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UNITED STATES SENATE

"WHAT IS THE FDA DOING TO REDUCE THE DIABETES AND OBESITY EPIDEMICS IN AMERICA AND TAKE ON THE GREED OF THE FOOD AND BEVERAGE INDUSTRY?"

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Introduction

Chair Sanders, Ranking Member Cassidy, and members of the Committee, thank you for the opportunity to testify before you today to discuss efforts to reduce the chronic disease burden in America and the Food and Drug Administration's (FDA or the Agency) front-of-package nutrition labeling initiative.

This is an important time to testify before this Committee on a growing and vitally urgent issue facing Americans: chronic disease, including diet-related chronic disease. The food we eat is exacerbating America's tragic title for the lowest life expectancy among large high-income countries.[1]

Chronic diseases, including heart disease, cancer, and diabetes, are the leading cause of disability and death in America. They are also the leading drivers of the nation's $4.5 trillion in annual health care costs. Nearly everyone knows and cares for someone with a chronic disease: 6 in 10 Americans have at least one chronic disease and 4 in 10 have two or more chronic diseases.[2] Unfortunately, the toll of diet-related chronic diseases is even greater for racial and ethnic minority groups, those with lower socioeconomic status, and those living in rural areas. The burden of diet-related chronic diseases translates into astronomical health care and economic costs as well.

While there are myriad factors influencing health, the science is well settled to support that poor nutrition—including insufficient consumption of fruits, vegetables, and whole grains, as well as excessive consumption of saturated fat, sodium, and added sugars—increases the risk of diet-related diseases. Improving what we eat can be an effective remedy for diet-related disease, but changing diets is hard when challenged by externalities like finances, access to healthy food, education, health care, safe housing, job opportunities, neighborhood design, and transportation. Consequently, improving the American diet to help ensure food is a vehicle for wellness requires a whole-of-government and whole of society effort, including serious action from industry to be part of the solution.

Ultra-Processed Foods and Poor Health Outcomes

The health impact of ultra-processed foods (UPF) is at the forefront of many current discussions about nutrition. FDA agrees that the clear association between UPF and poor health outcomes is cause for major concern. Foods deemed ultra-processed are usually characterized by industrial processing, the presence of additives such as flavors or colors, and nutrients intended to make them appetizing (saturated fat, sodium, and added sugars).

There is still a lot we need to learn about UPF. For example, nutritious foods such as whole grain bread may be considered ultra-processed but are not necessarily associated with negative health

[1] "How does U.S. life expectancy compare to other countries?" Peterson-KFF Health System Tracker, https://www.healthsystemtracker.org/chart-collection/u-s-life-expectancy-compare-countries/
[2] https://www.cdc.gov/chronic-disease/about/index.html

outcomes and indeed have shown to be beneficial.[3] Yogurt and tofu are other examples. Additionally, infant formula and some medically necessary foods would also be considered UPF under some definitions, but are absolutely essential, nutritious foods. It is important that we better understand why and how UPF may be negatively impacting health to help inform targeted policies and avoid overly broad and impractical messages for consumers.

Still, we are not waiting idly for these answers. Later this month, FDA is convening a workshop with the National Institutes of Health (NIH) and a principal focus is to identify key priorities and critical next steps for research on UPF to help accelerate higher quality research. We are also aggressively taking policy steps where the evidence is clear.

A common characteristic of UPF is containing high levels of saturated fat, sodium, and added sugars. There is already substantial evidence of harm when these nutrients are overconsumed. In fact, much of the potential harm of UPF could be offset by taking actions that affect these nutrients.[4] FDA's efforts to better inform consumers through work on front-of-package nutrition labeling as well as on updating the claim "healthy," and our efforts to reduce sodium across the food supply, and strengthen our chemical safety review program, may help.

FDA's New Nutrition Center of Excellence - *Advancing Food as a Vehicle for Wellness*

FDA is well equipped to help lead the charge in improving nutrition in the U.S. On October 1, FDA undertook the largest reorganization in the Agency's recent history to establish the new, unified Human Foods Program (HFP), which included standing up a Nutrition Center of Excellence (NCE). Helping to ensure food is a vehicle for wellness is the vision of FDA's HFP, led by Jim Jones, FDA's first Deputy Commissioner for Human Foods.

The NCE elevates and empowers FDA's action on nutrition science, policy, and initiatives to play a central role in a broader, whole-of-government approach to reduce the burden of diet-related chronic diseases, improve health equity, and ensure the nutritional adequacy and safety of infant formula and other critical foods. A key characteristic of the NCE is expanding collaborations—inside and outside the federal government—to help achieve shared goals. The NCE also focuses strategic leadership and coordination of FDA's nutrition work and is prioritizing the Agency's ongoing efforts to encourage industry to offer more nutritious foods and help U.S. consumers make more informed food choices.

FDA's nutrition work provides significant dividends: for every dollar we invest in nutrition, we see a return of $119 in nutrition-related health benefits.[5] Even relatively modest investments can still have broad public health impact. We are eager to grow and strengthen the NCE to more adequately address diet-related disease and health equity and give these issues the attention they deserve.

[3] https://pubmed.ncbi.nlm.nih.gov/38417577/
[4] https://www.sciencedirect.com/science/article/pii/S2667193X24000401
[5] https://reaganudall.org/operational-evaluation-fdas-human-foods-programs

Front-of-Package Nutrition Labeling and Additional Actions to Advance Public Health

Empowering Consumers through Front-of-Package Nutrition Labeling

Front-of-package (FOP) nutrition labeling is one avenue that could quickly and easily inform U.S. consumers about the levels of certain nutrients in foods, such as saturated fat, sodium, and added sugars which can increase the risk of diet-related diseases when consumed in excess and are commonly found at high levels in UPF. It could complement the Nutrition Facts label by displaying certain nutrition information right on the front of the food package, so it is immediately visible at the point of decision making. It also has the potential to be as iconic as the Nutrition Facts label. For these reasons, publishing a proposed rule on FOP nutrition labeling is a priority for FDA.

There is tremendous value in getting the FOP nutrition labeling regulation right the first time. So, our effort to develop an FOP nutrition label has been vigorous and deliberative. FDA has done extensive research, analysis, and drafting, using all available tools and resources, to support a proposed FOP nutrition labeling rule so that it can benefit consumers.

As part of this effort, FDA built the scientific basis to inform our development of a proposed regulation to require an FOP nutrition label. We updated our thorough review of the scientific literature published in recent years by researchers in the United States and around the globe, foreign health agencies, and governmental bodies (such as the National Academy of Medicine). The literature review highlights that FOP labels have been widely found to be a useful tool in helping consumers identify and select healthy foods. With those research findings in hand, we then prepared our own research agenda.

We conducted two rounds of focus groups with U.S. adult food shoppers and conducted an experimental research study with over 9,000 consumers from diverse populations to ensure that everyone, including those most at risk for diet-related diseases, was adequately represented. The FOP schemes we tested align with insights from our focus group testing, review of the scientific literature, review of schemes from other countries, and with our legal authority. Findings from the scientific literature and the consumer research FDA conducted indicate that:

- FOP labels can help consumers identify healthy foods;
- Consumers prefer simple, interpretive FOP labels;
- FOP labels appear helpful for those with lower nutrition knowledge; and
- FOP labels complement the Nutrition Facts label.

Alongside our research efforts, we undertook extensive outreach to facilitate an open and transparent process, so all interested parties had the opportunity to share their views. During this process we heard from consumer and public health groups, academia, health care groups, community members, as well as food companies and food trade associations. This included numerous individual meetings, four roundtable listening sessions, coalition meetings, and a public meeting on FOP Nutrition Labeling hosted by the Reagan-Udall Foundation for the FDA.[6]

[6] https://reaganudall.org/news-and-events/events/front-package-labeling

The goal of these engagements was to hear interested parties' points of view and learn from their experiences with FOP nutrition labeling. While we are limited in the extent of information we can share with interested parties when developing a rule, we continue to share information as we are able, and we have an FOP webpage that is routinely updated. For example, our literature review and detailed information about our consumer research is available on the webpage.[7] We have also discussed our plans to develop a FOP nutrition label with our federal partners and had numerous discussions with foreign health officials in countries that have adopted FOP nutrition labeling to learn more about how their labels were designed, implemented, and evaluated.

And finally, we carried out the many steps to develop regulations, including an economic analysis, peer review of the data, and a legal analysis. We look forward to being able to discuss the details of our research and our proposal with the Committee and the public soon. We are confident it will reflect the research and what we have learned from consumers, academics, health advocates, and the food industry, as well as many others.

Providing a Refreshed Tool for Consumers by Updating the "Healthy" Claim

FOP nutrition labeling is one part of a suite of nutrition initiatives FDA is prioritizing. FDA also is working to finalize updates to the definition of the "healthy" nutrient content claim to reflect current nutrition science in the very near future. Voluntary claims like "healthy" on food labels can convey information to shoppers at a quick glance and help consumers identify foods that are the foundation of a healthy dietary pattern. FDA is also developing a "healthy" symbol that would be a graphic representation of the claim and is engaging with interested parties to find ways to support use of the claim and future symbol.

Fostering a Healthier Food Supply by Lowering Sodium

FDA continues to make great strides to help reduce sodium across the food supply, which has the potential to be one of the most important public health initiatives in a generation. In 2021, we issued Phase I voluntary sodium reduction targets, and we are seeing promising progress toward those targets.[8] We are very encouraged that our initial assessment of the Phase I targets showed that, in 2022, 40 percent of the Phase I targets had already been reached or were within 10 percent of meeting the targets. Additionally, recently released National Health and Nutrition Examination Survey (NHANES) 2021-2023 data show sodium intake levels at 3,113 milligrams (mg) per day, down from over 3,300 mg/day prior to 2021. This appears to be one of the largest decreases in decades and aligns with the trends we saw in our preliminary assessment—a very positive signal for the Agency's investment in sodium reduction efforts.

In August 2024, we started the next phase by issuing draft Phase II voluntary sodium reduction targets.[9] Together, the Phase I and Phase II targets would support reducing average sodium intake by about 20 percent from previous levels. FDA is receiving public comments on the draft Phase II targets and looks forward to finalizing them.

[7] https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/front-package-nutrition-labeling
[8] https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/sodium-reduction-food-supply#progress
[9] https://www.fda.gov/food/food-labeling-nutrition/sodium-reduction-food-supply

Together, FOP nutrition labeling, the "healthy" claim and symbol, and helping to reduce sodium in foods work cohesively as part of a government-wide approach to better inform consumers, improve nutrition, and reduce diet-related chronic diseases. These efforts can also help consumers more easily identify foods recommended by the Dietary Guidelines for Americans and may assist them in reducing consumption of certain nutrients that can be found in foods that are commonly considered ultra-processed.

Ensuring Food Chemical Safety and Protecting Human Health

FDA recognizes that there is also significant attention and concern around the presence of certain additives, such as flavors or colors, that are another common characteristic of UPF. During our public meeting in September on the Development of an Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food,[10] FDA heard from a wide range of interested parties regarding UPF, the chemicals they contain, and the potential role these chemicals may play in chronic disease. Congress, state legislatures, and others have made clear that food chemical safety is a priority we need to address. We agree, and we are committed to leading the way on food chemical safety.

Under the new HFP, we are leveraging our scientific expertise and developing a more nimble and systematic approach to evaluating chemicals in the food supply. In particular, the Agency now has an office specifically dedicated to post-market assessments and is developing a process for conducting post-market assessments of chemicals previously evaluated for use in foods, which was discussed at the public meeting in September. FDA uses toxicity and biological data, along with data to estimate exposure, to support regulatory decisions allowing or restricting uses of substances according to our safety standard of reasonable certainty of no harm. This general approach assures there is an adequate margin between doses that can cause adverse effects and the exposure level in food.

FDA recognizes that there is a clear nexus between our nutrition goals and chemical safety goals. And we will act when data demonstrates a chemical in food causes harm. As an example, in 2015 FDA revoked the "generally recognized as safe" status of partially hydrogenated oils (PHOs) because various studies consistently linked PHOs consumption with heart disease. However, to date, the literature connecting UPF-related adverse health effects to specific food chemicals is neither robust nor settled. FDA continues to monitor the food supply, evaluate new science, and take action when we find that a chemical causes a food to be unsafe.

The workload in the food chemical space has increased and become more complex. There has been a proliferation of new scientific data and methods, increased development of new food ingredients, technological advancement in new sustainable food contact materials, and other innovations. There are also important gaps that need to be addressed as we undertake the work to strengthen our food chemical safety activities. We know that use patterns and use levels of chemicals and ingredients have changed over time, so we need updated exposure and safety data, including from industry, to support our reassessment work. Access to these data would allow

[10] https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meeting-development-enhanced-systematic-process-fdas-post-market-assessment-chemicals-food

FDA to take any necessary regulatory actions in a timely manner to protect consumers and help ensure food safety.

Closing

All people in this country should be able to live better, longer, and more productive lives – free of the burden of preventable food and diet-related illness, disease, and death. Giving people nutrition information via labeling, and improving the quality of our food supply, are of paramount importance. Change cannot happen soon enough.

Nutrition labeling is an important tool, but we need more than one lever to help Americans build healthier diets. We must continue to learn more about UPF, develop a stronger chemical safety review program, and build on the success of other nutrition initiatives like updating the "healthy" claim and sodium reduction.

Finally, when it comes to food, FDA shoulders an enormous responsibility, but we do not act alone. Improving the food supply and advancing nutrition is a shared responsibility. Industry must also do more to offer healthier foods; it is in everyone's best interests for the U.S. food supply to be a source of wellness. We at FDA are firmly committed to working with this Committee and Congress, with our regulatory partners, and with all of those who play a role in the nutrition of the U.S. food supply, to tackle head-on the challenges we face in our increasingly complex food system.

Thank you for the opportunity to testify today. We will be happy to answer your questions.