

Kyle: Good afternoon, everybody. I am Kyle Kinner. I coordinate government affairs for food and health programming at the Pew Charitable Trust. I'm a member of the board of the Alliance for Stronger FDA. I'm joined today by Steven Grossman, the Alliance's Executive Director, as well as fellow board members, Alison Bodor, President and CEO of the American Frozen Food Institute, and Thomas Gremillion, Director of Food Policy at The Consumer Federation of America.

First, a quick word about the Alliance for a Stronger FDA. We are a multi-stakeholder coalition that advocates for increased appropriated resources for the Food and Drug Administration. We are strongly committed to strengthening the resource base needed to advance FDA regulatory and public health mission. We have been an important force in doubling the FDA's annual budget authority from 1.6 billion to more than 3.2 billion dollars in recent years.

The Alliance is the only advocacy organization focused on resources for both food safety and medical products as well as the other components of FDA's mission. Our members include consumer and patient groups, research advocates, health professional societies, trade groups, and industry. We are about 150 members strong. We always welcome new organizations to that list to further strengthen our advocacy and educational efforts.

Regarding procedures for today's conversation, our speaker has kindly agreed to the format that has worked very well in our earlier webinars. Dr. Mayne will interview herself using questions the Alliance has provided and we will be followed by ample time for Dr. Mayne to answer some of your questions, as well. So, in terms of logistics, you may submit questions at any point in this webinar by clicking on the Q&A button at the bottom of your screen.

I now have the privilege of introducing our esteemed speaker for today's webinar, focusing on FDA's work to foster good nutrition policies and healthy eating practices for all Americans. With us today is Dr. Susan Mayne, Director of FDA's Center for Food Safety and Applied Nutrition. Dr. Mayne leads the center's development and implementation of programs and policies related to the composition, quality, safety, and labeling of foods, color additives, and cosmetics. CFSAN's responsibilities also include fostering the development of healthier foods and ensuring that consumers have access to accurate and useful information to make healthy food choices.

An internationally-recognized public health leader and scientist, Dr.

Mayne received a BA in Chemistry from the University of Colorado. She earned her Ph.D. in Nutritional Sciences with minors in Biochemistry and Toxicology from Cornell. She came to FDA in 2015 from Yale University where she was the Winslow Professor and Chair of the Department of Chronic Disease Epidemiology at the Yale School of Public Health and Associate Director of the Yale Cancer Center.

Dr. Mayne, thank you so much for your long-standing commitment to advancing food safety and improved nutrition policies and for agreeing to spend some time with us today to help us understand how collectively we can work with you and your colleagues at FDA to accomplish the goals that we share. So, with that, Dr. Mayne, I'll turn it over to you. The floor is yours.

Dr. Mayne:

Thank you so much, Kyle and thank you to the Alliance. We are just really pleased to have this opportunity to speak about some of our work and just thank you for all the work you're doing advocating for resources. I'll try to get into some of those areas today in my remarks. I'm going to focus primarily on nutrition today.

So, we will use the Q&A format, so I will be interviewing myself with some of the questions that you all have targeted for me. The first one is can you provide a little background on what CFSAN does? As most of you know, we have very broad responsibility for the safety and labeling of almost 80% of the nation's food supply. CFSAN also oversees the safety and labeling of cosmetics and dietary supplements.

Last time I spoke with you, I discussed the intersections of our work on toxic elements, things like lead, arsenic, mercury, cadmium and how that intersects with nutrition. So, today, I'm really excited about the opportunity to talk to you more, just focusing in on the nutrition side of our portfolio.

The next question is what are our nutrition responsibilities and how are our nutrition programs organized in CFSAN? Our role in nutrition goes back to our initial statutory authority, the Federal Food, Drug and Cosmetics Act, which provided the agency the authority for food and nutrition labeling. That role was significantly expanded in 1990 with the enactment of the Nutrition Labeling and Education Act or NLEA. The NLEA provided FDA with more specific nutrition labeling authority. I'm hopeful everybody here is familiar with the most visible result of the NLEA, that is the nutrition fact label.

The first major revision of the Nutrition Facts label was published in 2016 to align with the most recent nutrition science and the updated requirements for the nutrition facts label recently went into effect.

Beyond the Nutrition Facts label, we are engaged in various other nutrition activities, things like nutrient content claims, health claims, menu labeling, sodium reduction, and consumer education. All with the goal of helping consumers build healthier diets more easily. Within CFSAN, the primary office that works on nutrition is our Office of Nutrition and Food Labeling, which oversees the policies and regulations for nutrition labeling, working food standards, infant formula, as well as medical foods.

But other offices in CFSAN also have a really important role to play in nutrition. As an example, our Office of Analytics and Outreach conducts consumer research. They lead the development of our educational materials. Additionally, our Office of Food Additive Safety has been leading the work we've done to help remove trans-fat from the food supply and they've led the development of our sodium reduction targets. This work is led out of the Office of Food Additive Safety because trans fats and sodium are food ingredients that are intentionally added as food additives. So, there are many different offices that contribute to the nutrition portfolio I'll be talking about today.

The next question is why is nutrition important to me? First, it's my background. I did earn my Ph.D. in Nutritional Sciences and then spent most of my career researching the complex role of food and nutrition to determine the product risk. Second, and most importantly in terms of why we're here today, is that the United States and much of the world is suffering of an epidemic of diet related chronic diseases including obesity. FDA and CFSAN can really help make a difference in changing that.

Next question, can you tell me more about why the increasing amount of diet related chronic disease is a concern? So, to begin with, the human and economic costs of diet related chronic diseases are stunning. Hundreds of thousands of Americans die every single year from these leading causes. For example, in 2019, 800,000 people died from cardiovascular disease. Just to register the strength of that number, that's a greater number than the horrific toll of COVID-19 that we've seen over the past two years. But that's what we lose to cardiovascular disease in one year, 2019.

The cost of heart disease alone has been estimated at more than \$350

billion dollars per year. A substantial burden of those costs is borne by the government. In 2018, government spending, including Medicare and Medicaid, to treat cardiovascular disease, cancer, and diabetes accounted for 54% of the \$384 billion in health care spending to treat those conditions. The impacts ripple throughout our society, including reducing productivity, creating even national security concerns. Obesity is one of the top reasons that Americans do not qualify for the military. So, this is a major, significant issue.

When you take into account all of the costs of diet-related chronic diseases, effects on productivity, healthcare spending, military readiness, and more, estimates of the total economic costs range upwards of a trillion dollars per year.

Next question, how has the COVID-19 pandemic affected the trend of diet-related chronic diseases? I'll start with an example using obesity, which is both considered a disease, obesity is a disease in and of itself, but it's also a condition that increases risk for other diet related chronic diseases like diabetes, cardiovascular disease, and certain types of cancer. Unfortunately, what we're seeing with COVID-19 is an increase in obesity. In September, CDC released some updated obesity statistics for adults in 2020. And we are seeing that they are continuing to increase.

CDC data also shows some very disturbing increases in childhood obesity that has occurred during the pandemic, especially for school aged children. This is so concerning because childhood obesity puts a child at increased risk for obesity and other diet-related chronic disease later in life.

Next question, are all segments of the US population equally effected by diet-related chronic diseases? The answer to this question is no. Unfortunately, diet-related chronic diseases are experienced disproportionately by racial and ethnic groups as well as those with lower socio-economic status. As one example, more than four in 10 American adults have high blood pressure. That number increases to about six in 10 for non-Hispanic Black adults. These disparities cut across racial and ethnic groups and across multiple diet-related chronic diseases. It is a widespread problem that is continuing to grow.

I mentioned that childhood obesity increased during the COVID-19 pandemic. One recent study showed that the increases were more pronounced in children who were Hispanic, non-Hispanic Black, publicly insured, or lower income. Improving nutrition is an important way to address these health disparities. Again,

underscoring why our nutrition work is so important.

That leads me to the question of, well, what is FDA doing to help address the problem? Well, we really see that we have a generational opportunity in front of us to help turn the tide on diet-related chronic diseases. We are focusing on three areas to help improve nutrition and advance health equity.

The first one is creating a healthier food supply, giving consumers more choices to eat healthier. The second one, establishing a health start to set the foundation for a long healthy life. And the third one is empowering consumers by providing informative labeling and tailored education for specific subgroups.

Creating a healthier food supply has significant potential to improve American diets, even in the absence of behavioral change. We took a big step in creating a healthier food supply in October when we published our final guidance establishing voluntary short-term sodium reduction targets. Americans consume about 50% more sodium than what's recommended on average. That's a problem because excess sodium consumption is directly linked to hypertension, which is the leading risk factor for heart attacks and strokes.

The vast majority of sodium in our diets comes from processed, packaged, and prepared foods. So, encouraging sodium reduction across the food supply will make it easier for people to access lower sodium options. The short-term sodium targets aim to help reduce people's sodium consumption by 12%. We anticipate that this modest reduction over the next several years will yield substantial improvements across the population in terms of improving health outcomes.

But this is just the beginning. We plan to monitor the food supply to assess industry's progress towards meeting the targets, engage with our stakeholders, and then issue revised targets in a few years. This gradual, iterative approach has been successful in other countries like Canada and the UK.

Labeling is another tool in our toolbox that we are leveraging to create a healthier food supply and to empower consumers. You may be surprised to know that after we required trans-fat be declared on the Nutrition Facts label, we saw an 80% reduction in trans-fat in the food supply. We anticipate this has led to tens of thousands of cases of cardiovascular disease being averted and lives saved. I think this just really underscores the power of labeling and how it can lead

to enormous public health benefits.

Our immediate priority in labeling is to update the nutrient content claim “healthy”. Nutrition science has evolved since we first established the claim in the early 1990s. So, we’ve been working hard and have developed a proposed rule to update the criteria. And that rule is now with OMB in final stages of clearance. We are eager to publish this rule very soon. Along with helping consumers better identify foods that are part of healthy eating patterns, the updated criteria could also incentivize industry to reformulate their products so that they could bear the “healthy” claim.

We are also conducting consumer research on a potential “healthy” symbol. A symbol could be particularly helpful for those with lower nutrition literacy.

Lastly, we’re looking at ways we can expand our work to help establish healthy starts in young children. Focusing in on younger populations is so critical because healthy dietary patterns early in life can influence the trajectory of eating habits and health behaviors throughout life. We’re taking a holistic approach that encompasses some of our work on toxic elements and our Closer-to-Zero plan that I discussed with you last time.

We see great value in addressing our work on toxic elements and nutrition in young children holistically because many foods that can be higher in toxic elements like fruits and vegetables are the foundation of healthy eating patterns. We held a public meeting on our Closer to Zero plan in November. During that meeting we discussed the scope of our plan as it relates to toxic element exposure and nutrition at different crucial developmental stages during growth and development.

As we implement our Closer to Zero plan, we will work to provide parents and caregivers accessible, science-based information to help make nutritious choices to ensure their children’s healthy development while also reducing their exposure to toxic elements from foods to as low as possible.

So, this is just a snapshot of our nutrition work. As I mentioned, we really see a huge opportunity in front of us right now to advance nutrition and we anticipate that 2022 will be a significant year.

Next question, can you give an example of how CFSAN is coordinating with federal partners? We recognize that we are one agency in a larger, complex nutrition ecosystem. This makes it

critically important for us to collaborate and coordinate with our federal partners. We are working very closely with our federal partners, which include USDA, CDC, and NIH, and others on many nutrition related efforts, including calls nearly every week. And we are exploring new ways to coordinate, leverage, and amplify each other's nutrition work.

We have regular meetings with our federal partners, including CDC and various parts of USDA to share updates and to identify areas to collaborate on our food and nutrition efforts. More specifically and most recently, we've been working very closely with other HHS agencies, CDC, NIH, ACL, and USDA on how our recently released sodium targets can be leveraged across the federal government, for example, through food procurement standards and federal food service programs.

Next question, can you give us a brief overview of our budget? FDA's overall food program, the entire food program, includes 3800 FTEs from funding of about \$1.1 billion dollars. However, two thirds of that goes to field operations such as inspections of food facilities, meaning CFSAN has about 1,100 people with a budget of about \$345 million dollars. Unlike most FDA centers that receive significant funding through user fees, 97% of CFSAN's budget comes from Congressional appropriations, which makes us an outlier and leads us to significant funding shortfalls relative to most other FDA centers.

For example, prior to the passage of the Prescription Drug User Fee Act, or PDUFA, FDA's food and drug programs were about the same size. Today, FDA's drug work is double the size of its food program and CDER is roughly five times as large as CFSAN. In fact, CFSAN is smaller than all of the FDA centers with exception of CVM. Of course, the foods program has a very big and a much larger field responsibility given it has oversight of over 100,000 food manufacturing facilities in the US compared to a little over 3000 drug facilities for the drug side of FDA.

What is your thinking about the need for funding in CFSAN's nutrition program? As I shared when we met last time, our FY '22 funding request included \$18 million dollars for maternal and infant health and nutrition, as well as \$19.5 million dollars to address emerging chemical and toxicological issues. However, those requests mostly focused on the many chemical contaminants in food that need to be better monitored and less on reducing diet-related chronic diseases.



Our current nutrition funding accounts for seven percent, I'll just emphasize, seven percent of the budget or 23.5 million dollars per year. This allows us to have 67 people directly supporting nutrition work in the center. By comparison, tobacco and nutrition similarly contribute to the chronic disease burden that I spoke about earlier. However, the Center for Tobacco Products budget is nearly 30 times larger than the budget allotted to our nutrition work. Considering the severity of the problem related to diet-related chronic diseases, there is no question that we could do more, much more, to move the needle with a more robust program.

Next question, what would be the impact of more resources for your program? I think there's a very strong case that could be made for how our efforts can contribute meaningfully to improving people's lives and lowering the enormous cost of diet-related chronic diseases. We could dramatically reduce the risk of chronic diseases, prevent disabilities, and premature deaths from these diseases and help all of us lead healthier lives.

As for economic costs, some estimates of total economic costs, as I mentioned, range upward of a trillion dollars per year. This includes health care costs and lost productivity due to diet-related chronic diseases. Let me provide an example. Research has estimated that lowering US sodium intake by about 40% over a decade could save 500,000 lives and nearly 100 billion in healthcare costs.

Our short-term sodium reduction targets, if fully implemented by industry are expected to result in a 12% reduction in sodium. But as I mentioned, this is only the first step in our sodium reduction work. We are planning to issue revised targets in a few years to further reduce sodium intake. The updated targets will be informed, in part, by monitoring the food supply and by industry's progress.

While it may not sound like a flashy activity, monitoring is at the crux at developing achievable sodium targets. Monitoring the food supply in a robust way benefits everyone, including industry and public health. It allows us to develop and refine targets that are more specifically tailored for various food categories because we know a one size fits all approach is not appropriate here due to food safety and technology considerations. Additional funds would allow us to hire more staff and collect the necessary voluminous data to monitor the food supply and implement achievable sodium reductions resulting in hundreds of thousands of lives and billions of dollars in healthcare costs saved.

These same data systems could be used for numerous other nutrition



efforts. And it's consistent with FDA's focus on better data for decision making more broadly. In short, there are significant returns for investment when it comes to nutrition.

Next question, what would you spend additional resources on? I really appreciate the Alliance asking this question. We are working closely with the administration and other federal partners on our plans for the future here. And we do see lots of potential. Our FY '22 requests, which I spoke with you last time, includes requests for money to work on the intersection between nutrition and toxic elements. We really think about this as a down payment for building our capacity to deliver on a healthier food supply and consumer education.

Looking at some of our recent accomplishments, I'd say that monitoring sodium in the food supply is, of course, one of the areas where with more, we could build a strong monitoring system as I just described. But beyond sodium, additional funds would be particularly helpful in our labeling work. In particular, additional resources would help support our work in labeling in e-commerce. Consumers use of e-commerce to shop for groceries has dramatically increased in recent years and further accelerated dramatically during the COVID-19 pandemic. However, our labeling requirements pre-date the trend of online sales of foods that would be delivered directly to consumers.

This makes it important for us to learn more about the current online labeling landscape, and use our tools to assure consumers continue to have access to important food labeling information at the point of purchase, no matter the setting. Specifically, additional funds could be used to support additional stakeholder engagement such as public meetings, research, and potential policy development. Additional resources would make it possible for us to expand our education and outreach to consumers. Education is essential to the success of nutrition policies to drive public health gains. Education raises awareness and understanding of the labeling updates we are making.

For example, when we finalize our update to the "healthy" claim and potentially a symbol, additional funds would allow us to develop and promote education materials, including for tailored ones for sub-populations on the "healthy" claim to help empower consumers to use the claim to make healthy choices. We could then partner with our federal colleagues to further disseminate our messages and materials to targeted audiences.

So, what's your vision for all of this will help? The resulting vision

from this work is an environment where all Americans have greater access to healthy foods by default. We want to create a healthier food supply where Americans are consuming more fruit, vegetables, whole grains, and less sodium and added sugars by default. We want to empower consumers to make healthier choices through updated and more accessible labeling.

And we have to focus more on young children, one of our most vulnerable populations to help set them up for a long, healthy life. Along with moving the needle on diet-related chronic disease, we see this work helping to reduce disparity. One of the most important responses to addressing health disparities relates to improving the quality of food and nutrition. But as I mentioned earlier, FDA is only part of a complex nutrition ecosystem. We can't do this alone. We need to work together with our federal partners and stakeholders like you to take bold steps right now to reverse the course of diet related chronic diseases.

But with that, the self-interview, I'm going to turn it back to the Alliance where we're happy to entertain some questions and answers.

Kyle: Dr. Mayne, thank you for that rich window into your work and CFSAN's efforts to advance nutrition policy and healthy eating in America. Let me first turn to my colleague Alison Boder to talk with you about some questions that we have and then we'll turn it over to the audience.

Alison: Great, thanks Kyle. Dr. Mayne, first up, how did COVID affect FDA's operations around nutrition? And also relatedly, how are you getting information now about the impacts of both COVID and supply chain disruptions on the food industry? And how is the agency taking that into consideration moving forward into 2022?

Dr. Mayne: Thank you for that question, Alison. I think, as Alison knows very well, early in the pandemic, we had these temporary market imbalances where we had these instantaneous closures of restaurants and large food service operations. So, all the food that was destined to go into that source couldn't be readily transferred to help alleviate everybody now getting food in grocery store shelves. So, it was just an imbalance in the supply chain there.

Part of that was because of different regulatory requirements, as well, that some of the food that was, for example, destined for restaurants, wouldn't necessarily have met labeling requirements for sales to consumers, like nutritional labeling. So, in conversations we

had with industry, we rapidly got into gear and did everything we could in our power to help maintain that food supply chain.

So, we knew that there was food out there. But we had to get some guidance and create some regulatory flexibilities to allow that food to be sold directly to consumers. So, we quickly got into gear. We developed some temporary flexibility guidance around labeling. Many of these guidance were developed by our nutrition labeling staff. These guidance are still active and there hasn't been a need for more. So, our nutrition labeling resources are now focused on the reduction in diet-related chronic diseases, which have been exacerbated during the COVID-19 pandemic.

I will point out, as I said before, COVID-19 has really revealed the impact of these diet-related chronic diseases. We know that people who have diseases like diabetes, obesity, cardiovascular disease, six times more likely to be hospitalized from COVID-19 and 12 times more likely to die from COVID-19.

So, to the other part of Alison's question, where are we now, how do we continually to know what is happening? We do have regular engagement with many members of trade associations to maintain as best information as we have available about what is happening in the food supply and what those challenges are. We have been using a whole-of-government approach throughout the many months of the pandemic. So, when we hear about particular challenges that the food industry has been having, even if they are not in FDA's Lane, we work with our federal partners to try to address those.

A critical part of that has been working to help keep food workers safe. That was a huge focus early in the pandemic. So, giving guidance on what measures, what did we know, what could we tell food workers in order to be safe. How do we help them procure the necessary personal protective equipment? How do we get information, guidance out, guidelines, it's not official guidance, in many of these cases, just sharing best practices and information?

So, it has been quite a journey as we have worked with OSHA, as we've worked with USDA to do what we can to keep food workers safe. Because we know, if food workers are not safe and they get sick, then that jeopardizes the food supply chain. That jeopardizes their health, their family's health, their community's health. So, we all have the shared goals of really helping to address these issues.

As I mentioned, we're not done yet and we continue to engage with industry through multiple mechanisms to hear what the challenges

are and do our part to either share those with other federal partners, whether it be transportation or steel industry or whatever it may be, we share those lessons learned with our federal partners in an all of government response to do what we can to help support the food supply chain.

I will note that despite all the challenges, we've managed to keep up with all of the good work that has been done by the food industry, and food supply chain has stood this test. We've all seen temporary disruptions but there have not been any wide-scale food shortages. And I think that's a credit to the industry and the work that we have all been doing together to get through what has been an unprecedented challenge.

Kyle: I'm just going to turn it over to Thomas. But I wanted to alert the audience, again, we're going to turn to audience questions in a bit. If you have questions, feel free to click the box at the bottom that says Q&A and type your question in and send it to us. Otherwise, we will continue to talk with Dr. Mayne. Thomas?

Thomas: Thanks, Kyle. Thank you, Dr. Mayne. You mentioned CFSAN's work on developing criteria for a "healthy" icon on foods. I wonder if you could talk a little bit how that work fits in CFSAN's general goals for labeling. And also, whether you anticipate any other front of package labeling initiatives that might compliment a healthy icon and prospects down the road.

Dr. Mayne: Thank you for that question, Thomas. The way I would respond, we have this regulatory definition of "healthy" that's been out there for a long time, almost three decades. We are working to update the definition itself, the criteria that could be used to better reflect current nutrition science and better align with the Dietary Guidelines. As we've seen, our Dietary Guidelines are really emphasizing food patterns, healthy foods. But we also pay attention to nutrients that we don't want excessive amounts of, things like added sugars and sodium.

So, the first step in this process is to update the criteria for "healthy." At the same time, one of the things we've been looking at is, are there ways that we could communicate an updated healthy claim so that consumers can easily access it and understand this is FDA's healthy claim and identify those products. That's where this work has been looking at the utility of a potential symbol that could be used on the front of the pack.

So, we have put out notices, through the PRA (Paperwork Reduction

Act) process, about the research that we are doing that's moving along to understand what that could look like, where can we learn from consumer focus groups, what can we learn from testing about the potential utility of a symbol like that. So, that's where the symbol comes in. One of the things I highlighted in my remarks is for people that have problems with nutrition literacy, this could be one thing that they could easily access to help identify healthier products when purchasing these foods. So, that is one utility there.

You asked me if there are other things we would consider and I'd say we're always looking at our labeling authority and the package, the food package, from a holistic perspective so that we can empower consumers with the most useful information that we have available. We have looked at that literature on labeling on front of pack and we are open to utilizing our authority in the most effective way possible to help impact the burden of diet-related chronic diseases.

So, at this point in time, the highest priority and the one that is most imminent, like I said, is the proposal for "healthy" which, of course, needs to go through comment. We need to get a lot of feedback on what we're proposing before that would ever move forward into a final rule. That will all inform the symbol as well. I hope that answers your question, that we look at the food package holistically. We've got things on the back of the pack, the Nutrition Facts label, the ingredients statement, the allergen labeling. We look at what's on the front of the pack and what we need to do to meet our public health mission.

Thomas: Thank you.

Kyle: Dr. Mayne, there's been a lot of discussion about the Closer to Zero proposal and the sort of underlying issues related to the safety of infant foods. There are food issues that animate parents of young children more than the safety and quality of the foods they give their kids. I wonder if I could just invite you to talk a little more about the program, about the initiative and how you see that unfolding over the next couple of years.

Dr. Mayne: Sure, I'd be happy to. Thank you for the question, Kyle. So, as a status update on Closer to Zero, the action plan was released in April of this year. We communicated our holistic goals of Closer to Zero are to reduce the levels of these toxic elements, again, we're talking about lead, arsenic, cadmium, and mercury, from foods commonly consumed by babies and young children as much as is feasible.

And we know it's going to be difficult to reduce these levels because as we all know, these toxic elements are in our environment. They're in soil, they're in air, they're in various places. What that means is that it's going to be difficult, if not impossible to get to a place where there is zero exposure. That's why the concept is closer to zero. Because we know that there are steps that all of us working together can take. And we can get us closer to zero for this important concept, as you said. These are our babies and our young children, our most vulnerable Americans.

So far, some of the steps we have taken is first we've reminded industry of the obligation under FSMA to put in place preventive controls to manage chemical contaminations in these products, these and all products. We've updated our advice to consumers on fish and mercury to account for the update to the dietary guidelines. That's because the dietary guidelines for the first time provided advice for birth to 24 months.

So, our fish advice did not previously, again it was linked into the dietary guidelines, it did not cover under age two. So, we recently updated that this fall. This is one way we're ensuring that we can help support families by providing education on the amounts and types of fish that are really nutritious and safe to eat. But we need to make sure that we can reduce the exposure to these toxic elements during these really crucial windows of child development.

As I talked about previously with you and as outlined with our action plan, it's an iterative approach where we would be developing and revisiting action levels over time. In the first year of the plan, we are really focused in on lead action levels for food commonly consumed by babies and young children. That would include products like juices. We have a lot more work to do over the coming years. We have a very significant role to play here. But in order for us to really have the greatest possible impact and be successful, we have to work with many partners. That includes USDA, EPA, CDC, NIH, as well as all of our stakeholders on all sides on this issue.

So, our plan includes many opportunities and outlets for discussion, interaction, collaboration. Many of you may be aware, we had our first public meeting in November. We held a jointly sponsored colloquium on the impacts of arsenic on children's health with the Society of Toxicology earlier this month. And we have future meetings planned. One in the spring, we are co-hosting with USDA to look at the issue of agricultural efforts and what can be done in the agricultural setting to help mitigate these risks.

So, this is a journey we are on together and we look forward to interacting with many of you on this issue in the months and years ahead. It's a complex multi-faceted challenge and it's going to require complex multi-faceted solutions.

Kyle: It looks like we might have time for a couple more panel questions and then we'll move on to audience. Alison, do you want to go next?

Alison: Sure. Dr. Mayne, there's been talk about a White House conference on food, nutrition, and hunger. And if there is one, what would FDA bring to the table?

Dr. Mayne: Thanks, Alison, for that. As I explained earlier, at FDA, we know that some of our regulatory authorities and some of the work we are doing that I described in nutrition is critically important in terms of nutrition and diet-related chronic disease. But we are just one player in a much larger complex nutrition ecosystem. Again, these problems in diet-related chronic disease, they are multi-factorial. These diseases are caused by many different things and that requires multi-factorial solutions.

We know that healthy eating is influenced by so many different factors, access to healthy, safe, and affordable food, consumers' knowledge, attitude, behavior, culture, all of the things can impact diet-related chronic disease.

So, I think what a White House conference would accomplish is it would provide the opportunity to bring everyone together, not just all the federal government – we are already having a lot of conversations within the federal government – but this provides an opportunity to really bring together the food industry, the public health, and the consumer advocacy groups, academia. It would really help bring to bear the best minds and ideas to create the kind of cohesive federal plan that is really needed to systematically address nutrition and to help turn the tide on diet-related chronic diseases.

We have a lot of ideas that we want to pursue. But we also want to think outside our four walls. How can our policies be leveraged across the federal government to amplify impact? And what can we do to amplify and support other agency's work and policies? For example, how do we work with our federal partners to implement sodium reduction? And how can our labeling policies like "healthy" be leveraged in and align with other federal programs? Just imagine if we could put the whole purchasing power of the federal government behind healthier foods.



We are working closely with our federal partners, USDA, CDC, NIH, on many nutrition related efforts. As I said, we have calls nearly every week. And we are exploring new ways to coordinate, leverage and amplify that work. So, a White House conference could just build on the existing collaborations and coordination we have to create a more comprehensive national plan.

Kyle: Thomas, is there a question you'd like to ask?

Thomas: Yeah, since you mentioned the sodium guidance, Dr. Mayne, wondered if you might walk us through the timeline for how that will be implemented. The two contingencies which either the industry successfully lowers sodium in line with the guidelines and the other in which it doesn't. How would that play out and when could we expect those things to happen?

Dr. Mayne: Make sure I understand, say one more, what were the two contingencies there?

Thomas: Whether there is voluntary compliance in line with the guidelines or whether there's not and sodium levels continue to be too high.

Dr. Mayne: Okay, great. So, the path ahead on sodium, the targets that we released, we are hoping the food industry will work to achieve these targets as soon as possible. But the timeline we put in the guidance is over the next two and a half years. So, that is the timeline that we are asking industry to work on this problem of sodium reduction. In that two and a half years, we are going to have extensive engagement with industry because we know that there are challenges with sodium reduction. It's harder in certain areas than others. And we need to learn from the experience of what's happening across the industry.

In terms of your comment of what about progress, we really do expect that we will make significant progress over the next two and a half years. That's based on a lot of factors. One being that the targets themselves are based upon the information we have, data we have, information on top selling products in those categories in our U.S. food supply. That tells us that these reductions have been achieved in similarly situated products that are top selling in the U.S. market. But we really need to see what those challenges are as we move forward with industry.

The other thing that you're aware of, I know, and you've heard me speak about is that there are other countries that are also reducing

sodium at the same time. And they have made significant progress. So, we've seen it can be done in an iterative process, gradual reduction process. We've seen that happen in other countries. So, we're learning from what's happening there. And we also know that many of the companies that are selling these products will sell products with differing sodium levels to different countries based upon consumer expectations.

So, the importance is that we need to really level the playing field. We know that many of our industry partners have told us they want to sell healthier products. They want to sell lower sodium products. But it has to be done gradually and it has to be done across the food supply to level that playing field.

So, that's the path we are on. We will be monitoring, as I indicated, and additional resources will help facilitate our work to continue monitoring what's happening with the U.S. food supply with regard to sodium. But that's the journey we're on. We will reevaluate where we are in two and a half years. That will inform the next steps in an interactive process to continue to try to reduce sodium in the US food supply.

Thomas: Thank you.

Kyle: With that, I'll turn to questions from the audience. Again, as folks hear us talk to each other, if ideas come to you, feel free to include them in the Q&A. Dr. Mayne, one question we've gotten is focused around the dietary guidelines. The process, obviously, is an interactive, collaborative one that takes place on a regular basis. Are there opportunities for FDA to have greater involvement in the development of Dietary Guidelines, from your perspective?

Dr. Mayne: What I'd say is we are part of the Dietary Guidelines process. The Dietary Guidelines is coordinated jointly between the U.S. Department of Agriculture and the Department of Health and Human Services. Because we are part of HHS, we, along with other HHS agencies like CDC and NIH, we weigh into the Dietary Guidelines process. So, we are part of that process. We look at and give technical assistance as we review the documents.

So, that is established in the process already, that FDA has an important seat at the table in developing those Dietary Guidelines. As you note, there is a statutory requirement that they be updated every five years. So, the process really never ends. As soon as one set of Dietary Guidelines is out, people start planning for five years from now because there's a large number of steps that occur,

including getting the Dietary Guidelines advisory report out which proceeds the development of the actual policy document, the dietary guidelines policy document that is issued between USDA and HHS.

Kyle: I was intrigued by the observation you shared earlier that while, for example, tobacco and food as product categories contribute similar levels of mortality and morbidity burden to the American life. One is significantly more robustly funded than the other in terms of its component share at FDA. That's a striking contrast. Just sort of thinking about the administration's cancer moon shot, for example, as being this all of government commitment to something that genuinely sort of everyone in America knows and wants to get its arms around. If we had a kind of nutrition moon shot, from your perspective both as an agency leader and as a nutrition scientist, what would that look like?

Dr. Mayne: I think we saw that happen previously with the first White House conference on food and nutrition. That occurred, I think it was in 1969. It was basically everybody coming together and saying we have some issues we want to address. Issues around food availability, food insecurity, nutrition, all of these issues. And people came together in 1969 and it was a very collaborative, inclusive, engaged effort. I think the result of that that led to many of the federal food assistance programs and many of the programs we have today, 50 years later. So, that really set the stage for a comprehensive look with recommendations about what can the federal government do to improve public health, to improve food and nutrition security in this country.

So, if we want to do it again, things have change since 1969. We still have enormous nutrition challenges. One of the biggest things that has changed, as I highlighted, is the really dramatic increase of obesity in this country. And if you haven't looked at the CDC obesity map to look at those trends and how it's rolled out across the country, it is stunning. So, that is something that was not really contemplated as much in 1969 because we didn't have that problem to the same extent that we do today.

So, we have this incessant increase in obesity and overweight in this population. Right now, two thirds of adults in the U.S. are either overweight or obese. So, that kind of moon shot could look at that issue and really say what else do we need to do now because that was not really the public health issue in 1969 that it is today. So, I think the White House conference on nutrition certainly could provide that opportunity for a moonshot like approach where we hear the best ideas from everybody, from industry, from academia

from states, and local communities.

There's a lot of extraordinary innovative work going on in local communities and how do we leverage that and expand upon that from the federal roll so it's a very inclusive setting in how we tackle a national problem. It's not just U.S., obviously, it's an international problem as well.

Kyle: Maybe I'll turn to my panelist colleagues. Alison, is there anything else you'd like to ask?

Alison: Sure. So, Dr. Mayne, I think processed foods, you read a lot about processed foods in the news and most of it seems to have a negative bent. Yet processed foods, speaking from the CEO of an organization that represents many frozen foods, many of which are very healthy and have great attributes. How do we help consumers in the public engage in a dialogue that's based in fact around benefits of food and what to watch for then so we're not painting all processed foods with a negative brush.

Dr. Mayne: That's a very good question, Alison. I'd say one thing is it's part of the Dietary Guidelines. In the Dietary Guidelines, we make recommendations that we want consumers to eat, for example, more vegetables. That can include fresh vegetables, that can include canned vegetables, that can include frozen vegetables. So, it's already in the Dietary Guidelines in that way.

I think when consumers are looking at that term processed, I don't think they necessarily look at it the same way that a food technologist would look at the term processed. So, what we're trying to do from our perspective is follow the science, use the tools and the educational opportunities that we have to really communicate to consumers what we do know about nutrition and highlight those things where we have strong nutrition information in Dietary Guidelines. Those tools include the Nutrition Facts label, obviously, to make sure people get the nutrients requirements.

If people are studying our nutrient requirements in some of these products, like you mentioned frozen vegetables, these things can be loaded with good nutrition. And hopefully consumers will rely on those Nutrition Facts labels to learn about that. So, that's a tool. "Healthy" is another tool. We want to drive our consumers towards the types of foods that can help them put together healthy dietary patterns. So, that is another tool. So, those are the types of things we're committed to doing, is to really focus in on where we have the correct science and really translate that information for consumers.

We need help from other federal agencies, as well. We're not the only ones who do nutrition education. So, we work with USDA, we work with CDC, others in communicating this important information about nutrition.

Kyle: Thomas, anything you'd like to ask?

Thomas: More of a big question here. It seems like nutrition science has shifted in emphasis from access to food and food deserts to kind of an excess of the wrong foods and food swamps the obesogenic environment. I wonder how FDA's policies have responded to that evolution in nutrition science.

Dr. Mayne: I'd say, in terms of, you mentioned the obesogenic food environment, some of the changes we made to the Nutrition Facts label were directly responsive to that. So, things like making the calorie disclosure large, bold, prominent, so when people look at the back of the pack and they see the Nutrition Facts label, the calories jump out at you. That was one of the changes we made. We also wanted to make sure consumers were empowered with information about serving sizes. Serving size was made bolder, more prominent.

We also made some changes because we learned, for example, if you think about certain products a consumer may easily consume in one serving, the product may actually contain two or three servings, two and a half servings. We actually made a change in the rule that if a product contains two and a half servings, the Nutrition Facts label needs to include that information for the entire package, based upon what consumers are doing. So, some of the changes we made with the Nutrition Facts label were meant to make sure that some of these problems about the obesogenic environment, that consumers were armed with the information they needed to really have that information.

I'll point to the menu labeling regulations that were implemented to make sure consumers have access to nutrition information on foods away from home. We know that a third of calories pre-pandemic were consumed outside of the home. I think it's a lot less than that right now. But hopefully, we'll return to a situation where people can readily consume a large part of their diet away from home. So, making sure they have nutrition information away from home has been another priority for us.

And the last thing I mentioned about this is e-commerce is a whole new world for us. We want to make sure that consumers do have

information about products when they're ordering online and that they would have that same type of nutrition information available when ordering online.

Again, our labeling authority is meant to empower consumers. And we're using those tools to address some of these challenges in public health.

Kyle: Dr. Mayne, I see that we're coming up on the top of the hour. This will probably be our last question. You mentioned in your remarks the importance of addressing sort of the particularly challenging issue of disproportionate burden of obesity and its impact on minority populations and on people of color. And I know the administration as a whole has a broad commitment to addressing health equity issues and addressing the social determinants of health. From your perspective, are there policies or strategies that are uniquely directed at vulnerable populations that you think we should particularly accelerate in order to help them succeed?

Dr. Mayne: I would say the approach is we want to get healthier food for everybody. So, regardless of nutrition literacy, we're getting healthier defaults. Sodium is one of the tools to do that. That will help reduce health disparities. If we can reduce the amount of sodium in the U.S. food supply, I already highlighted the disparate prevalence of hypertension, high blood pressure, by different races, ethnicities. That's an example of a healthier default that would benefit everybody. So, that's part of it, get those healthier defaults and a healthier food supply.

In addition, targeted education to different segments is critically important. That's an area we want to work on. We do have an Office of Minority Health and Health Equity at FDA that we are working with. We work with many different organizations to try to really target educational needs. Many of our materials are available in multiple languages to really address this problem.

So, it's twofold, getting a healthier food supply and targeting education to try to address these issues.

Kyle: Thank you for that answer and for spending time with us today. It's been really informative. I know our members are deeply interested in CFSAN and your work and applaud your efforts to advance a healthy eating environment. On behalf of our members and the panelists here today and the leadership at the Alliance, including Steve Grossman, we very much appreciate your participation, look forward to staying in dialogue with you and with FDA. I know we

will have future webinars with attendees here today. Feel free to tune and watch for future notices because we are going to continue to do these events in the new year. So, looking forward to staying in dialogue with the FDA.

Dr. Mayne: Thank you all for your support of FDA. We really, greatly appreciate it.

Kyle: Absolutely. Thank you so much. Have a great day.

Dr. Mayne: Bye.

**[End of Audio]**

**Duration: 57 minutes**