CENTER FOR Science IN THE Public Interest
Your Food and Health Watchdog

CITIZEN PETITION

April 6, 2023

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

Submitted electronically via Docket No. FDA 2013-S-0610

Re: Citizen Petition Requesting that the U.S. Food and Drug Administration Finalize its 10-Year Sodium Reduction Goals and Take Other Actions to Reduce Sodium Consumption

To Whom It May Concern:

The Center for Science in the Public Interest (CSPI) hereby submits this petition under 5 U.S.C. § 553(e) and 21 C.F.R. § 10.30 to request that the Commissioner of Food and Drugs issue a final guidance identifying 10-year voluntary sodium-reduction goals. In addition, we ask that the agency establish intermediate targets, develop a plan to monitor and evaluate compliance by industry, and maintain a public database of the products that are the largest contributors to sodium exposure. These requests are consistent with the White House National Strategy on Hunger, Nutrition, and Health which recommends "facilitating sodium reduction in the food supply by issuing longer-term, voluntary sodium targets for industry."[1]

These actions are needed to address overconsumption of sodium, a serious threat to Americans' health through elevated rates of hypertension and cardiovascular disease (CVD).[2] Adult Americans are regularly consuming about 50 percent[3] more sodium than is recommended by the National Academies of Sciences, Engineering, and Medicine (NASEM) and the Dietary Guidelines for Americans (DGA), among other health authorities. Most sodium consumption in the U.S. occurs through commercial food processing and preparation (including restaurants), with only limited exposure due to home cooking or addition at the table.[3] In one study, a reduction in daily sodium consumption of 1,200 mg/d (about what is needed to reach the Dietary Reference Intake (DRI)), would save between 44,000 and 92,000 lives and $10 billion - $24 billion per year.[4]

FDA took steps towards addressing this crisis in 2016 when, in response to an earlier petition by CSPI,[5] FDA issued a draft guidance with both short- (2-year) and long-term (10-year) targets.[6] On October 13, 2021, five years after the original targets were drafted, the Agency finalized part of the guidance, establishing short-term (now 2.5-year) voluntary targets that, if met, would reduce average daily sodium intake to 3,000 mg/day.[7] However, the agency has not proposed intermediate goals or finalized the long-term (10-year) goals that were published in draft form in

2016. These 10-year goals, if finalized and met by industry, would reduce average daily sodium intake to the national recommendation of 2,300 mg/day,[3] significantly reducing the national impact of CVD.

CSPI is a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public's health through better nutrition and safer food. The organization does not accept government or corporate grants and is supported by subscribers to its Nutrition Action magazine, as well as grants from individuals and private foundations. CSPI has an extensive history of advocating for policies related to sodium reduction through food labeling, menu labeling, restaurant nutrition standards, school meals, and competitive foods nutrition standards, as well as in federal dietary guidance.

I. Actions Requested

In this Petition, CSPI calls on FDA to:

1. Finalize 10-year voluntary sodium reduction goals on processed, packaged, and prepared foods by April 2025.

2. Simultaneously, establish an intermediate voluntary sodium reduction goal, between the 2.5- and 10-year goals, by April 2025.

3. Publish a plan that details how industry compliance with the voluntary targets will be monitored and evaluated on an ongoing basis, including monitoring aggregated changes in the food supply with respect to target means and upper bounds for each sodium category, and publish periodic progress reports.

4. Identify the particular products that represent the largest contributors to sodium exposure and maintain a public database of these products.

II. Statement of Grounds

A. Regulatory History and Recent Scientific Evidence Strengthens the Basis for Sodium Reduction

CSPI has fought for over four decades to prompt the FDA to reduce the amount of sodium in processed foods. This campaign began in 1978, with a citizen petition to FDA requesting that the agency require sodium labeling on all packaged foods (and a warning on the highest sodium foods), revoke the "generally recognized as safe" (GRAS) status of salt, and limit the amounts of sodium in processed foods. In 2005, CSPI re-petitioned the FDA to take action to reduce sodium.[6] In 2010, the Institute of Medicine recommended that "The Food and Drug Administration (FDA) should expeditiously initiate a process to set mandatory national standards for the sodium content of foods."[8] In 2015, CSPI sued FDA for not acting on that 2005 petition.[9] In 2016, in response to the lawsuit, FDA proposed voluntary 2- and 10-year sodium targets for processed and

restaurant foods.[7] CSPI then agreed to withdraw its lawsuit.

Finally, on October 13, 2021, five years after the release of FDA's 2016 proposal, FDA released its long-awaited voluntary guidance on sodium reduction goals.[8] In essence, the guidance created 163 food categories, representing the largest contributors of sodium to the diet, and then developed category-specific sodium-reduction goals for processed, packaged, and prepared foods so that sodium consumption goals for an average U.S. diet would be reached. The category sodium targets were comprised of product-specific maximums and category-specific sales-weighted mean sodium concentrations. The final guidance was originally intended to provide recommendations for short-term (two-year) and long-term (10-year) sodium targets. But, following FDA's review of more than 150 public comments on the draft guidance, the final guidance included only 2.5-year targets that, if met, would reduce average daily sodium intake to 3,000 mg/day. There has been no Agency commitment to a 10-year target or to a specific plan for monitoring progress in sodium reduction.

In the authoritative 2019 NASEM "*Dietary Reference Intakes for Sodium and Potassium*" report, NASEM confirmed its previous recommendation to lower sodium intake to 2,300 milligrams per day for adults and recommended daily intakes of 1,200 to 2,300 mg for children, depending on their ages.[2] The new recommendations are similar to earlier targets, but, importantly, NASEM now refers to these recommendations as Chronic Disease Risk Reduction intakes because they are based on evidence that lowering sodium intake to these levels not only reduces the risk of hypertension, but also of CVD.

Various authoritative bodies have made similar recommendations to lower daily sodium intake. The DGA, which is published by the U.S. Departments of Agriculture (USDA) and Health and Human Services, adopted the NASEM recommendations and endorsed a daily adult sodium limit of 2,300 mg/day.[3] Recommendations from the World Health Organization call for even lower daily sodium intakes: no more than 2,000 milligrams per day for adults.[10]

Prior, highly publicized observational studies that reported a J- or U-shaped association of sodium intake with cardiovascular events (suggesting that both high *and* low sodium intakes are harmful),[11,12,13,14] created controversy that, in part, thwarted progress on public policy changes. The 2019 NASEM report dismissed these studies, saying that their findings "are likely observed because of methodological limitations of the individual observational studies,"[2] including systematic error in sodium assessment and the potential for reverse causation.[15] Indeed, two studies demonstrated that single spot urines, the technique used in several of these studies, can inaccurately assess sodium intakes and that J- or U-shaped curves can be an artifact of such methods.[16,17]

The NASEM Committee, placing a notable emphasis on randomized, controlled trials, where available, conducted its own assessment of the relationship between sodium and health outcomes and concluded "there is moderate to high strength of evidence for both a causal relationship and an intake–response relationship between sodium and several interrelated chronic disease indicators: CVD, hypertension, systolic blood pressure, and diastolic blood pressure."[2] This evidence led NASEM to confirm its previous recommendation to lower sodium intake to 2,300 milligrams per day for adults based on these Chronic Disease Risk Reduction (CDRR) intakes. The report also concluded that there is insufficient evidence that low sodium intakes are associated with

potential harmful health effects.

Additional evidence generated since the NASEM report has further confirmed the relationship between sodium intake and heart disease. Most notably, a report in the *New England Journal of Medicine* in September 2021 described the results of a randomized, controlled trial among 20,995 adults in rural China who were over the age of 60 and had hypertension or had a history of stroke. Their villages were randomized to either a salt substitute (75% sodium chloride, 25% potassium chloride) or to regular salt.[18] After a median of 4.7 years of follow-up, the intervention group had lower rates of stroke (29.1 events vs. 33.7 events per 1,000 person-years; rate ratio (RR): 0.86; 95% confidence interval [CI]: 0.77 to 0.96), major CVD events (49.1 events vs. 56.3 events; RR: 0.87; 95% CI: 0.80 to 0.94), and death (39.3 events vs. 44.6 events; RR: 0.88; 95% CI: 0.82 to 0.95). These results underscore the potential effectiveness of salt substitution.

B. There is an Urgent Public Health Need for Federal Action to Reduce Sodium Across the Food Supply

As noted, Americans are consuming an average of about 3,400 mg of sodium per day,[3] roughly 50 percent more than the 2,300 mg limit recommended by federal guidelines. That excess consumption, as the DGA and NASEM Committees have noted, increases blood pressure and the risk of heart attacks and strokes. As mentioned above, the majority of sodium consumption in the U.S. is attributable to commercial food processing and preparation, including restaurants. Nearly half of all U.S. adults suffer from high blood pressure, with higher prevalence among men and non-Hispanic Black adults.[19]

On average, children of all ages consume between 2,525 mg and 3,888 mg of sodium per day (in comparison, the CDRR for children is between 1,200 mg and 2,300, depending on age).[3] Studies show a link between high blood pressure in childhood and high blood pressure in adulthood, and high blood pressure in childhood is linked to early development of heart disease and risk for premature death.[20] According to a 2018 report by the Centers for Disease Control and Prevention (CDC), hypertension in youth is on the decline, but more than 1 in 7 youth ages 12 to 19 still had high blood pressure or elevated blood pressure in the 2013 to 2016 time period. Children who eat higher-sodium diets are 36 percent more likely to have elevated blood pressure than children who eat lower-sodium diets.[21]

Excess sodium consumption therefore has critical public health and economic implications. We identified nine national studies that weighed the costs and/or benefits of reducing sodium consumption in the U.S. These studies are summarized in detail in Appendix A; here we only provide a brief summary. Two of these studies[22,23] examined the burden of typical dietary exposures to sodium and daily intakes exceeding 2,000 mg per day, respectively. The former study estimated a burden of about 100,000 deaths per year, while the latter estimated about 57,000 CVD deaths per year. These studies did not make economic estimates.

Five additional studies calculated the impact of various degrees of reduction in sodium consumption, either to specific levels (2,200 to 2,300 mg per day) or by specific amounts.[5,24,25, 26,27] Other than one study that modeled only limited sodium reduction (and did not make economic estimates),[38] these studies all showed large direct savings, in the billions and often tens of billions of dollars per year.

Finally, two studies used microsimulations to model the impact of the FDA guidelines themselves. In the first,[28] 100% compliance with FDA's proposed 2-year targets prevented 120,000 CVD cases over 20 years at a net savings of $12 billion. Similar compliance with the proposed 10-year target prevented 450,000 CVD cases and 35,000 deaths at a net savings of $41 billion. The second study[29] modeled the impact of the FDA guidelines on people working in the food system and the processed food industry itself. Complying with FDA's proposed 2-year targets prevented 540 to 10,400 CVD cases and 80 to 1,100 CVD deaths over 20 years. Compliance with the proposed 10-year target prevented about three times as many CVD cases and deaths and was more costly. In some scenarios, savings to just the food industry, which would bear the brunt of the costs of the program, exceeded those costs.

In sum, these studies used a wide range of different approaches, but invariably estimated substantial reductions in CVD and death rates. While the costs of industry compliance with the FDA guidelines could be substantial (in the $6 to $17 billion dollar range),[41,42] in most scenarios the interventions were actually cost-saving from a societal perspective.

C. FDA Should Finalize a 10-Year Goal and Also Simultaneously Set an Intermediate One

In 2016, the Agency proposed 2 sets of voluntary sodium goals, a first that would be achieved within 2 years and a second to be achieved within 10 years. We are asking in this petition that FDA finalize its 10-year target and set a new intermediate (e.g., 6-year) target by April 2025. The new goals should follow the current model of both sales-weighted food category means and within-category product maximum levels. To the extent that technological feasibility permits, these targets should be front-loaded to secure health and social benefits sooner.

This step-wise approach is in keeping with sodium reduction approaches taken by other U.S. agencies and abroad. We are not aware of any international sodium goals that left an implementation gap longer than four years, or proposed only a single, short-term target. Yet FDA's proposed draft guidance left an unprecedented eight-year gap, and now, because FDA's final 2021 Guidance did not set a 10-year target, we have only the short-term (2.5-year) targets. The lack of either intermediate or long-term targets has led to uncertainty for industry and the public about the Agency's long-term goals and about how progress in sodium reduction will be evaluated over time.

In 2006, the United Kingdom set goals for sodium reduction. The UK's program, a model for FDA's, divided the food supply into 85 food types in 30 categories and prescribed average sodium levels for each category. The program had goals for gradual stepwise sodium reduction for each of those food types to achieve a 2,400 mg/day target intake, on average, across the population over four years.[30] Subsequent revised goals were set in 2009, 2011, 2014, and 2020.[31,32]

In 2009, New York City's Department of Health and Mental Hygiene organized what was then known as the National Salt Reduction Initiative (NSRI), based upon the UK salt reduction model. The NSRI set out voluntary, category-specific sodium targets with the goal of reducing sodium in packaged and restaurant foods by 25% over five years (by 2014), with intermediate goals set for 2012. NSRI identified 62 categories of packaged and 25 categories of restaurant foods and

aimed to reduce the sales-weighted average sodium for products in each category by 15 to 40 percent.[33] The Initiative was supported by over 100 nonprofit health organizations and local and state government health agencies.[34]

The lack of an intermediate target is likely to hamper progress. Companies would be forced to continue to pay attention to reducing sodium levels in their products (particularly if the government issued periodic reports) if they had goals that declined gradually every four or so years instead of having one goal at two years and no deadlines for eight years (or, at present, no impending deadline at all). Similarly, the potential eight-year gap would likely mean that experts at FDA would move on to other activities or employers, reducing Agency momentum. Moreover, gradual reductions would help consumers adjust to less salty foods and encourage industry to more quickly test new technologies and salt alternatives that reduce sodium levels and consequent health risks. Gradual reductions would also support sodium reduction goals in the National School Lunch Program and the School Breakfast Program. School nutrition providers for years have expressed concern that changing children's taste preferences to accept lower sodium school meals is hampered by lack of sodium reduction in foods consumed outside of school.

Notably, Congress has supported the establishment of intermediate and long-term goals, noting in the report associated with the FY2023 omnibus spending bill that "the [House Appropriations] Committee encourages FDA to coordinate with other government agencies, such as USDA and the Centers for Disease Control and Prevention on these monitoring efforts and instructs the FDA to set a timeline for the establishment of interim and long-term voluntary targets that would aim to fully bring sodium in the food supply to align with the Dietary Guidelines for Americans recommendations."[35]

D. Voluntary Sodium Reduction Targets are Legal, Feasible, and have Public Health and Industry Support

With respect to legal authority, FDA has the same authority to propose new intermediate sodium-reduction goals and long-term goals as it had to issue its current 2.5-year goals.[8]

Regarding feasibility, it is reasonable to expect that consumers can adapt to less-salty foods over time.[36] In addition, both new and old technologies could help companies to lower sodium without affecting palatability. Variations of table salt could reduce sodium exposure, such as Diamond Crystal Kosher Salt (a low bulk density salt produced with the Alberger process) or "MicroSalt" (very tiny salt crystals that dissolve more fully on the tongue so the food tastes as salty with less salt—appropriate for French fries, potato chips, crackers, etc.). Salt alternatives, such as potassium salt, which taste somewhat salty, could also cut sodium in many foods.

Of course, in many products companies could simply use less salt (or reduce portion sizes). To assist smaller companies with meeting these goals, we recommend that FDA, USDA, and local health agencies provide technical assistance.

In December 2020, FDA approved "potassium salt" as an alternative name for potassium chloride on food labels.[37] It is believed that "potassium salt" sounds more recognizable to consumers than potassium chloride, may be more acceptable to companies with "clean label" policies, and could therefore lead to more companies using potassium chloride to reduce the sodium content

of their foods. Some companies may also lower sodium levels by changing recipes to incorporate additional flavorful ingredients, such as vegetables or meat/poultry, or by using salt-free seasoning blends like Dash™.

Voluntary sodium-reduction targets are supported by public health organizations and some major elements of the food industry. Members of the Sustainable Food Policy Alliance (SFPA)—which includes Danone North America, Mars, Nestlé USA, and Unilever United States—had called for FDA to finalize the two-year sodium-reduction targets. They also joined CSPI, the American Diabetes Association, American Heart Association, and the American Public Health Association on a 2019 letter to Congress that successfully requested the removal of an appropriations rider that blocked FDA from advancing the longer-term sodium-reduction targets.[38] SFPA notes that they "firmly agree with FDA that reducing sodium levels can be a powerful public health action to reduce blood pressure, a leading risk for heart disease. These targets will help to guide the food industry's efforts to continually improve the nutrition profile of products and ensure sodium reduction across the food supply."[39]

E. FDA has Not Developed a Plan that Details how Industry Compliance with Voluntary Targets will be Monitored or Evaluated on an Ongoing Basis

FDA's 2021 guidance setting the 2.5-year targets fails to include any methods for assessing compliance with those targets. For these voluntary targets to have any teeth, FDA must identify specific data sources and, on a predetermined public timeline (e.g., at a minimum to coincide with all targets), publish 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 each particular milestone. This will allow the Agency to identify which food and beverage target categories are not on track to meeting the sodium reduction goals and adjust its strategy accordingly.

Fortunately, Congress recently provided $1 million in the FY2023 omnibus spending bill for FDA to develop a monitoring and evaluation plan. In its committee report, Congress requested that FDA "…develop an overall sodium monitoring and evaluation plan detailing how industry compliance with the short-term voluntary targets will be monitored and evaluated including how FDA will identify data sources, collect and analyze data, create a timeline for assessments, and work with industry on voluntary compliance."[50]

F. FDA Should Identify the Particular Products that Represent the Largest Contributors to Sodium Consumption and Maintain a Public Database of these Products

FDA should also list, on a public database, particular products that exceed the upper bound sodium concentrations for their category, for those categories that together, on a sales-weighted basis, comprise the top 60 percent of the U.S. sodium burden. Sodium is widely dispersed throughout the food supply and most individual categories contribute to the overall sodium burden in only a limited way. As the table from CDC below indicates,[40] the top 10 food categories together represent 40% of all exposure, with the largest exposure from deli meat sandwiches (6.3% among

all age groups) and the 10th eggs and omelets (2.7% of exposure). The 60% cutoff is intended to allow the Agency and the public to identify the worst offenders in the most important food categories.

TABLE 1. Top 10 food category contributors (%)* to sodium and potassium intake, by age group — United States, 2015–2016

	Proportion (%) in diet, by age group (yrs)								
Food category and dietary contribution†	All age groups (≥1 year) (N = 7,976)	1–3 (n = 561)	4–8 (n = 828)	9–13 (n = 829)	14–18 (n = 756)	19–30 (n = 963)	31–50 (n = 1,617)	51–70 (n = 1,669)	≥71 (n = 753)
Sodium§									
1. Deli meat sandwiches	6.3	2.7	5.9	5.6	7.0	5.9	6.7	6.5	6.4
2. Pizza	5.4	5.1	6.9	7.7	10.7	6.8	4.5	3.8	—¶
3. Burritos and tacos	5.3	2.3	3.8	4.7	4.9	5.9	7.1	4.0	—¶
4. Soups	4.1	4.2	3.8	3.3	2.5	3.0	4.0	5.3	5.2
5. Savory snacks (e.g., chips, crackers, popcorn)	3.8	7.2	6.8	5.9	4.2	3.7	3.0	3.4	2.9
6. Poultry (excl. nuggets and tenders)	3.7	3.4	2.5	2.6	3.2	5.2	4.1	3.1	2.4
7. Pasta mixed dishes (excluding macaroni and cheese)	3.0	4.0	3.1	3.5	2.9	3.5	2.8	2.3	3.6
8. Vegetables (excluding white potatoes)	2.9	3.0	1.9	1.6	1.6	2.3	3.0	4.0	4.0
9. Burgers	2.8	—¶	2.7	2.5	4.2	2.7	3.0	2.7	1.4
10. Eggs and omelets	2.7	3.7	2.2	2.0	1.7	3.3	2.6	2.5	3.2
Total contribution of top 10 food categories	**40.0**	**35.6**	**39.6**	**39.4**	**42.9**	**42.3**	**40.8**	**37.6**	**29.1**
Mean daily sodium intake (mg) (SE)	3,397 (34)	1,929 (58)	2,655 (43)	3,260 (62)	3,423 (90)	3,861 (98)	3,722 (68)	3,431 (46)	2,861 (88)
Mean daily sodium density (mg/1,000 kcal) (SE)	1,692 (12)	1,465 (25)	1,549 (14)	1,663 (24)	1,689 (25)	1742 (32)	1,726 (22)	1,723 (20)	1,653 (32)

The database should be publicly accessible on the Agency's website and in a format that would allow members of the public to easily search, sort, and download information by food category. Each listing should provide information on the product's brand, name, package size, serving size, and nutrition facts. The database will serve to motivate companies to reformulate their products, if necessary, to avoid inclusion in the database and to appear favorable in comparison to their competitors within a category. At a minimum, the database should be refreshed on a timeline to correspond to all the targets in the sodium reduction strategy.

The data to support the database could come from existing publicly available sources such as USDA FoodData Central. However, FDA may need to purchase label data to obtain comprehensive and up-to-date product nutrition and ingredient information. In the alternative, the database could be maintained at FoodData Central itself.

III. Environmental Impact

Under 21 C.F.R. § 10.30(3), petitioners must provide an environmental impact assessment or claim a categorical exclusion from such a requirement. The action requested herein is subject to a categorical exclusion under 21 C.F.R. § 25.32(m), and therefore does not require the preparation of an environmental assessment. Further, the undersigned believe that the action requested in this petition would have no significant environmental impact.

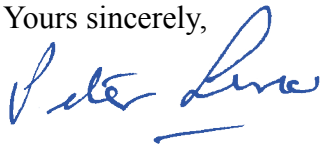
IV. Economic Impact

No overall statement of the economic impact of the requested action is presented because none has been requested by the Commissioner, but the health and economic benefits are estimated in Section II.B and Appendix A.

V. Certification

The undersigned certifies, that, to their best knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition. Correspondence related to the petition should be directed to Emily Friedman at efriedman@cspinet.org.

Yours sincerely,



Peter Lurie, MD, MPH
President and Executive Director

Appendix A: Summary of National Studies on the Health and Economic Costs of Excessive Sodium Consumption in the United States

Author, Year	Design, Duration	Intervention	Reduction in CVD	Reduction in Mortality/QALYs	Total Costs	Direct Savings	Net Savings
Palar, 2009[35]	Cross-sectional simulation	Mean sodium consumption = 2,300 mg/d	11M cases of hypertension	312,000 QALYs/y		$18B/y in health care From QALYs: $32B/y	
Danaei, 2009[33]	Burden of sodium > 500mg/d	N/A		102,000 deaths/y, mostly CVD			
Smith-Spangler, 2010[36]	Markov model Lifetime of 40-85 year-olds	1. Industry collaboration (mean Na decrease 9.5%) 2. Sodium tax (mean Na decrease 6%)	1. 514K strokes; 480K MIs 2. 328K strokes; 306K Mis	1. 1.3M life-years; 2.1M QALYs 2. 840K life-years; 1.3M QALYs		1. $32B 2. $22B	
Bibbins-Domingo, 2010[5]	Markov model 10 years	1. Reduction in average sodium by 400 mg/d 2. Reduction in average sodium by 1,200 mg/d	1. 20-40K CHD cases/y; 11-23K strokes/y; 18-35K MIs/y 2. 60-120K CHD cases/y; 32K-66K strokes/y; 54-99K MIs/y	1. 15-32K deaths/y 2. 44-92K deaths/y; 194-392K QALYs/y	1. Phase-in over 10 years: $0.3B 2. Phase-in over 10 years: $0.3B	1. N/A 2. $10-24B/y	1. $15-26 per dollar spent 2. $45-76 per dollar spent
Coxson, 2013[28]	Computer simulations 10 years	Reduction to mean Na 2,200 mg/d over 10 years	383K CHD deaths 145K stroke deaths	505K deaths; 1.8M person-years			
Mozaffarian, 2014[34]	Burden of Na > 2000 mg/d	N/A	35K CHD deaths/y; 10K stroke deaths/y; 12K other CVD deaths/y; 57K all CVD deaths/y				
Pearson-Stuttard, 2018[30]	Microsimulation 20 years	1. 100% compliance with 10y FDA target 2. 50% compliance with 10y FDA target 3. 100% compliance with 2y FDA target	1. 450K CVD cases 2. 220K CVD cases 3. 120K CVD cases	1. 35K CVD deaths; 2.1M QALYs 2. 1.1M QALYs 3. 0.7M QALYs	1. $17B 2. $10B 3. $7B		1. $41B 2. $19B 3. $12B

Appendix A: Summary of National Studies on the Health and Economic Costs of Excessive Sodium Consumption in the United States, continued

Author, Year	Design, Duration	Intervention	Reduction in CVD	Reduction in Mortality/QALYs	Total Costs	Direct Savings	Net Savings
Collins, 2019[31]	Microsimulation 20 years Limited to people working in the food system and processed food industry ("current" vs "ever" workers)	1. 100% compliance with both 2y and 10y targets a. Food system ever workers b. Food system current workers c. Processed food industry ever workers d. Processed food industry current workers 2. 100% compliance with 2y target but with no further reformulation a. Food system ever workers b. Food system current workers c. Processed food industry ever workers d. Processed food industry current workers	1. a. 38.7K CVD cases; 3.0K deaths b. 10.1K CVD cases; 1.2K deaths c. 7.1K CVD cases; 0.6K deaths d. 2.0K CVD cases; 0.2K deaths 2. a. 10.4K CVD cases; 1.1K deaths b. 2.6K CVD cases; 0.5K deaths c. 1.9K CVD cases; 0.2K deaths d. 0.5K CVD cases; 0.08K deaths	1. a. 180K QALYs b. 67K QALYs c. 32K QALYs d. 11K QALYs 2. a. 62K QALYs b. 25K QALYs c. 11K QALYs d. 4K QALYs	1. a. $11.2B b. $15.1B c. $15.6B d. $16.4B 2. a. $5.5B b. $6.8B c. $7.0B d. $7.3B	1. a. $5.2B b. $1.4B c. $1.0B d. $0.3B 2. a. $1.8B b. $0.5B c. $0.3B d. $0.1B	1. a. $6.8B b. -$8.3B c. -$12.4B d. -$15.1B 2. a. $0.7B b. $4.4B c. $5.9B d. $6.8B
Dehmer, 2020[39]	Microsimulation 10 years	Reduction to mean Na 2,300 mg/d over 10 years	895.2K CVD events; 252.5K deaths			$36.9B estimated reduction in medical costs; $18.2B societal productivity gains	

Presented by Peter Lurie, MD, MPH, President, Center for Science in the Public Interest, to the Office of Information and Regulatory Affairs on September 19, 2019.

Endnotes

1 Biden-Harris Administration. National Strategy on Hunger, Nutrition, and Health. Washington, DC, September 2022.

2 National Academies of Sciences Engineering and Medicine 2019. Dietary Reference Intakes for Sodium and Potassium. Washington, DC, The National Academies Press.

3 U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. DietaryGuidelines.gov. (accessed November 12, 2022).

4 Bibbins-Domingo K, Chertow GM, Coxson PG, et al. Projected effect of dietary salt reductions on future cardiovascular disease. *N Engl J Med.* 2010;362(7):590-599.

5 Center for Science in the Public Interest. Petition to revoke the GRAS status of salt, to set ceilings on the amount of sodium in processed foods, to require a health warning on packaged salt, and to reduce the daily value for sodium. November 8, 2005. https://www.cspinet.org/sites/default/files/media/documents/resource/fda_salt_petition.pdf (accessed March 13, 2023).

6 U.S. Food and Drug Administration. Draft Guidance for Industry: Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods, June 2016.

7 U.S. Food and Drug Administration. Guidance for Industry: Voluntary Sodium Reduction Goals; Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods, October 2021. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-voluntary-sodium-reduction-goals (accessed November 12, 2022).

8 Institute of Medicine. Strategies to Reduce Sodium Intake in the United States. 2010. Washington, DC, The National Academies Press. https://doi.org/10.17226/12818.

9 *Ctr. for Sci. in the Pub. Interest v. FDA*, No. 15 Civ. 1651 (D.D.C. filed Oct. 8, 2015).

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