



Indian Health Service

Division of Diabetes Treatment and Prevention

Advancements in Diabetes Seminar FDA Update on Menu and Nutrition Facts Labeling

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Dr. Kavanaugh who is also an RD has been with the FDA for 13 years and her recent activity includes restaurant menu and vending machine labeling, updating the Nutrition Facts label, and sodium reduction. Dr. McKinnon has been with the FDA for almost two years and has previously worked as a health quality specialist at the NIH for 10 years in which she led advanced policy-relevant research on diet, obesity and physical activity. She managed a grant portfolio focused on policy and environmental intervention to improve population nutrition and physical activity behavior and weight outcomes.

So with that, I would like to welcome Dr. Robin McKinnon to start our presentation today.

Dr. Robin McKinnon:

Great. Well, thank you so much, Kelli and Jan. Welcome to everybody who's joining today especially thank you to Kelli and Jan for your wonderful organization. It's been a pleasure to be involved and looking forward to sharing and having this opportunity to share some of the exciting things that are happening at the FDA related to nutrition. I will, moving to the next slide, just provide some outline. Here's an outline of what we're planning to share. I'll provide a bit of an introduction then hand over to my colleague, Claudine who will be speaking about menu labeling, the updates to the Nutrition Facts label that were recently announced last year. I'll talk then about our voluntary sodium reduction initiative and some relevant dates.

With that now, just briefly, the FDA nutrition responsibilities, overall FDA is responsible for regulating about 25% of all products that are purchased in the U.S. and in addition to that, we regulate the safety and labeling of about 80% of all food that's consumed in the U.S. and in case you're wondering, the other 20% falls under the responsibility of the USDA, mostly meat and poultry. But our goal really is to help optimize health through nutrition and help improve the way consumers make dietary choices so that that ultimately enhances public health. We work closely with our colleagues at the CDC, with NIH, the USDA, as well as many other federal partners, especially exciting to join our colleagues at IHS today, a sister agency within HHS.

So turning to some of our nutrition objectives and major nutrition initiatives, two key ways that we can help improve dietary choices and help maintain healthy dietary practices is to ensure that consumers are provided with accurate and useful information via the food label. So this is direct to the consumer and a couple of the examples here, we're going to be talking about in more detail so I won't spend time here but the menu and vending machine labeling, and then updating the Nutrition



Facts label are just two examples there. And then secondly, we can encourage the food industry and food manufacturers to encourage food product reformulation to create healthier products so that consumers have greater choices to choose from.

An example there includes the Voluntary Sodium Reduction Initiative that I'll talk more about later. Another example that I won't talk more -- won't discuss here but others may be aware, firstly, the requirement, that trans fat be declared on the Nutrition Facts label. That was back in 2006 and then in 2015, the determination that partially hydrogenated oils or PHOs which are the artificial forms of trans fat are no longer generally recognized as safe and in 2018, those will need to be phased out of the food supply unless you submit a citizen petition to the FDA. Both direct the consumers, providing the information and then providing incentives and encouraging food product reformulation to create healthier products are key ways that we can help improve nutrition profiles.

At the Center for Food Safety and Applied Nutrition, which is my office, we focus a lot also on food safety as well as on nutrition and I just want to make the point there that food safety is a key component of improved nutrition habits as well, because the last thing that we want -- we're advising people to eat more fruits and vegetables, and those types of things. We don't want people to be concerned from a food safety standpoint that they may have those food safety concerns. So we work very hard on both of those angles to make sure that people have the information they need and they can be confident in the food that they're choosing to improve their health and their dietary practices, overall.

With that, I think I'll turn it over to Claudine who will talk first about menu labeling and then the Nutrition Facts label. Claudine?

Dr. Claudine Kavanaugh:

Okay, great. Thanks, Robin and I want to thank IHS for having us today and letting us talk a little bit more about menu labeling and the Nutrition Facts label. My slides sometimes go into a little bit more detail. I'll try and give you a little bit more of the big picture but I wanted to provide some details for you so at least you have them especially if you get the slides for follow-up. Menu labeling requirements, we were authorized in 2010 under the Affordable Care Act to have menu labeling in restaurants and other similar retail food establishments and this slide goes over a little bit about, kind of the process that FDA does. First Congress passed the statute that authorized us to have menu labeling. We issue some proposed regulations and then get a lot of feedback from stakeholders about the regulations and then we issue final regulations. We issued final regulations in December of 2014. Usually, on big regulations, we have to follow up with some guidance. We issued that last year and menu labeling is going to go in effect on May 5, 2017. So just a couple months away, it will be mandated on most chain restaurants and other establishments. So I'm going to get into more details on where you'll see it soon.

So who's basically covered? It's restaurants and similar retail food establishments and they have to meet specific criteria. They have to have 20 or more locations so it is looking -- this is why it's for bigger change, not kind of more of your mom-and-pop local restaurant or store. They have to do business under the same name and offer substantially the same menu items. I'm not going to go into it today but this also covered part of the requirement for this also covered vending machines. So you may start noticing calorie labeling on vending machines. That actually went into effect in December of last year for vending machine operators who have 20 or more machines.

Getting back to menu labeling, so what does this law require? So, when you see it, you'll know what they have to do. They have to actually disclose the calories on menus and menu boards for standard menu items. Things like daily specials or seasonal items don't have to be labeled but the things that you get every day that when you go into a restaurant that are typically on the menu would be labeled. Also, if they have self-service foods like you go up and pick a pastry out of a case or at a salad bar or a buffet, those also have to be labeled. They have to post a succinct statement that kind of gives

them, puts the calorie information and context. I'm going to show you in a couple more slides about that because I think that's particularly helpful for dietitians and healthcare professionals that are giving nutrition advice. It also provides that written nutrition information has to be available upon request and have a statement on the menu saying this. I think that's also very helpful since calories are the only thing that needs to be posted on the menus and menu boards for maybe clients that you have that need information on the saturated fat, cholesterol, or sodium levels. They can request that and get that information.

Some of the examples of the facilities that would be covered, so basically your regular restaurants but also a lot of grocery stores and convenience stores, again, may have to meet the criteria that I outlined, having 20 or more facilities and offering substantially the same foods. But for those facilities that have more restaurant-like foods, they would be covered. And if you think a lot of convenience stores and grocery stores, they are kind of getting more into the restaurant type foods. Your take-out foods, entertainment venues, one of the major movie theater chains across the U.S., AMC has already implemented it. It's up in their things, in their movie theaters already and if you also have been to a theater lately, usually you can get more than popcorn and soda at the movie theaters now. You can almost get whole meals. Cafeterias, coffee shops and then super stores as well, because again, a lot of the super stores are getting to have more restaurant type foods.

Just to give you a little bit more background on what they have to do, the menu boards and menus, if you think about it, there are lots of different menus and menu boards at restaurants. You can have the drive-thru menu, a menu board that you might go into the establishment. If you're going to more of sit-down place, you'll probably have a drink menu, a dessert menu, a kids menu, all of those menus, even if it's online and you can order the food online, it has to be labeled with the calories. The calories have to be labeled for each standard menu item listed on the menu or menu board and we have specific requirements on how big it has to be. It has to be in a type size, no smaller than the name or the price of the item, and we also have some criteria so it has to be very visual. They can't put like yellow on white, or something like that.

We also have information for sometimes you'll see things on menus like soda and you have a broad range of soda selections. Those would be listed in a range to give people the context. And that's actually part of the statute. I know I get asked a lot, "Why can't you just make them list out all the varieties and then calorie information?" The law doesn't actually permit us to do that.

Self-service food or foods on display also have to have the calorie information and they have to have a sign near the food. If you think of like a coffee shop that you go into with like muffins and pound cake and things like that, it would have to have a sign saying "300 calories per muffin," or per slice.

Now the Succinct Statement, as a dietitian, I thought this was a really key component of the menu labeling. On all the menus or menu boards, they have to have the statement that's bolded on the slide which is 2,000 calories a day is used for general nutrition advice, but calorie needs vary. I think it's really key because it puts the context of the calories in the total daily diet. So while everyone doesn't need 2,000 calories, that's kind of a good ballpark for a lot of people and when they see the information on the menus of like a meal that's a thousand calories, they'll be able to put that in the context of their diet, that that's half their calories. So I think this is really important information. Also, it's optional, they have specific things for children's menus and they have different calorie levels, succinct statements for the children's menus.

Now I'm going to go into a little bit of the Nutrition Facts label, which we recently updated. The Nutrition Facts label came out in 1994 so it's almost over 20 years old and it only had one update in 2006. We added trans fat, so it really hadn't been updated in a while. Again, FDA used its regulatory process and issued proposed rules. We actually issued a supplemental proposed rule and then we actually got on these rules over 300,000 comments. So we got a lot of stakeholder input on this. And then in May of last year, we issued our final regulations to update the Nutrition Facts label.

I'm going to show you the slide right here. It shows you the new label that you can look at. We definitely gave manufacturers some time to change their labels so while I've started to see this on a few packages, it's going to probably take a little while before you will actually start to see them on more just because as manufacturers update their labels, it just takes them a while to get into the marketplace. Looking at this label, probably one of the things that strikes most people is the calories is a lot bigger on the label. We also tried to make the serving size information at the top of the label a little bit bolder and easier to see. We updated the serving size information which I'm going to talk about as well as the daily values. We added "added sugars" to the label, that's something new that we added and that is basically based on the new dietary guidelines and the data behind them that encourages people to have less added sugars in their diet. We also changed the nutrients that are required on the label and updated the footnote.

I'm going to go through these changes in just a little bit more detail for everyone.

Dr. Robin McKinnon:

This is Robin. You might want to mention also the calories from fat.

Dr. Claudine Kavanaugh:

Yes, calories from fat is actually removed from the label as well. That's one of the things we took away. We just didn't add.

Dr. Robin McKinnon:

Right.

Dr. Claudine Kavanaugh:

So for added sugars, that is now mandatory and we had that, it's under total sugars. You can see it's a little bit different. We added "includes" because we actually had done some of our own consumer research and found that a lot of people, if you just had "sugars" and then "added sugars" underneath it, they didn't realize it was a sub-component of total sugars. So we tried to clarify that in the label. And the daily value for added sugars is 10% of the calories and for our food label, that's based on a 2,000-calorie diet. That's about 50 grams of added sugars for a 2,000-calorie diet.

For calories and servings, you can see calories are a lot bigger. On the current label, if you see it's about 8 point font. This is now about 22 points so we really increased it. We wanted to be able to have people focus on that especially given the public health issues with obesity and overweight. We also reversed the order of the serving size and servings per container. Part of that was everything on the Nutrition Facts label below is really based on the serving size so we thought it would be helpful to have the serving size below but obviously, the servings per container is so important information as well.

We also updated our footnote at the bottom of the label. That is still fairly small to see but that kind of highlights for people what the daily value is. That's a concept that's very challenging for people to understand. The daily value really puts the context of the vitamins and minerals and some of the macro nutrients in the context of the total daily diet. It's a hard concept but we tried to revise it to help people understand. And you'll also notice in the footnotes that it says 2,000 calories is general nutrition advice; that kind of links up to our menu labeling succinct statement. We wanted some cohesion between menu labeling as well as the Nutrition Facts label and really getting people a little bit more honed into that 2,000 calories kind of as a ballpark calorie level. Again, individuals have different needs and I think as nutritionists and nurses, we definitely need to counsel our patients and clients on what they need but I think a lot of people just have no context, so hopefully, that will be helpful.

We also updated the daily values on the Nutrition Facts label. I think this is an area where consumers probably aren't going to notice the information as much as healthcare professionals will. The old daily values, some of them were based on RDAs from like 1968 so they really needed to be updated on the current science and in the last, from I think 1997 through 2011, the Institute of Medicine had updated the dietary reference intakes for a lot of nutrients so we used that to update them.

We also changed, this slide and it illustrates the nutrients of public health significance, and these are the nutrients that are required to be on the label, kind of at the bottom of the level. You'll see now we have Vitamin D, calcium, iron and potassium. Calcium and iron have been required since 1994. Vitamin D and potassium are new ones that are required. We actually are not requiring vitamins A and C any longer. Those were originally required nutrients. Manufacturers are certainly permitted to put those on voluntarily if they want to but we found that with looking at food intake as well as biochemical measures from the Nutrition Health and Examination Survey, that vitamin D and potassium were really more critical nutrients that people were missing, so we wanted those on the Nutrition Facts label.

Now dietary fiber, that didn't change on the Nutrition Facts label but the definition for dietary fiber did. Right now, if you see dietary fiber on the Nutrition Facts label, it's based on the chemical analysis of how much fiber is in the product but really, now that a lot of people are adding fibers, isolating them, or making synthetic fibers and adding them to food and a lot of times, it's just to bulk up the fiber declaration. We wanted to make sure that all the fiber that's actually going in the food has some type of physiological beneficial effects to human health. So fiber sometimes can lower cholesterol, it can increase laxation, it could help other nutrients be absorbed so there are a lot of different things that the fiber can do but it does need to have some physiological effect. So when people start using the new Nutrition Facts label, all the fiber that you actually see on that line will have some type of physiological effect. We're actually reviewing a lot of fibers now and are planning to give more input to the industry on what fibers we've found have enough evidence to actually have the physiological effects.

We've also made some changes to serving sizes. By the statute, serving sizes are based on what people actually customarily consume. They are not based on recommendations. So we looked at the NHANES data and looked at what people are actually eating. The data the labels are based on now, we looked at consumption data from like the '70s and '80s, so certainly, people's eating patterns have certainly changed since then. So we have updated a lot of serving sizes. One of them that has changed that you will see on this slide is ice cream. It used to be a half of a cup so if you had a pint of ice cream, you would have four half-cup servings. Now it went up to two-thirds of a cup and there are three servings now in a pint. A lot of questions that I get from dietitians are "Why don't you have recommended servings?" Part of it is we can't do that because the law doesn't allow us to but I think recommended servings, if you think about foods that you want people to eat are very easy but what kind of recommended serving would you really have for something like soda or candy? I think it kind of breaks down when you think about the foods that are maybe considered more as a treat than something you want to have in your diet all the time like fruits and vegetables.

We also changed our requirements for labeling single serving packages, so if you look at a 20-ounce soda now, they have the option in our old regulations of either labeling a 20-ounce soda as a single serve container or as a multi-serving container. And we actually did some research. We have a consumer studies team and they found that when people looked at the soda in a 20-ounce -- soda, that if it had that, it was two servings, people didn't realize it was two servings. They only thought the nutrition information was for the whole bottle. So for some of these products, particularly sodas, some frozen meals that have large serving sizes, if they have less than two servings, they need to be labeled as a single serving package.

We also finally have something called dual column labeling. This is actually going to be required on packages that can be consumed in one or multiple sittings. Basically, anything that is two servings to about three servings would have to have these dual column labels and that would have -- the nutrition information would then be presented in a per serving and per container so if you think of

something like -- the example on this slide is a three-ounce bag of chips that you sometimes could get at a convenience store, kind of at the check-out, sometimes you can get these in vending machines, a three-ounce "Big Grab" of chips, a lot of people are going to eat that whole bag of chips in one sitting; some people probably aren't and might save it for later or perhaps share it with a friend. But that way, when they look at the Nutrition Facts label. It's very clear what the calorie and nutrient content is per serving or per container and they can look at that and the math is already done for them. They can have that information.

I think that is the last slide for updating the Nutrition Facts label and I'm going to pass the baton back over to Dr. McKinnon to talk about our voluntary sodium reduction targets and initiative.

Dr. Robin McKinnon:

Great. Thanks so much, Claudine. I'll just add on, with the dual column labeling and the single serving packaging for nutrition, part of the changes for the Nutrition Facts label updates, that a lot of what we saw was that people were confused about having to do the math with the serving sizes, whether it was single serving or whether there are multiple servings in a product. In this way, hopefully, with both dual column labeling, the changes for the single serving packages and then some of the -- so that now the math will be done and people will be able to really understand what they're consuming much more easily.

Turning now to the voluntary -- and this is a draft -- voluntary sodium reduction targets, this is different so we were talking before about labeling and providing information to consumers. Of course that can also impact some food manufacturing decisions as well, but this sodium reduction initiative is more targeted towards food manufacturers and those in the restaurant environment. So going to the next slide, we announced back in June of 2016 draft voluntary guidance on reducing sodium in processed and packaged foods. We announced this is intended to be a gradual approach. We'll have short-term targets and longer term targets overall trying to reduce people's average sodium consumption down in the short term to about 3,000 milligrams per day and then over the longer term down to what is now the upper limit, the DRI for sodium of 2,300 milligrams per day. We announced these targets for 150 categories of food that sales wanted to focus on the dominant sellers in each of the categories. As I mentioned, this applies to food manufacturers, restaurants and then other food service operations. Exactly what we were hoping for has happened. We announced these draft targets. We received a lot of really helpful comments and feedback on the guidance. We released the information that was the best available, that was publicly available, and a lot of the food manufacturers have other information because they're the ones who are involved in creating a lot of the food products. So we received, as I mentioned, a lot of very helpful feedback. So we're in the process now of combing through those comments.

Just a little more about why we're doing this, why do we need these targets in the first place? And that's because a lot of the sodium that people consume in their daily diet is already in the processed and prepared foods in restaurants. If you look at the chart here that's on the slide, a lot of people will say, "Gosh, I don't add a lot of sodium. I don't add salt to my food," but if you can see here, a lot of what people can actually control is pretty minimal. It's only -- like the teal piece of the pie and the lime green is home cooking and added while eating. Those are the contributions to sodium consumption overall. The rest is naturally occurring but most of it, about three quarters, is already part of the processed and packaged food. So it's actually very difficult to meet and to limit your sodium intake if you're consuming processed and packaged foods from the current food supply in the U.S.

Overall, sodium content in the food supply is still relatively high. We do know that there've been a number of food manufacturers who have made some great strides in this, but despite that, the overall average sodium intake is still relatively high. It's about 3400 milligrams on average, far above the recommended upper limit of 2300 milligrams. But we do see this variability in sodium across similar foods in the food supply. We know that it's possible in a lot of cases.

And so the process that we used to set the targets was in three main steps. Firstly was we were looking across the entire food supply and developed from that about 150 food categories. And a lot of people say or might have thought, "Maybe you would just take a one-size-fits-all okay everybody needs to reduce sodium in their foods by 10 or 15%," or something like that but that really does not account for the variability within a lot of different types of foods. So it's much better to take a tailored approach and see what was possible, what was selling well in the market and adjust and create targets based on feasibility and how appropriate it was for these different categories.

So we developed these 150 categories. We determined a baseline of the different sodium concentrations based on milligrams per hundred grams and then set these quantitative goals. Firstly, an overall target or an average level which would be for a category, not for individual products but overall for a category and a target mean level and then also a recommended upper bound and that would apply to individual products. And that's intended to discourage products from having excessive sodium.

Sodium plays an important role. I just wanted to make this point, that a lot of people think it may be relatively easy to remove sodium from processed and packaged foods but actually, sodium plays an important technical role in food technology and from fermentation, certainly for flavor, often color development, even texture development and then also, it has antimicrobial properties as well, so it does an important food safety component and certainly, we want to be very, very mindful especially as the Center for Food Safety and Applied Nutrition, we want to be very mindful of food safety overall and reducing sodium in the safest possible way.

This is an example of one of the 150 categories that we created targets for. I know that there's a lot going on in this slide but just to orient you a little, on the Y axis, you can see the number of products. So the sample category here is pre-cooked sausage. The number of products is on the side. Thank you, Claudine or whoever is providing the pointer. That's extremely helpful. Across the bottom is the sodium concentration which is sodium per 100 grams. And these are the top 80% of products selling on the market. Firstly, you'll notice here that there's quite a range. These are successfully selling products on the market that range from about 450 milligrams per 100 grams of sodium, up until over almost 1,500 and over -- milligrams of sodium per 100 grams. That's quite a range. So we start from a 2010 baseline and then created both short-term goals and then the longer term goals which are in yellow and green respectively.

One thing you can see from that is already, there are some successfully -- products that are selling successfully on the market that are meeting those targets. That's the type of information that we've provided. There's a lot more. We've provided links that you can go to check more information out on individual categories and targets and things like that if you would like, but I just wanted to give you a feel for what we're doing, again, focusing on food manufacturers and restaurant foods, gradually lowering sodium across the food supply. And that's what's most important because what we know from research is that people's palates will adjust but what's critical is, if it's done slowly and if it's done very broadly. People will notice if it's done too quickly and if a substantial portion of the food supply doesn't reduce their sodium, then people's palates won't adjust. So the broadness and the speed at which -- or how gradual we are bringing things down is important.

I have a quote here that was from former Senators Bill Frist and Tom Harkin that ran in the Hill talking about the potential for this reduction in sodium and the real potential to improve public health as a result. This is the link. You can go to www.fda.gov/sodiumreduction for a lot more information on this if you would like.

I'll move on to some final wrap-up information if you like and then we'll turn to questions but just a brief refresher on some of the relevant dates. For sodium, as I mentioned, we recently had a public comment period that ended in December of 2016 so we're going through all of those comments right now. Menu labeling as Claudine mentioned, it's coming up, May 5, 2107 in restaurants and similar retail food establishments to post calorie information and the other requirements that are part of the rule. Most of the rules for vending machines went into effect or most of the requirements went into

effect for vending machines in December of 2016 so you should see those. And then for the Nutrition Facts label, in 2018, July 26, 2018, for all manufacturers and then small businesses with under 10 million in revenue have an extra year to comply. So those are the relevant dates.

And then I did want to highlight some additional educational materials, especially for the RDs, but maybe for others as well. If you are interested in more information to provide to patients or to clients, these changes to the Nutrition Facts label, other FDA Nutrition Programs and materials, and also particularly this last link on food safety and nutrition resources for healthcare professionals and there are Spanish language materials in here as well. But also wanted to highlight the CME video on the Nutrition Facts label that was developed in partnership with the American Medical Association, focusing on healthcare professionals and how you can use the Nutrition Facts label when working directly with patients.