January 13, 2025

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Draft Guidance for Industry (Edition 2); Availability (Docket No. FDA-2014-D-0055)

Dear Dockets Management Staff:

The undersigned respectfully submit the following comments on the U.S. Food and Drug Administration's (FDA's) draft guidance for industry on Phase II voluntary sodium reduction targets for commercially processed, packaged, and prepared foods. We are a group of non-government organizations and public health advocates with extensive expertise and experience in nutrition science and policy.

To ensure successful sodium reduction across the food supply, we offer the following feedback on FDA's sodium reduction efforts:

1. **FDA action to spur industry-wide sodium reduction is crucial for Americans' health, and we generally support the agency's efforts.**

2. **Lessons from other sodium reduction initiatives show that FDA must be more aggressive with its sodium reduction efforts.**

    a. **FDA must set more aggressive Phase II targets with additional serving-based maxima to reduce population sodium consumption lower than the 2,750-mg/day goal in the Proposed Guidance.**

    b. **FDA's monitoring and evaluation of Phase I and II targets must be timely, transparent, and methodologically rigorous.**

    c. **FDA should more actively and transparently engage with the food industry and should urge companies to publicly commit to sodium reduction targets.**

    d. **FDA should strongly consider setting mandatory sodium reduction targets if Phase II voluntary targets are not met.**

Our comments are as follows:

1. **FDA action to spur industry-wide sodium reduction is crucial for Americans' health, and we generally support the agency's efforts.**

We concur with former FDA Commissioner Scott Gottlieb's assertion that "there remains no single more effective public health action related to nutrition than the reduction of sodium in the diet."[1]

Americans consume an average of about 3,100 mg of sodium per day,[2] roughly 35 percent more than the 2,300 mg limit recommended by the National Academies of Sciences, Engineering, and Medicine (NASEM)[3] and the Dietary Guidelines for Americans (DGA).[4] Overconsumption of sodium is a serious threat to Americans' health, because it increases blood pressure and the risk of cardiovascular disease.[5] Nearly half of all U.S. adults suffer from high blood pressure,[6] and cardiovascular disease is a leading cause of death in the U.S.[7] In 2010, a reduction in daily sodium consumption of 1,200 mg/day (about what was needed at the time to reach the federally recommended limit) was estimated to save between 44,000 and 92,000 lives and $10–24 billion per year.[8]

The majority of sodium in the U.S. diet comes from commercially processed, packaged, and prepared foods (including restaurant foods), with only limited sodium coming from home cooking or addition at the table.[9] This means that sodium consumption is largely out of consumers' control, necessitating federal action to spur industry-wide reduction.

We were heartened when FDA took steps towards addressing this crisis in 2016 by issuing a draft guidance with both short- (2-year) and long-term (10-year) targets.[10] In October 2021, five years after the original targets were drafted, the agency finalized part of the guidance, establishing "Phase I" short-term (2.5-year) voluntary targets that, if met, would reduce average daily sodium intake to 3,000 mg/day.[11]

We are pleased to see that FDA has now proposed an updated set of 3-year ("Phase II") targets for industry across 163 food categories, with full compliance bringing Americans' sodium consumption to safer levels.[12] We support FDA in continuing its work to reduce average sodium consumption to 2,300 mg/day, and we look forward to seeing FDA's full evaluation of Phase I targets (only a preliminary assessment has so far been released).

2. Lessons from other sodium reduction initiatives show that FDA must be more aggressive with its sodium reduction efforts.

FDA's sodium reduction target model was informed by the United Kingdom's (UK's) Salt Reduction Campaign and the New York City Department of Health and Mental Hygiene's (NYC DOHMH's) National Salt Reduction Initiative (NSRI),[13] and the evaluations of those initiatives provide important lessons. The UK launched voluntary sodium reduction targets for 85 packaged and restaurant food categories in 2003.[14] From 2003 to 2011, salt in many UK food categories decreased by 20-50%, and population sodium intake decreased by 15%.[15] An evaluation of the initiative found that key components for success included: timely and rigorous monitoring of both sodium in the food supply and population sodium intake; close engagement with the food industry to secure public commitments to the targets, along with public identification of companies that did and did not make progress; and maintaining the prospect of mandatory targets should industry fail to act voluntarily.[16] Progress stalled thereafter, however, after a new administration adopted a more industry-friendly posture and reduced or eliminated all three of these components.[17]

In 2009, the NYC DOHMH used the UK's earlier efforts as a model to launch the NSRI,[18] a partnership with state and local health authorities and national health organizations.[19] This initiative also aimed to

encourage food manufacturers and restaurants to voluntarily reduce sodium in their products. An evaluation of the NSRI from 2009 to 2014 found a 6.8% reduction in sales-weighted mean sodium density in foods, which was far below the 25% reduction target.[20] A more extended evaluation from 2009 to 2018 found that food manufacturers reduced sodium in the earliest years of the NSRI (2009 to 2012), but progress slowed thereafter.[21] The researchers posited that this early industry action was largely driven by widespread media attention with the launch of the NSRI, the broader political attention on sodium reduction, and industry's resulting anticipation of regulatory oversight.[22]

These experiences illustrate that, for FDA's voluntary initiative to succeed, the agency must maintain pressure on the food industry by: a) setting more aggressive Phase II targets; b) monitoring and evaluating targets in a timely, transparent, and methodologically rigorous manner; c) engaging more actively and publicly with the food industry; and d) setting mandatory sodium reduction targets if Phase II voluntary targets are not met.

a. FDA must set more aggressive Phase II targets with additional serving-based maxima to reduce population sodium consumption lower than the 2,750 mg/day goal in the Proposed Guidance.

While we support FDA in its sodium reduction efforts, full industry compliance with FDA's new draft guidance would only reduce average sodium intake to 2,750 mg/day,[23] which is still far from the 2,300 mg recommended daily limit. Given the life-saving potential of sodium reduction, FDA must set more aggressive Phase II targets to more quickly reduce consumption to recommended levels. FDA's Phase I targets represented a 12% reduction in sodium, from 3,400 to 3,000 mg/day, over 2.5 years; the proposed Phase II targets represent a smaller reduction in sodium (8%, 3,000 to 2,750mg/day) over a longer period (3 years). Larger reductions over a shorter timeframe are needed.

We urge FDA to be more aggressive with its Phase II targets, aiming to reduce overall sodium intake to at least 2,640 mg/day, which is another 12% reduction in keeping with Phase I, and is also roughly halfway between the 2024 target of 3,000 mg and the ultimate goal of 2,300 mg. This is especially important because it is likely that industry will not fully comply with these voluntary targets. We recognize that FDA's proposed Phase II targets align with the Healthy People 2030 goal of reducing average U.S. sodium intake to approximately 2,750 mg/day by 2030, [24,25] and we appreciate coordination of sodium reduction efforts across the U.S. government. However, we believe that more aggressive FDA targets would only help the U.S. population meet the Healthy People 2030 goals.

It is disheartening to see that FDA adjusted several Phase II targets to be higher than Phase I targets, which we understand was informed by "the distribution of sodium concentrations [FDA] found in products within that category [in 2022]."[26] In other words, these adjustments appear to have been made due to a lack of industry progress on Phase I targets. Instead of accommodating industry's lack of progress, FDA must follow its charge of protecting public health by following the strategies below to hold food manufacturers accountable to reasonable, stepwise sodium reduction.

In addition to setting more aggressive targets, we urge FDA to add an additional set of targets to ensure individual products do not contain exorbitant levels of sodium. FDA's Phase II draft guidance currently contains category-specific targets for sales-weighted mean sodium content across all products within each food category, as well as product-specific upper-bound (maximum) targets for all products within a category. These maximum targets are the only ones that apply to individual products, and thus the only ones food companies can be held directly accountable for. The targets are designed to decrease overall

sodium density (mg sodium/100g of food), which is important to adequately reduce sodium across the food supply. However, there are currently no maximum targets for how much sodium a single serving of a product should contain, which allows products to meet these targets while still containing exorbitant levels of sodium depending on their portion size. For example, the proposed Phase II upper-bound target for restaurant soups is 420mg/100g.[27] With no per-serving limit, a 12-oz bowl of chicken noodle soup served in a restaurant could meet the Phase II proposed upper-bound target with 1,543mg of sodium per serving (67% of the daily limit).[28] No single product should provide 2/3 of a person's daily sodium intake. FDA should fix this by adding upper-bound per-serving sodium targets (e.g., no more than 20% of the daily value per serving) in addition to the upper-bound sodium density targets.

b. FDA's monitoring and evaluation of Phase I and II targets must be timely, transparent, and methodologically rigorous.

For these voluntary targets to have any teeth, FDA must conduct methodologically rigorous, timely, and transparent monitoring and evaluation for both Phase I and Phase II targets. FDA's evaluation plan should identify the specific data sources FDA will use and its exact methodology for analyzing the data. Any datasets assembled by FDA or otherwise in the public realm should be made available to the public in raw form. In its evaluations, FDA should evaluate the magnitude of change in sales-weighted mean sodium in the food supply over time overall (weighting food categories by their contribution to sodium consumption in the American diet) and by food category and subcategory. To isolate the specific effects of Phase I and Phase II targets to understand whether or not they are working, the agency must also evaluate more granular (e.g., annual) trends over time. FDA should also track category-specific progress towards sales-weighted mean sodium targets and product-specific progress towards upper-bound targets by the largest packaged and restaurant food manufacturers. FDA should also use population-wide sodium consumption data to understand how changes in the food supply are associated with overall changes in consumption. In addition to tracking sodium content and consumption, FDA should evaluate how the food industry is reformulating packaged and restaurant foods in response to the sodium reduction targets. This includes potential changes in other nutrients like added sugar and saturated fat, and in additives like potassium chloride.

FDA should publish and publicize its findings in reports with aggregated data on its website for all the food categories covered in its guidance. In addition to these technical progress reports, FDA should publish corresponding summary reports that are written for a general audience. These reports should indicate how industry is faring compared to the established target means and product upper bounds in each category at the end of each Phase. FDA should publicly praise companies that are meeting the upper-bound targets, and identify companies that are lagging behind.

As part of the agency's ongoing monitoring of the food supply, FDA should—on its own or in collaboration with other government agencies—launch and maintain a publicly accessible database with regularly updated nutrition information for branded packaged and restaurant foods that allows the public to understand which companies are failing to meet the upper-bound product targets. Agency decisions must be transparent to allow for meaningful democratic engagement, so if FDA is relying on proprietary sources for its evaluation, it should, as far as possible, enter only into agreements that allow the data to be shared with the public. There is already a precedent for this type of public-private data partnership for packaged foods, as the USDA currently maintains the publicly accessible Global Branded Food Products Database, which sources food-company-uploaded nutrition and ingredient data from

private data vendors.[29] In cases in which FDA is relying on public sources—which it has indicated it will do for restaurant data[30]—FDA should also share these consolidated data via a publicly accessible database.

These activities will allow FDA, other government agencies, industry, advocacy groups, researchers, and the public to: 1) identify which food and beverage target categories and specific products are/are not on track to meeting the sodium reduction goals; 2) understand which food companies are most successful at sodium reduction and which need additional technical assistance to meet the targets; and 3) catch unintended changes to the food supply resulting from sodium reduction efforts that may make it more dangerous to consumers (e.g., increasing amounts of added sugar). FDA should adjust its strategy and coordinate with relevant stakeholders based on its findings.

c. FDA should more actively and transparently engage with the food industry and should urge companies to publicly commit to sodium reduction targets.

As mentioned above, we believe that sodium reduction efforts in the UK and New York City have illustrated the importance of active engagement with the food industry in ensuring compliance with voluntary targets. We urge FDA to engage with the food industry to understand barriers and facilitators to successful sodium reduction; connect industry stakeholders to one another so that those who are lagging can learn from those who are leading; and be as transparent as possible with the public about these engagements and what the agency ultimately gleans from them. We also urge FDA to increase industry accountability by pushing packaged and restaurant food companies to make public commitments to meet FDA's sodium reduction targets, as has been done in New York City's sodium reduction efforts.[31]

As a starting point, we recommend focusing engagement with food industry players who manufacture foods that contribute the largest amount of sodium to the U.S. diet, as their commitments present the greatest potential for impact on sodium intake reduction. A recent analysis of dietary data from the combined National Health and Nutrition Examination Survey, What We Eat in America, 2009–2018 found that the food subgroups contributing the most sodium to the U.S. diet include store-bought lunchmeat sandwiches and hot dogs, restaurant-prepared burgers, store-bought and restaurant-prepared tacos/burritos, restaurant-prepared pizza with meat, and store-bought white/wheat bread.[32] We thus urge FDA to engage most closely with the packaged and restaurant food manufacturers that produce those foods to reduce their sodium content.

We also recommend FDA conduct outreach with chain restaurants that continue to offer items that are very high in sodium. FDA should have these data from its preliminary assessment of restaurant progress, and we encourage the agency to also review a recent study that assessed the sodium content of menu items in 91 of the highest-grossing chain restaurants in the U.S.[33] This study found that at limited and full-service chain restaurants, respectively, 3% and 11% of single-serve menu items exceeded the daily recommended sodium limit for U.S. adults, and 17% and 33% of menu items exceeded half the daily recommended limit.[34] The study also identified the five highest-sodium items across all restaurant chains from each food category, and we encourage FDA to use these data (in addition to the article's restaurant-chain-level data) to identify restaurants to prioritize. The study used data from 2019, the most recent year available from a national database (MenuStat) at the time of analysis, but updated 2024 sodium information affirms that restaurant chain menu items still have astronomically high levels of sodium—

including a bowl of chicken noodle soup from Frisch's Big Boy with 10,320 mg of sodium (449% of the sodium Daily Value, DV), and a turkey muffaletta sandwich from Jason's Deli with 8,520 mg of sodium (370% DV).[35]

d. FDA should strongly consider setting mandatory sodium reduction targets if Phase II voluntary targets are not met.

If FDA's evaluation of Phase II voluntary reduction targets finds little to no industry progress, FDA must modify its approach to protect Americans' health by strongly considering setting mandatory sodium reduction targets (e.g., making product-specific upper-bound targets mandatory). While the process of setting mandatory targets through regulation (or legislation) may take substantial time and effort, we believe it is the clear next step if industry continually fails to meet FDA's voluntary targets. The U.S. could follow the lead of the 19 other countries that already have mandatory sodium reduction targets in place.[36] The mere prospect of mandatory targets is useful for voluntary industry compliance.

In conclusion, FDA has an obligation to protect Americans' health by ensuring that industry reduces sodium across the food supply. We encourage the agency to hold industry accountable by setting aggressive reduction targets, implementing a strong and transparent monitoring and evaluation plan, and working actively and publicly with packaged and restaurant food companies to achieve sodium reduction. We urge FDA to act quickly on these recommendations to ensure a safer U.S. food supply.

Sincerely,

Academy of Nutrition and Dietetics

American Public Health Association

Balanced

Center for Science in the Public Interest

Defeat Malnutrition Today (DMT)

Food is Medicine Institute at the Friedman School of Nutrition Science and Policy at Tufts University

Interfaith Public Health Network

National Association of Nutrition and Aging Services Programs (NANASP)

National Association of Pediatric Nurse Practitioners

Partnership for a Healthier America

Resolve to Save Lives

The CAUSE (Campaign to Address Ultra-Processed and Sugar-Sweetened Epidemic)

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