about you, but I have trouble meeting the Dietary Guidelines for Americans, and I think that most other people do, too. And you know what the biggest

barrier to that is? It's the perception that healthy foods don't taste good. It really is. Yet, taste is almost completely ignored in the development of dietary guidelines and food labeling regulations for that mind.

For example, the current dietary guidelines use the word "healthy" 426 times. Do you know how often it uses the word "taste"? You've guessed it, nada. But taste may not be the enemy. There's accumulating signs that shows that you can make healthy foods more appealing and increase the consumption with -- by adding taste, and you can do it without adding sugar, fat, or salt.

For example, research funded by the McCormick Science Institute has shown that spices and herbs have helped free-living people, free-living adults lower their sodium intake by about 1,000 milligrams per day during a five-month period. We have acute studies that show that you can make foods lower in fat, calories, and some foods lower in added sugar taste better by adding spices and herbs. And the right combination of spices and herbs can actually increase the selection and consumption of vegetables in the real-world cafeteria settings.

It doesn't have to be all about spices and herbs. There are other ways to add flavor without adding sugar, fat, and salt, but the bottom line is, MSI believes it's time to change the paradigm. We believe that public health can best be served by factoring in taste as we develop labeling regulations and dietary guidelines. Not to compromise the science, but to make it easier and more enjoyable for consumers to eat a healthier diet, because all the healthy foods in the world don't do any good unless people eat them. Thank you so much.

MS. BARRETT: Thank you. Our next speaker is Meredith Whitmire, Defeat Malnutrition Today. Is Meredith here? Okay. We'll -- we'll move on, Sonia Hartunian-Sowa. I'm not saying that correctly, DSM, National Products.

DR. HARTUNIAN-SOWA: I'll introduce myself. So, my name is Dr. Sonia Hartunian-Sowa. And I'm here on behalf of DSM Nutrition Products which its

headquarters in Parsippany, New Jersey.

In support of FDA's interest to innovate and make labels more readable and understandable, DSM puts forward their citizen's petition entitled, "Simplified Vitamin Naming Convention." The Citizen's Petition was submitted in October of 2017 and has received widespread support across the food and supplements industry. In the Citizen's Petition, DSM requests FDA to allow for the use of simple vitamin letter names on the Nutrition and Supplement Facts Panel and ingredient declaration lines in place of the chemical vitamin name.

At present, regulations require that most vitamins be listed as their chemical name and there are only a few exceptions where synonyms are allowed. Consumer research has shown that the average American is not aware of the chemical names of vitamins and perceive the name as less healthy as compared to just simply the letter. This was confirmed in a survey that was sent out to 1,049 constituents across all 50 states. In the survey, the participants were randomly presented with 15-letter names, vitamin names, either the chemical name or the letter name, and asked to rate the healthfulness. In nearly all cases, consumers rated the simple letter name as just vitamin A or B1, or B2, or D, as simply more healthful as compared to their chemical name.

And similar to the IFIC data, the studies show that 91 percent of consumers surveyed rated vitamin C as more healthful as compared to only 33 percent rated ascorbic acid as healthful. Similarly, 87 percent rated vitamin E as more healthful where only 14 percent rated Alpha-Tocopherol acetate as healthful.

So, it shouldn't be more surprising that, moreover, consumers are just really not sure about vitamin names for Vitamin B3. As an example, niacinamide was rated worse than niacin and just as worse than simply Vitamin B3. All of us in this room know that all three names are simply just the same name for the fortificant of vitamin B3. Contrary to USDA guidance on the 2015 and 2020 Dietary Guidelines for Americans, lack of familiarity as a chemical vitamin

nomenclature puts consumers at risk for not purchasing vitamin fortified or enriched foods, which play a very important role in our diet.

Additionally, the trend of clean label has encouraged some manufacturers to reject fortification of common foods, such as bars, cereals, beverages, yogurts, and more. These trends do not fair well for encouraging consumers to make good food choices that are nutrient dense and can help improve the overall diet. Additionally, these trends and the shifting sentiments, may jeopardize the longstanding assumptions that the FDA has held on fortification policies.

Therefore, DSM urges FDA to act and consider the simple proposal carved out just for fortificants as an innovative way to modernize ingredient labels, make the public more aware of what they are eating, help alleviate consumer confusion, and save space on pack. More importantly, we feel that if this is adopted, the simple regulations will help encourage manufacturers to produce foods that are healthy and play a role in improving public health.

DSM thanks the FDA for the opportunity to present in this public forum.

MS. BARRETT: Thank you. Haley Swartz, National Consumers League.

MS. SWARTZ: Hi, everyone. Thank you for giving me the chance to speak this afternoon. My name is Haley Swartz, and I lead the Food Nutrition Policy Department of the National Consumers League.

The League is America's Pioneer custom -- excuse me -- Consumer Advocacy Organization working to ensure our food supply is safe nutrition -- nutritious and adequately represented since 1899. It's fitting then that 114 years ago at the World's Fair in St. Louis the league demonstrated that canned green beans, touted by food processors as both innovative and cost effective, had actually been dyed green to appear more appetizing. Such blatant forms of misbranding adulteration are largely a relic of a past era, primarily due to consumer advocacy at first with our colleagues in the National Alliance for Nutrition and Physical Activity, many of whom are here and have spoke

today, alongside the political willingness of the FDA to consider innovative regulatory actions.

However, as we approach new challenges and changing consumer demand, questions as old as these arise. First, we commend the FDA for continuing the conversation on defining what is a healthy food product, and we look forward to reading the proposed rule on the definition, which will be forthcoming.

The 2016 volunteering guidance for industry, while a well-meaning start, just scratches the surface of how nutrition scientists define a healthy diet, one that is nutritious, diverse, balanced and inclusive of all seven groups. As we've heard this morning, it's extremely difficult for a food product to be considered healthy without placing it in a context of an individual's overall diet and personal health status. As such, we wish to caution the FDA on implementing a healthy icon without simultaneously reviewing the same product within a broader context of what a consumer would be in a packaged food marketplace. This includes products that depict images of fruits, vegetables, and/or wholegrains on the package, use words such as "wholegrain," "fruit," or "veggie" in the product name, contains the phrase "made with" or "contains real fruit" despite none of these ingredients having a minimal or meaningful contribution to the integrity of the product.

Any product that does not fit the criteria of the healthy icon should not be permitted to have images, text, or claims that would fit within the healthy criteria. FDA should use all possible enforcement to ensure no products fall through these cracks. A well-meaning consumer should not be expected to infer food and nutrient benefits of a product that does not even fit the regulatory definition of healthy.

Any healthy icon should reflect both food and nutrient criteria of the Dietary Guidelines of America. We believe both of these actions, enforcement of an explicit visual cue, and any implicit health claim, icon, or text, are necessary for a holistic regulatory system.

Visual cues extend far beyond a one-word claim

and include all elements of a product package. To regular both "healthy" and "natural" as two terms in isolation without reference to any other images or texts that could be reasonably associated with the -- these concepts would result in increased costs for produces and a negligible change in consumer understanding and related purchasing behavior.

Second, we welcome the process of modernizing standard of identity. It is imperative that regulations speed up to meet innovative food production methods. These include salt substitutes IN cheeses and safe and suitable ingredients in can tuna, the last of which has not been updated since the 1950s. We believe relaxing these standards necessary for industry competition and with the help of consumers is long overdue.

Last, the league has long advocated for the development of a standardized mandatory front-of-pack label that can balance the overwhelming visual and textual cues on product packaging that consumers face every day in the grocery store. The intent of front-of-pack labeling is not to simplify or dilute all nutrition information into a single color, numerical score or rating but to provide a summarized snapshot of the products overall contribution to a healthy dietary pattern. We look forward to working with the FDA, industry partners and our colleagues in developing and piloting a cost-effective and behavior sound front-of-pack labeling scheme.

Thanks for your time this afternoon. We will be submitting written comments to the docket. Thank you.

MS. BARRETT: Okay. Thank you. Our next speaker is Kelly Horton, The Sustainable Food Policy Alliance.

MS. HORTON: Good afternoon. I'm Kelly Horton with Mars Incorporated, representing the Sustainable Food Policy Alliance, which was launched by Mars, North America, Nestle USA, and Unilever United States earlier this month.

As four of our nations largest food companies, we seek to accelerate the pace of change in the food

industry, direct collective scale to drive progress and public policies that raise the bar and inspire further action in this important journey. Innovative science-based solutions are vital to ensure the integrity, quality, and safety of food products and the global food supply chain, and for building customer trust.

We have already made broad changes to our portfolio -- portfolios in recent years, collectively and voluntarily advancing issues including improving the nutrition profile of our products, adhering to responsible marketing, increasing transparency, and reducing our impact on the planet. We continue to seek ways to do more, and view FDA's Nutrition Innovation Strategy as a critical part in this journey.

Our alliance is already on record as being very support of FDA's efforts to move forward with voluntary guidelines for sodium reductions in package foods. Reducing sodium consumption to improve public health is the responsibility that must be shared among consumers, government, and industry. Where applicable, our member companies have independently reduced sodium in their products, demonstrating sodium targets can be met without reducing consumer demand or approval.

Establishing common product category benchmarks can help support alternatives for consumers and level the playing field for companies. In addition, we support the safe use and acceptance of salt substitutes like potassium chloride. We support consumer friendly and informative labeling.

Separately, some of our members have independently reformulated their products to reduce saturated fat and sugar and to also increase the nutrient density of their portfolio to help Americans enjoy more nutrient-dense foods without giving up taste. As an alliance, we support FDA in modernizing existence standards of identities as there is a need for flexibility and standards that allow for more healthy foods.

We strive to improve the quality and accessibility of information available to consumers about the foods they purchase for themselves and their families. We will continue to encourage timely

implementation of the Nutrition Facts Panel, and we believe a robust and effective education campaign to help people understand the Nutrition Facts Panel is important as we work to empower consumers to make food choices that are right for them.

Our alliance also supports comprehensive updates of -- update of the definition of terms important to people, such as "healthy," including strong evidence, science-based regulations on how these terms can be used on packaged foods. Updates should focus on helping consumers make healthy choices.

At the Sustainable Food Policy Alliance, our collective commitment to developing a range of nutrition transparency initiatives demonstrates our commitment to being a productive collaborative partner with FDA and other food policy stakeholders on these important issues. We appreciate the opportunity to participate today. Thank you.

MS. BARRETT: All right. Thank you. Next speaker, Aaron Stauffacher, Edge Dairy Farmer.

MR. STAUFFACHER: Hi. I'm Aaron Stauffacher with Edge Dairy Farmer Cooperatives speaking on behalf of nearly 800 midwestern dairy farm members that make up our cooperative. Thank you for this opportunity to share how dairy products can fit into FDA's Nutrition Innovation Strategy.

We recognize that a major focus of this effort is providing customers with the nutrition information needed to make decisions in the grocery store to meet their individual nutrition needs. Our farmers, who proudly produce that milk, is a key ingredient for a variety of nutritious and wholesome foods. They have strong feelings and progressive ideas to help you accomplish just that.

Giving customers the best nutrition information starts by accurately labeling food products. The first step towards accomplishing this begins with FDA's enforcement of existing standard of identity, particularly for dairy products. Whether it's milk, cheese, or yogurt, dairy foods have a high nutritional value and taste that customers easily recognize and have to come to expect when buying a

product.

Products do not -- that do not fit those standards of identity for dairy products should not be allowed to be labeled as such. It's an issue that many of our farmers across the country feel strongly about, to say the least. Inaccurate labeling is simply not fair to the farmers who have invested in those standards or to the customers who may be misled into purchasing nutritional inferior alternative products. We do applaud the commissioner on his remarks last week that FDA intends to resolve this problem. We're encouraged by this announcement and ask that FDA act quickly to enforce those current standards of identity for milk.

While we believe that existing standards of identity should be protected, this is an important opportunity to encourage innovation within the dairy case. The ability of our farmers and processors to keep up with customers ever-changing taste preferences, wants, and nutritional needs is important to provide the options that will help ensure proper nutrition and healthy lifestyles. The dietary guidelines tell us that most Americans under-consume dairy products and therefore miss out on access to an important nutritional makeup. The dairy community must have the flexibility to develop new and nutritious food and beverage products that can compete in the market place and meet customers nutritional expectations. We -- we need room for FDA to enforce -- to label innovative foods made with milk as a nutritious dairy product that they are.

Lastly, as you consider a new label for healthy products, we would like to emphasize that dairy foods are a well-known important part of a healthy diet as they provide nine key nutrients. Please consider that both reduced-fat and full-fat dairy products deliver nutritional value.

We want to -- overall we want to provide a wide range of options for customers to help them fit their individual taste and nutritional needs. As Dairy Farmer Cooperative appreciates FDA leadership for undertaking this important effort, we look forward to

submitting comments, and please continue to include the dairy community in this process as discussions move forward. Thank you.

MS. BARRETT: Okay. Thank you. Next, we have Sarah Ohlhorst, American Society for Nutrition.

MS. OHLHORST: Hello. The American Society for Nutrition commends the FDA for its continued focus on nutrition and health and appreciates the opportunity to comment on FDA's Nutrition Innovation Strategy.

Use of a well-defined healthy icon should be aligned with current evidence-based dietary recommendation to help consumers select more nutrient-dense food products that are part of a healthy eating pattern. The term "healthy" and any symbol or icon denoting "healthy" should be thoroughly informed by consumer research. Use of an icon should be accompanied by an updated, clear definition of "healthy" from FDA as well as robust consumer education. FDA definitions of other terms, such as "nutrient-dense" may also support healthy food innovation.

A more efficient review strategy for evaluating qualified health claims should still require sufficient scientific data to support the claim and ensure that all required scientific evidence will be carefully examined. It's important that the scientific review portion of evaluating qualified health claims not be compromised in any way to produce a more streamline review.

Dietary guidance claims related to health and recommended food groups could potentially facilitate innovation to improve consumers food choices. However, FDA would need to define what is a meaningful amount of a food group in a serving and set thresholds for nutrients to limit so that the product is consistent with existing scientific evidence based federal dietary guidance. FDA should review Canada, New Zealand, and Australia's front-of-pack labeling initiatives as potential examples of approaches that may promote more helpful foods and food choices.

Modernizing standards of identity could be made more flexible, simplified, and clarified to

promote industry innovation and allow for healthier food products when adequate data or new manufacturing methods and technology support lowering amounts of ingredients to limit in the standard so long as such a change would not compromise a product's integrity or call it the public health risk.

FDA might find example opportunities to make the ingredient list more helpful to consumers by looking to Health Canada's innovative changes, including grouping all sources of sugar in brackets after the name "sugars" and listing all food colors by their individual common name. FDA can also consider allowing the use of simple vitamin letter names as opposed to chemical names.

ASN fully supports the comprehensive consumer education campaign with a major focus on the new elements of the updated Nutrition and Supplement Facts Panel. It would be beneficial for FDA to collaborate with various partner organizations to educate consumers on the new label and to pursue multiple education campaigns targeted to various stakeholders including healthcare professionals. The use of QR codes may be an innovative way to facilitate consumer education.

The FDA Nutrition Innovation Strategy is critical to the health of our nation and ASN thanks you for your efforts.

MS. BARRETT: Thank you for your comments. Our next speaker, Jeri Kirschner, Primus Pharmaceuticals.

MS. KIRSCHNER: Good afternoon. My name is Jeri Kirschner, Government Affairs Manager for Primus Pharmaceuticals and also a representative of Nutrition and Medical Food Coalition.

Thank you to the FDA for this opportunity to learn more and comment here today on the Nutrition Innovation Strategy. We all know healthy nutrition is important, but the reality is that many people suffering from chronic conditions have a hard enough time just getting out of bed every morning to go to work, take care of their kids, and perform basic functions in life, let alone spend the time preparing meals. They're not able to consume the amount of food

that meets the dietary requirements for managing their disease. Additionally, social determinants of health include lack of access to healthy foods, making it difficult for underserved populations with unmet medical needs to easily buy and consume the foods necessary to fight disease.

An example of this is I'm in Phoenix, the fifth largest city in the U.S. In Maricopa County alone, in which Phoenix is part, we have more than 50 food deserts. Medical foods are a logical extension of the nutritional needs for people with chronic conditions and diseases to safely manage their health under medical supervision and must be included in the Nutrition Innovation Strategy.

Medical foods make it easier for patients, especially those who have failed on drug treatments or experienced various side effects, to consume the concentrated bioactive compounds and nutrients they need, giving them another option to manage their disease through scientifically based, safe and effective therapies.

Medical foods dispensed by prescription, strengthen the doctor/patient relationship and keep the patients more engaged in their care, creating a patient-centered care model. Patients who wholly self-manage chronic conditions can end up using a greater amount of healthcare dollars especially when emergency room visits result from their lack of care.

Improving access to medical foods is paramount. Despite how medical foods are designed in the Orphan Drug Act, only some states have an active medical food legislation, and even those are for narrowly defined conditions that fail to address the needs of the chronically ill. Unfortunately, federal health plans exclude prescription medical foods from their formularies, and coverage among commercial plans continues to decline largely from the misclassification of the category by a large drug compendium.

Additionally, we ask FDA to also focus on an educational component for healthcare professionals as part of its Nutrition Innovation Strategy. Only about one-fifth of American medical schools require students

to take a nutrition course. Nutrition education is essential for physicians, nurse practitioners, physician assistants, and other healthcare providers to delivery proper care. This education should also include medical food in the management of chronic diseases and conditions. Thank you.

MS. BARRETT: Thank you. And next speaker, Douglas MacKay, Council for Responsible Nutrition.

MR. MACKAY: Hi. My name is Duffy MacKay, and I am speaking on behalf of the Council for Responsible Nutrition. We are a trade association that represents dietary supplement and functional food manufacturers of ingredient suppliers.

The nutritional profile of the American diet must improve to reduce the burden of chronic diseases that result from poor nutrition. CRN believes that modernizing FDA's regulations related to health claims, label statements, and standards of identity will help consumers make more informed decisions about what they eat. Today, I will discuss three ways that FDA can improve nutrition communication and education.

First, we suggest the FDA reevaluate its current though outdated health claim review process. Nearly a decade has passed since the health claim guidance was issued and yet the guidance remains unchanged. Meanwhile, the scientific methodology for an evidence-based systematic review to establish causal relationships for health outcomes has progressed, enhancing its transparency, its consistency, and its objectivity.

Because the current evidentiary standards for health claims is not fit for purpose, foods and nutrients seldom meet the standard as evidenced by the fact that only 12 health claims have been approved in nearly 30 years. As a result, most foods evaluated only meet the qualified health claim standard. The qualifying language required by FDA are lengthy, convoluted, and making qualified health claims is an ineffective tool to communicate potential health benefits to consumers, and they are commercially unusable by industry. Therefore, we request that FDA consider updating its systematic review process and its

methodology for health claims evaluation to keep pace with current best practices.

A second priority area for FDA should be to educate consumers about the changes to the Nutrition and Supplement Facts Label. CRN applauds FDA's modernization of the units of measure for some essential nutrients. However, industry and FDA will need to invest significant resources to make sure consumers understand the new units of measure as well as the revised recommended intake levels.

We have a shared responsibility to help consumers reach targeted intake levels for critical essential nutrients like Vitamin D and folic acid to ensure that we do not undermine previous successful public health efforts regarding these essential nutrients and disease risk reduction.

Finally, CRN agrees with the standards of identity for foods should be updated to support current public health efforts related to improving nutrition and preventing chronic diseases. Certain standards of identity are restrictive and hinder innovation that is intended to improve the nutrition or quality of some standardized foods.

So, CRN thanks FDA for holding this public meeting and this opportunity for input, and we look forward putting additional comments on the docket. Thank you.

MS. BARRETT: Okay. Thank you. Our next speaker is Sarah Brandmeier, American Frozen Food Institute.

MS. BRANDMEIER: My name is Sarah Brandmeier, Manager of Scientific and Regulatory Affairs for the American Frozen Food Institute. Acting on behalf of its member companies, thanks FDA for the opportunity to comment on the agency's Nutrition Innovation Strategy.

AFFI commends FDA for their efforts in promoting public health and ensuring that consumers of access to accurate, useful information to make healthy food choices, as well as foster the development of healthier food options.

AFFI appreciates that attention is being given to revising requirements for food claims such as

"healthy," modernizing certain standards of identity to address current barriers to the development of healthier products, and advancing guidance on dietary sodium reduction.

As these efforts impact important nutrition policies, it is imperative that any recommendations be based on the latest available science. First, AFFI believes that as an implied nutrient content claim, the healthy criteria should primarily focus on nutrient content as relevant to creating a healthy dietary pattern. Other factors such as degree of processing, presence of an ingredient derived from plants that were genetically engineered are not relevant to whether a food can help consumers maintain a healthy diet. We encourage the agency to assist industry in educating the public on the definition of nutrient-content claims.

In terms of processing and with respect to freezing in particular, the dietary guidelines recognizes that all forms of food, including fresh, canned, dried and frozen, can be included in healthy eating patterns. Keep in mind to the value that the food industry offers in producing products that make consumer demands for nutritious and delicious food. FDA has consistently recognized that foods developed from biotechnologically do not differ from their traditional counterparts in any meaningful or uniform way, and that biotechnology does not change the essential nature of the plant. Therefore, there is no reason that biotechnology should form the basis for any distinction in whether a food is considered healthy.

Regarding the creation of label claims, AFFI recommends that FDA should conduct consumer education that can inform the appropriate use of a new label to help consumers understand the meaning of a healthy label. The label itself should be clear and not mislead consumers. Additionally, after implementation of a new label, consumer research is imperative in order to evaluate the label's effectiveness in promoting public health. AFFI stands ready to help in assisting the agency as we believe many of our products can bear this claim.

Second, regarding sodium, if FDA does finalize the upper bound targets, we ask that FDA redefine the upper bound targets to clarify that these are not maximum allowable levels of sodium. FDA should not finalize the guidelines until after the National Academy has issued an updated DRI for sodium based on available scientific evidence.

With respect to the short-term targets, FDA should provide four years rather than the proposed two-year timeframe. We recommend FDA conduct an assessment of the progress for the goals four or five years following implementation before finalizing the set of voluntary sodium targets. FDA should re-issue a revised version of the draft guidance for additional comment based on the input and research it has received from public comment prior to finalization.

Finally, AFFI supports the agency's approach to modernizing certain standards of identity based on their public health value. As new definitions require reformulation of some products or new labels, industry needs time to comply with updated standards of identity. Therefore, AFFI appreciates that FDA will issue a request for information to prioritize which potential standards of identity should be modernized based on their public health value.

AFFI is committed to aiding the agency and empowering consumers to make better and more informed decisions about their diets and health. We ask that the agency keep in mind that nutrition science is ever evolving, and only the totality of evidence can amount real nutrition recommendations.

Thank you again for the opportunity to provide feedback and input on Nutrition Innovation Strategy.

MS. BARRETT: Thank you. Our next speaker, John Shan Lee On (ph). Okay. All right. We'll move on. Tom Balmer, National Milk Producers Federation.

MR. BALMER: Thank you. My name is Tom Balmer and I'm with the National Milk Producers Federation. National Milk represents the nation's dairy farm families and the cooperatives they own. Notwithstanding Commissioner Gottlieb's statement issued earlier today, the comments to follow remain on point and will

primarily address why standards of identity even matter in today's marketplace.

They matter because they help safeguard consumers from making purchases of products whose labels are false and misleading. Food standards help guarantee that consumers' expectations are met both in terms of minimum levels of key ingredients and consistency of key sensory attributes in many everyday foods. Although standards weren't initially developed for specific reasons of nutrition or public health, there is a direct link between the specified type and amount of characterizing ingredients found in a standardized food and that food's overall nutrient content.

For dairy, consumers use shorthand names like "milk," "cheese" and "yogurt" to make informed purchasing decisions and they expect a certain level of product performance and nutrition in return for their money. Standards also help maintain honesty in the marketplace. It's through standards that food marketers communicate the origin of required ingredients, such as being derived from lactating mammals, and an anticipated measure of quality in the end product.

For far too long, standardized dairy terms have been coopted by the marketers of fake milk and other alternative products. Impostors, like almond milk, soy cheese, and rice yogurt, typically bask in dairy's halo by using those familiar terms to invoke the positive traits typically associated with real dairy foods, including significant levels of various nutrients. This is purely a marketing gimmick and a clever one at that. Such products not only lack ingredients specified by the standards, they frequently fall short in expected characteristics, like mouth feel, taste, and texture and are nearly always less nutritious. They are marketed in merchandise to resemble real milk and dairy products in all ways possible, and many consumers don't realize they're being short changed.

In closing, it seems inconsistent to talk about modernizing standards to improve nutrition and

assure accurate information to consumers when FDA has been allowing nutritionally inferior products to use standardized terms like "milk" for so long. FDA might have forgotten about 21 CFR 101.3E, but we haven't.

Commissioner Gottlieb was right. Almonds don't lactate. So, instead of continuing to look the other way, let's start enforcing current standards of identity, and then talk about potential improvements. And while we're at it, let's stop confusing deceitful marketing practices with technological innovation.

America's dairy farm families are once again asking for FDA to do its job and reign in the current marketplace chaos. And they are not alone. A recent independent poll found that American consumers, by a two to one margin, opposed the use of "milk" as a designation for non-dairy beverages. The reality is that enforcement doesn't need to take a year or more. It needs to start now.

Thank you for this opportunity. We will also be filing written comments.

MS. BARRETT: Thank you. Our next speaker is Bruce Burnett, Nutrition and Medical Food Coalition and Digestive Disease National Coalition.

DR. BURNETT: Hi. My name is Dr. Bruce Burnett. I represent the Nutrition and Medical Food Coalition. I am also V.P. of Medical Affairs for RedHill Biopharma. The Coalition is composed of member companies that manufacture, develop, and promote medical foods as well as patient groups and physician societies.

We appreciate the FDA's Nutrition Innovation Strategy and endorse the agency in its efforts to reduce mortality and morbidities through healthy nutrition, but also nutrition as a therapeutic. We agree with Commissioner Gottlieb's statement that developing strategies to improve nutrition can be a transformative step towards reducing burden of many chronic diseases. However; the Coalition urges the FDA to support the category of medical foods for the management of chronic conditions and diseases.

Medical foods have existed as a standalone food therapeutic category separate from drugs since the

passage of the update to the Orphan Drug Act of 1988. Medical food is defined "as a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements based on recognized scientific principles are established by medical evaluation."

Medical foods must be generally recognized as safe, like foods purchased in a store, but are specially formulated, meaning that the bioactive ingredients and nutrients are concentrated at a point that one cannot get them in the same amount merely by changing the diet. They are given due to a medical need for specific food ingredients caused by and for the management of chronic conditions and diseases.

Medical foods must have clinical support for their intended use. Their administration and use requires medical supervision under active and ongoing care. Medical foods can come also in many forms including pills, tablets, liquids, and powders.

Many patients who take medical foods have unmet medical needs or serious comorbidities making the management of their chronic conditions complex. Medical foods are often the only therapies patients can take safely after failing on drugs. Unfortunately, patient access is now severely compromised due to a recent change in classification by a large drug compendium which resulted in a loss of insurance coverage.

The FDA is aware of this issue and has stated in a correspondence to this entity and I quote: "Importantly these products cannot be simply obtained from a retail establishment, but rather must be acquired through pharmacy's physicians or directly from manufacturers, based on evidence of diagnosis of disorder response to such a product."

Over the past 30 years, the science behind medical foods has advanced, such that they have -- we have greater knowledge regarding their safety and efficacy but lack clear regulations and guidance for development. Including medical foods as part of the

FDA Nutrition Innovation Strategy preserves the medical food category, increases scientific advancements around medically necessary nutrition to help the FDA achieve its nutrition goals, as well as improves patient access and lowers the overall costs of care to the healthcare system. Thank you for your time.

MS. BARRETT: Thank you for your comments.

Our next speaker is Shannon Campagna, Plant Based Foods Association.

MS. CAMPAGNA: Thank you. And thank you all for hanging in there, those of you who -- who are still here.

Good afternoon. My name is Shannon Campagna. I'm a senior policy advisor at the Law Firm Alston and Bird, and I'm here on behalf of the Plant Based Foods Association. PBSA was founded in 2016 to represent the interest of companies producing meat and dairy alternatives. In this short time, the association has grown to 114 members. We appreciate the opportunity to speak here today and we join others in applauding the FDA's goal of modernizing standards of identity.

While grocery sales overall are generally flat, sales of plant-based foods are growing quickly. PBSA will soon release new data from Nielson, that shows growth in the double digits over the past year. American consumers are sophisticated and well-informed. Consumers -- consumers who purchase plant-based foods are keenly aware of why they are making these choices and do so for many reasons: sustainability, health, allergies, ethics, variety, and taste.

There's much discussion about the use of the word "milk" to identify plant-based alternatives. For our members, and as the data shows for many consumers, the word describes the functionality of the product. Our research shows that 78 percent of cow's milk drinkers agree that the word "milk" is the most appropriate term for products such as soy milk and almond milk. Our use of the term is not meant to diminish the value of cow's milk produced by dairy farmers, but rather to use the terms that have been understood and accepted in the marketplace as the common and usual name for more than 30 years.

To help ensure a consistent approach among our members, last year PBFA convened a standards committee to establish voluntary standards for the labeling of plant-based milks. We recently shared that finished document along with the results of our consumer survey with the FDA.

The voluntary standard recommends that labels clearly identify the main ingredient as part of the word "milk" or be labeled as "plant-based milk" along with clear disclosure of the main ingredient. We also recommended that the principle display panel contained the word "dairy free" or "non-dairy" as these were the phrases that resonated the most in our consumer survey.

Ultimately, the question is whether current regulatory definitions can keep up with innovation. We are living in a time of rapid innovation in food, and American is leading the way. Consumers are entitled to the benefits of this innovation and the many new plant-based offerings in the marketplace from both startups and established brands. We urge the FDA to adopt policies that encourage this innovation, not stifle it, and that will allow consumers to make informed choices.

Plant-based food producers offer options that consumers want and recognize. If those foods are forced to be identified by obscure, contrived names that consumers are unfamiliar with, innovation will be stifled, and consumers will be deprived of the choices they deserve. The FDA has the unique opportunity to support this growing industry and the millions of American consumers who are voting with their dollars.

Our members are committed to working with FDA and look forward to finding a solution to this important issue. Thank you.

MS. BARRETT: Okay. Thank you. Our next speaker is Robert Post, Chobani.

DR. POST: Good afternoon. Thank you. I'm Robert Post, Senior Director for Chobani Health and Wellness at Chobani.

Chobani is the leader in Greek yogurt and produces strained, high-protein yogurt from products from our New Berlin, New York and Twin Falls, Idaho plants.

At Chobani, we believe that business should be a force for good, and we appreciate the opportunity to present our views on the -- on the FDA Multi-Year Nutrition Innovation Strategy. Our company believes every food maker has a responsibility to provide foods, or people, with better options and the products we develop must relate to consumer values, for nutritional and non-nutritional aspects to be accepted in the marketplace. And a policy and regulatory framework must support both for healthy innovation success.

Today, I'll focus my remarks on Chobani's views about the need to evolve and apply standards of identity to assure more healthful foods for a modern marketplace, foods that are consistent with the recommendations of the Dietary Guidelines for Americans. I'll give a little bit more detail than my remarks earlier.

There are three essential challenges with current standards of identity. They need to reflect today's marketplace, they aren't being applied consistent with their purpose, and they're not aligned among agencies leading to unequal application.

All of these challenges have direct implications for public health. About the first challenge, current standards of identity haven't kept pace with the marketplace. They don't recognize new and prominent products with better -- that better support consumers health and wellness. One example is the current standard for yogurt which does not reflect the large footprint of products available in the U.S. marketplace, particularly strained, high-protein yogurt, or Greek yogurt, which accounts for about 52 percent of the yogurt aisle. These products have a protein content two times higher than regular yogurt along with a host of natural nutrients due to a unique straining process. And because of the nutritional benefits, and high acceptance among children, USDA has incorporated these new products into school-meal patterns. But because there is no standard of identity to recognize the production methods that result in this naturally nutritious product, they haven't received full-protein crediting in school meals. And these

crediting inequities inhibit the use of products in school-meal programs. And with dairy consumption already below dietary recommendations, this is a problematic situation for children's health today. But a standard of identity will help correct this issue and ensure products' nutritional qualities or recognize and encourage in policies.

On the second challenge, standards of identity aren't being applied to do what they are intended, which is to name and establish the basic nature and essential characteristics of a food or beverage. There's ample room for all sorts of foods and beverages in the marketplace; however, words matter and standards of identity assure that foods are dependable sources of nutritional and health benefits recommended by the dietary guidelines. It's important to properly distinguish the authenticity of foods and the nutrition they provide, and there's ample room for innovation using technologies and ingredients that enhance natural nutrient density. Ensuring standardized terms are always associated with standards of identity will help to avoid consumer confusion or unintended public health consequences. Substitute products should have clear distinction. For example, consumers may inadvertently miss out on key nutrients by assuming substitute products have equal nutrition for their authentic counterparts -- to their authentic counterparts, when this isn't the case. And this is especially concerning for infants and children where recent fit-data show a segment of this sensitive life stage is receiving products that are not nutritionally profound, which may affect their development.

On the last challenge, agencies need to be aligned on the value and application of standards of identity to ensure nutritious products are equally recognized and encouraged via federal policies. The previous example of strained, high-protein yogurt being a subject of USDA specification for school meals, but not in FDA's standards of identity is a good example.

So, to address these three challenges, we suggest that standards of identity are modernized by first, building on the 2005 FDA USDA joint standard of

identity proposal which defines dieting principles that would promote honesty and fair dealing in the interest of consumers, allow for food technology advances and be clear, simple, and easy for both manufacturers and the agencies to enforce.

Second, create and leverage public private partnerships --

MS. BARRETT: And Dr. Post, we will need to wrap up.

DR. POST: -- to help reduce, thanks, to help reduce federal resources and keep faster pace with marketplace and consumer demands as well as purchase trends.

And third, incorporate the use of temporary marketing permits, which involves testing the marketplace for acceptance of a product, which can inform the need for standards of identity development. Thank you.

MS. BARRETT: Thank you. Cary Frye, International Dairy Foods Association.

MS. FRYE: Good afternoon. I'm Cary Frye, Senior Vice President of Regulatory Affairs at International Dairy Foods Association, a trade association representing the nation's dairy manufacturing and marketing industry.

Milk, yogurt, cheese, ice cream and dairy-ingredient companies are proud to manufacture a wide-range of nutritious, delicious dairy products that meet consumer demands for innovative new products. We commend Commissioner Gottlieb and the agency for undertaking its nutrition innovation strategy to encourage the industry's innovation to improve nutrition and healthfulness of food.

One key area that the dairy industry supports is the work on modernizing standards. Dairy products represent a third of the 280 federal food standards of identity. These standards are significantly outdated and stand in the way of new technologies, ingredients, and novel processes for dairy foods.

The current system of revising standards of identity is not working and desperately needs to be reformed. The dairy industry has filed citizen's

petitions requesting modernization of the yogurt standards that have been pending for 16 years, and it's also petitioned to amend the cheese standards to allow for the use of milk filtration almost 20 years ago. Clearly, a new approach is needed to allow dairy processors greater flexibility to create new, nutritious, healthful products that meet consumer demands.

One example is allowing new milk ingredient processing by filtration that can be used to concentrate proteins and remove sugar or lactose from milk. However, this technology, which is embraced around the world for making cheese and new milk beverages with lower sugar and higher protein, is not permitted under the U.S. standards for milk. Only recently has FDA provided guidance to the industry, to allow the use of ultra-filtered milk as ingredient for cheeses.

We urge the agency to complete its rule-making process on the pending dairy product standards as a top priority. We fully support the longer-term efforts of undertaking a holistic approach to modernizing food standards in a manner that maintains the basic nature of the food but allows the industry flexibility that will incentivize innovation. We will provide -- this will provide regulatory clarity and certainty to encourage investment without having to depend on petitioning for standards that may take decades.

We look forward to working with the agency on standards modernization and in the other areas of Nutrition Innovation Strategy. Thank you.

MS. BARRETT: Thank you. Joseph Profaci. North American Olive -- Olive Oil Association.

MR. PROFACI: Thank you. My name is Joseph R. Profaci. I'm -- I'm the executive director of the North American Olive Oil Association and our members' products represent about 85 percent of all the branded olive oil products sold in the U.S. We applaud and we strongly support the FDA strategy to empower consumers with knowledge to make healthy choices by modernizing regulations including the standards of identity.

We believe the FDA is correct to focus on

healthy dietary patterns, because, as Commissioner Gottlieb said earlier this year, people eat foods, not nutrients. The 2015-2020 Dietary Guidelines Advisory Committee Report found moderate to strong evidence to recommend Americans shift towards the Mediterranean Diet and other healthy diets like it. In a recent study by Dr. Carolyn Scrafford at Exponent found that increasing Americans' adherence to a healthy Mediterranean style diet pattern by as little as 20 percent "has the potential to save more than 20 billion in both direct and indirect costs associated with ten major health outcomes."

Olive oil, in particular extra virgin, is the poster child of the Mediterranean Diet and as a result has grown immensely in popularity over the past 25 years. A recent consumer attitude and usage study commissioned by our organization and the American Olive Oil Producers Association found that health was by far the strongest factor driving sales of olive oil.

Yet, there is a problem that is confounding both consumers and the industry. Significant consumer confusion remains about olive oils. Our data show that 24 percent of olive oil consumers would purchase more olive oil but for their confusion over the quality, types, and brands of olive oil, and some of the disreputable merchants are taking advantage of that confusion.

There are important differences in the health attributes among the different grades of olive oils and requiring merchants to play by the same rules across the country is imperative. What is needed is a new standard of identity for olive oils, that describe types and qualities of olive oils, and includes corresponding nomenclature, taking into account existing state and international standards. As Dr. Gottlieb has notes, standards of identity are critical both in terms of letting consumers know that what they're buying meets a certain standard and to prevent economic fraud.

The North American Olive Oil Association therefore calls on the FDA to adopt an olive oil standard to help resolve consumer confusion and assure

honestly and fair dealing in the industry. Imparting confidence in the purchase of olive oil products will promote good health and achieve the goals of the 2015-2020 Dietary Guidelines report. Once a specialty product, olive oil is now mainstream and consumers need the benefits of the standard of identity to help make healthy choices for their diets. Thank you very much.

Ms. BARRETT: Thank you. Our next speaker is Jennifer Parker of Fresenius Kidney Care.

MS. PARKER: Good afternoon. Hi. I'm Jennifer Parker. I'm a registered dietitian nutritionist and a specialist in renal nutrition, and I work with Fresenius Kidney Care.

Esteemed Commissioner and honored panelists, thank you very much for this privilege to highlight two areas for your consideration as you all and, hopefully some of us, are able to embark on this challenging and yet very noble work on making it easier to eat healthier, healthfully in America.

As a 13-year registered dietitian nutritionist practicing in nephrology, I have seen a new era emerge. One in which we are highlighting with our individuals what they can eat. We are taking a food first approach, and it's very exciting. We're trying to revitalize the renal diet. Unfortunately, I've also seen in the same era some research that concerns our individuals and also healthy Americans. The research that's emerging is concerning dietary phosphorus consumption and the significant implications that threaten the health of the general American population.

Once thought only to be a mortality risk for those with CKD, chronic kidney disease, the findings now support a relationship between high dietary phosphorus and cardiovascular disease and heart failure. It is even believed to be uniquely attributed to the inorganic phosphate, i.e., the manmade additive. And that can also come from our mineral sources.

So, may I ask for your help in reducing its use. May we talk to the USDA to carefully review the literature and the findings and potentially strip the phosphate additive of its unearned G-R-A-S, GRAS status. Should this phosphate additive and others,

like, potassium, for example, continue to be used, perhaps we can consider a more obvious labeling or include its added amount like what we're doing for added sugars.

Lastly, may you consider registered dietitians, like myself, and my many colleagues here and across the nation, to be the face of your educational campaign. It would be a dream come true for me to see registered dietitians across the nation being the face of food nutrition expertise. We are the food nutrition experts, and we want to leverage our expertise to improve public health. As dietitians, we can leverage what we know best, we can bring clarity to the fad diets, reveal affordable, healthy, delicious meals, and again, advance public health.

Thank you for your time and consideration to reduce phosphate additives in our foods and beverages and to showcase dietitians as your public health nutrition advocates. Thanks.

MS. BARRETT: Thank you. Our next speaker is Colette Heimowitz, Atkins Nutritionals.

MS. HEIMOWITZ: Good afternoon. I'm vice president of Education and Nutrition at Atkins. And we commend the FDA on your efforts to create Nutrition Innovation Strategy to empower consumers to make better and more informed decisions about their diets and health, foster the development of healthier food options, and expand the opportunities to use nutrition to reduce morbidity and mortality due to chronic disease.

Nutrition recommendations based on the strongest science will help course correct the public crisis that we're facing today. Currently, 52 percent of the population has been diagnosed with diabetes or prediabetes and nearly 70 percent of the population is overweight or obese. These are both diet-related diseases, and prioritizing health claims to help these populations can make a tremendous difference in the health of the American public.

First and foremost, we believe that is imperative that the FDA and all government bodies for that matter, use clear, science-based information in

making nutrition decisions. We defining the label claim "healthy" is the perfect opportunity for the FDA to set the standard for what clear, science-based decision making looks like. Which means using the most recent data from large prospective cohort studies, well designed, randomized controlled trials, and meta-analysis.

Regarding new definition of "healthy," it needs to be finalized from a holistic perspective. For instance, when it comes to sugar, the total amount, source of sugar, and taking it one step further, whether it's accompanied by fiber, which can slow down the release of the sugar into the bloodstream, can be taken into account when determining if it fits the science of healthy.

Any new definition of the term "healthy" should focus on intake of healthy fats. A large body of high quality research shows that reducing fat intake is not beneficial to human health when replaced by refined carbohydrates. If the FDA intends to influence consumer behavior and improve public health with label claims, fiber intake should be increased, sugar intake minimized, and healthy fats optimized.

We commend the 2020 labeling updates, and we recommend a limit on total added sugars as well as a requirement that products labeled as healthy represent the meaningful contribution to the new daily value for fiber.

As for depicting healthy on packages with a new symbol or label, we agree this can be useful too, if the parameters for what is considered healthy are clearly defined, reflect the latest science, and easily accessible to consumers to understand what that means. Taking a more holistic nutrition approach, can have a life-altering turn for the better for all Americans. Thank you.

MS. BARRETT: Thank you. I do want to acknowledge the time. We -- we will be going a little bit longer. And I appreciate everyone who is -- is here and your patience, but it does look like we may go to about quarter of. We may lose our webcast audience. I'm not sure if that ends at 5:30 or not. But we do

want to reserve a few minutes at the end to share back with you some of what we heard in the breakout sessions and we'll do that fairly quickly. But I just wanted to let you know that we are mindful of the time.

So, our next speaker is Al Lear, International Bottle -- 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 represents all segments of the bottled water industry, including spring, sparkling, mineral, artesian, and purified water products.

IBWA appreciates the opportunity to present these comments as part of the public dialogue to improve FDA's approach to nutrition policy. Consistent with FDA's nutrition policy agenda, bottled water has an important role to play in helping consumers achieve a healthy diet that conforms to dietary guidance. For that reason, and consistent with the dietary guidelines, IBWA has requested that FDA allow healthy claims on bottled water and provide enforcement discretion to allow such claim, while the agency works to revise the regulations defining the term "healthy."

Under FDA's current definition, the term "healthy" describes a food product that, because of its nutrient content, may help consumers maintain healthy dietary practices. Currently, bottled water does not qualify as healthy under the existing FDA regulations because it does not contain sufficient levels of specific beneficial nutrients. In recognition of the scientific consensus about the important role that water plays in a healthy diet, as reflected in the dietary guidelines, and to help consumers shape healthy dietary practices, IBWA believes bottled water products should be able to include the term "healthy" on the label and labeling.

FDA has previously determined that (inaudible 51:19d) exceptions to the beneficial nutrient's criteria are justified when dietary recommendations incurs consumption of the food and such consumption has been associated with health benefits. For example, fruits and vegetables such as celery and cucumbers do

not contain the required amount of any of the beneficial nutrients, but FDA has allowed them to use a healthy claim because increased consumption of these foods can contribute significantly to a healthy diet.

FDA has also previously exercised enforcement discretion when a particular product or category meets overall goals of the healthy claim while rulemaking is pending. The Bottled Water Industry would be interested in being able to use a standard icon or symbol for foods and beverages that meet the healthy definition it's -- if such claim were allowed for bottled water, either by itself, or in addition to the term "healthy."

IBWA thinks that providing for such an icon or symbol would be a valuable step to help consumers who want to eat a healthier diet by helping consumers to easily identify products that are consistent with the dietary guidelines. Of course, the Food and Beverage Industry and other interested stakeholders would need to work together with FDA to determine the design and content of the icon or symbol.

Thank you for seeking public input on this important issue. IBWA appreciates FDA's consideration of our earlier request to allow bottled water products the use of the term "healthy" on labels and labeling and the opportunity to present these comments regarding the use of a healthy icon or symbol on foods and beverages. Thank you.

MS. BARRETT: All right. Thank you. Our next speaker, Ed Rogers, Bonumose.

MR. ROGERS: Hi, my name is Ed Rogers. I am the CEO of the start-up food ingredient company called Bonumose, it's based in Virginia. My short statement will be directed to the Nutrition Facts Label and specifically the "added sugars" line, which is important because as we've learned today, and as we all know, most people are looking to reduce the inclusion of traditional sugars in their diet. But unfortunately, the definition that the FDA uses for sugars, for purposes of NFL, is unintentionally overly broad, confusing, and inconsistent with other definitions of sugar that the FDA uses, as well as we

believe inconsistent with the purpose for calling out added sugars.

The definition lumps together all monosaccharides and disaccharides and fails to recognize that some rare monosaccharides actually are good for you. So, the one I'll talk about is tagatose. Tagatose is a naturally occurring, rare monosaccharide. It occurs in tiny quantities, in nature, fruits, some grains, the cacao tree. It is great tasting. It tastes just like regular sugar. It's fully functional in foods, so it's a drop-in replacement. But the really good news is that it is healthy. It is low glycemic, it does not raise blood sugar levels. It actually reduces blood sugar levels. It is low calorie. It is safe for teeth. The FDA already recognizes it for a dental health claim, and it actually breaks up dental biofilm. And then finally, it is a prebiotic. SO, even though it is chemically a monosaccharide, the body think it's fiber. Eighty percent goes into the large intestine where it's fermented by the good gut bacteria. So, the prior speakers spoke about the combination of sugar and fiber, well, you've got a sweet fiber here.

So, what's interesting about tagatose is that it is beyond benign; it is actually beneficial. And the DGA, when it recommended the reduction of sugar, was not recommending the reduction of tagatose. But the problem is, is that the definition that you're currently using for sugars does not have the precision that it could have and that it should have.

If a consumer is trying to reduce sugar and they find a product with tagatose, and they turn over to the Nutrition Facts Label, which apparently, half of the people, that's the first thing they look for is added sugars, they're not going to know that the product contains a healthy sugar. And manufacturers are not going to have the incentive to use tagatose in replacement for sucrose.

And then finally, it could actually be dangerous. Somebody who is controlling their blood sugar and needs to take an insulin shot in anticipation of a high-glycemic load, if they eat something with

tagatose and it doesn't have that high-glycemic load, it could be a dangerous situation.

Now, due to work that our company is doing, our small company is doing, we have driven the price down of tagatose to where it can be viable for the mass market. And we're not seeking to just reduce the price slightly below the other guys; we want to reduce it down to where it can be viable for the mass market. So, we have filed a comprehensive citizen petition to the FDA seeking to have tagatose exempted from the definition of added sugars. We urge you to give that all due consideration and we think a very simple change would be productive towards public health and also nutrition education. Thank you.

MS. BARRETT: Thank you. Our next speaker is George Carlisle, AlterSciences. George Carlisle? Okay. Mark Pohl, Pharmaceutical Patent Attorneys, LLC? Mark? Okay. Janell Hendren, National Association of State Department of Agriculture? All right.

MS. HENDREN: Good afternoon. I'm Jenell Hendren, Associate Director of Public Policy and Food Safety Programs with the National Association of State Department of Agriculture. Thank you so much for accepting our comments today. NASDA, as background, is a non-profit, non-partisan association, which represents the commissioners, secretaries, and directors of the State Departments of Agriculture. State Departments of Agriculture are responsible for a host of regulatory and marketing programs, which ensure safe, affordable, and sustainable global food supply.

We appreciate FDA's focus on the issues before us today, many of which are of intense interest for NASDA members. As NASDA seeks to advance agriculture and -- as NASDA seeks to advance agriculture in the states, it is essential that strategies on nutrition innovation recognize the essential role of agriculture, the foundation of good food for good health. As FDA continues to develop and implement its Nutrition Innovation Strategy, NASDA stands ready to assist and also urges FDA to ensure robust consultation with NASDA and its members.

Today, we especially wish to highlight NASDA's

interest in FDA's work related to nutrition labeling and modernizing approaches to standards of identity, as well as articulate NASDA's policy related to these issues in order to inform FDA's next steps.

NASDA notes with interest Commissioner's Gottlieb's recent comments regarding approaches from modernizing standards of identity, particularly with respect to milk. There is significant interest within NASDA's membership on standards of identity, and we anticipate continued attention and dialogue on this issue in the coming months.

We wish to point out that recently 17 State Department's of Agriculture wrote to FDA in support of enforcing the current standard of identity of milk.

Real quickly, our policy on nutrition labeling states, " Federal policy related to nutrition or dietary guidelines should be based on sound and peer-reviewed nutrition science, should not prejudice particular agricultural commodities or products, and should not consider non-nutrition related elements such as environmental impacts or agricultural practices."

NASDA's policy on labeling and marketing claims states, " Food labeling required by federal law for the purpose of disclosing ingredients, allergens, and nutritional value of food products should provide accurate, science-based information to consumers. Such requirements should not prejudice particular agricultural commodities or practices. Additionally, terms or claims used (print, electronic, or otherwise) to market food products should be accurate, and should not mislead or misdirect consumers, prejudice particular agricultural commodities or practices."

So, in conclusion, thank you so much. We look forward to working cooperatively with the FDA to advance science-based, data driven, and pragmatic approaches to innovation in our food system. Thank you so much.

MS. BARRETT: Thank you everyone for your public comments, and we really appreciate that input. We look forward to your written comments to the docket.

I'm going to ask Robin McKinnon to come up. Robin is going to wrap up and close the meeting for us.

Robin serves as the Senior Advisor for Nutrition Policy at CFSAN, so, welcome, Robin.

DR. MCKINNON: Thank you, Kari. Thank you, everybody. Okay. So, thanks again. My purpose here, my goal is to really reflect back at a very high level, the comments and the -- the input that we've received throughout the day. I will say that we'll be providing a much more detailed summary of the meeting and the remarks and the comments that we've received throughout the day and we will be placing that information in the docket.

So, what we heard this morning, we heard a lot about the consumer trends over time and over -- particularly of interest was the uptick since about 2015, at least to me, since 2015 and some of that is the nutrients to encourage, and nutrients to limit, the overall interest in the Nutrition Facts label and some of the other interesting consumer trends.

We've heard a lot about the evolving landscape, both in the food -- that is rapidly innovating. Industry is rapidly innovating, both in the foods themselves but also in how we're purchasing, consuming foods as well. And also a key thing there was the importance of education, overall.

We also, as everybody here in the room and still online heard a diverse and very valuable set of comments and input for us to consider as -- as we move forward. But overall, I will say I was -- I've been so struck by the energy and the enthusiasm in the room from everybody. People pulling me aside, saying, "This meeting is great." Which is just terrific.

So, I'll go through some of the very -- again, very high-level comments that we received back on the breakout sessions, just one-by-one.

So, firstly in the claims and statements used on food labels and the icon for "healthy." We heard, in terms of claims and the statements -- statements used when to -- when to use claims is very much consumer driven. And how and what consumers would perceive from the -- from the claim itself.

And that also, certain claims are not as well accepted and may in fact, connote that health -- that

some foods may be not quite as tasty as -- as they might be. I think that -- we may have heard some people use the term "kiss of death" for -- for certain claims, so ...

We also heard the firms, some firms are not going to invest if consumers are not interested. There is a great deal of testing, this is a very expensive process to undertake.

The types of claims to -- to drive innovation and be most helpful, they should focus on food groups and not be nutrient focused. And really the positive claims that emphasize the positive are really seen as potentially the most valuable.

And lastly, on claims we heard that a regulatory frame -- frame work is really needed to help ensure the claims that manufacturers use convey science-based information, such as from the Dietary Guidelines for Americans, and not just reflect the latest fad or the latest something -- things that are popular among consumers, but that are really science based.

Now, in an icon for healthy, what we heard from several folks -- that several folks mentioned, that an icon could be helpful, particularly with low literacy and low numeracy consumers. And also, potentially using -- using this icon for comparison within categories.

However, we also heard some concerns. It might not be as useful for certain populations. For instance, for some who are suffering from certain chronic conditions. There may be competition with other existing icons. There also may be concerns about consumption or overconsumption like the quantity and frequency of consumption if -- if there was a healthy icon. And so we'd need more information -- there would need to be more additional information on portion size, indications on how much to consume, how often and that type of information.

We definitely heard that we need to do -- undertake consumer testing, and that is certainly part of the -- our plan. But to -- we would need to take a look also, and we heard this comment also just most

recently in the public comment portion of the -- of the agenda today, that the importance of taking a look at what other countries have done.

And then finally on the icon, that we would need to do education and any other efforts to accompany such an icon, in order to address any potential health halo effect.

So, on the -- the next session, that I was part of, the Nutrition Facts Label Consumer Education Campaign, we heard, again, a diversity of opinions. It was in both cases incredibly valuable. We heard that there were different sets of opinions on focusing on the changes of the updates to the Nutrition Facts Label but also balancing that with healthy eating messages overall.

And so very quickly, people jumped from nutrients and discussions of nutrients to overall fruits and vegetables and dietary patterns and so there is -- there is definitely a challenge in balancing how we target our efforts.

There were certainly some great examples of nutrition education efforts that were -- and some have been mentioned in the main session here like the MyPlate Partner network as well as SNAP-Ed and some of the work being done through the WIC network.

We -- we heard feedback to focus on message -- messages that many can agree on, particularly when you're trying to bring together such a broad -- a broad group that's focusing on a consistent set of messages that everybody could get behind is very important. And -- and let those be both positive and empowering wherever possible.

We heard opportunities for amplification of our messages and our education efforts through some great set of key influencing networks. So, there was a broad -- many of these networks we had considered ourselves, but we -- we heard even more so that was incredibly valuable. But -- and I have just a few here, SNAP-Ed, WIC, that I mentioned before, but some of the grocery and -- and grocery manufacturers and -- and convenience store associations, professional associations, school associations, as well as federal,

state, and local partners, as well as community and faith-based partnerships and organizations.

We want to leverage where people are making decisions and contemplating change. Sometimes that's in the stores, sometimes that's in planning in advance. So, in-store, online, also potentially within healthcare settings.

We also heard the need for different sets of materials, targeting different sets of audiences. So, nutrition educators, physicians, dietitians, as well as consumers.

And then finally, being mindful, the need to be mindful of key influences overall, whether they be through social media, for instance, or other methods, more traditional methods potentially through television or -- or other media. But for us to be considering both the media and also the messenger.

And then the final breakout session, Modernizing Standards of Identity and Ingredient Lists on the Labels. But -- so firstly, ingredients. We heard feedback on vitamin naming, that letter names to make things easier for consumers, that was a strong thing coming through. That -- that synonyms can be helpful in certain situations and for -- for some of the vitamins. That a format that is more readable could be very valuable, such as avoiding all caps.

And then potentially, requiring percent ingredient labeling for food recommendations. So, for instance, if wholegrains, if it was made with wholegrains, that -- that some requirement be there -- that a percent of wholegrains be part of that requirement on -- on the label.

And then lastly, standards of identity. There was certainly overall broad support for the concept of standards. Although, there -- there was also feedback that some of the standards are a little restrictive, and I think we heard some of that also this afternoon in the public comment section. And that those standards can limit innovation. We need to look at the intent of the standard of identity. What is -- is it the nutritional content or is it to maintain the authenticity of the food? Or is it both? But

certainly, we want to be looking to protect the consumer and to provide assurance, reassurance to the consumer and also level the playing field for industry as well.

We need to understand what the consumer understands, what they want and what they understand regarding standards of identity and what would be most helpful in the future.

And then how to describe products, given the rise of online purchasing. And then the need for horizontal regulatory framework and regulatory changes across all of the standards to allow for innovation, rather than going simply standard by standard, because with 280 or so standards that could take a little while.

And then finally, acknowledge or investigate the opportunity for public private partnerships in this area.

So, these -- these were in a very high level, some of the comments that we received in the different groups. I do want to encourage everybody to submit your comments to the docket. The deadline for that is August 27th. And in your handouts, actually, there are instructions on how to submit your comments to the docket.

I did also want to mention, I know there's a lot of -- a great deal of interest on the dairy standards of identity in particular, and of course, everybody is welcome to submit their comments to this docket for that. But as the Commissioner mentioned, we'll be opening a separate docket related to the dairy standards of identity in the coming months.

I do want to take one minute to -- to acknowledge that when -- when meetings run well, they kind of look like they have organized themselves and that is not the case. So, I do want to take a minute to acknowledge the FDA staff who worked so hard to plan and organize this meeting.

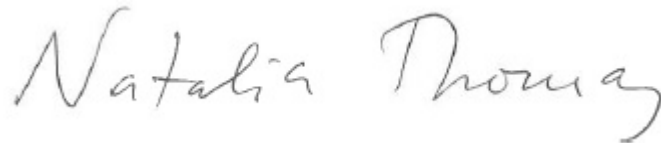
But mostly, I want to thank everybody who has participated, has shared their energy and their enthusiasm, their insights. Thank you for being here today. Thank you to everybody who participated online.

And we look forward to continuing the dialogue in the future. Thank you so much.

MS. BARRETT: All right. We are adjourned.
(Meeting was adjourned at 5:45 p.m.)

CERTIFICATE OF NOTARY PUBLIC

I, Natalia Thomas, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

A handwritten signature in cursive script that reads "Natalia Thomas".

Natalia Thomas
Notary Public in and for the
State of Maryland

CERTIFICATE OF TRANSCRIBER

I, Kelly McGrath-Johnson, do hereby certify that this transcript was prepared from audio to the best of my ability.

I am neither counsel for, related to, nor employed by any of the parties to this action, nor financially or otherwise interested in the outcome of this action.



August 3, 2018

DATE

Kelly McGrath-Johnson