CENTER FOR Science IN THE Public Interest

*The nonprofit publisher of Nutrition Action Healthletter*

September 16, 2021

The Honorable Shalanda Young
Acting Director
Office of Management and Budget
Executive Office of the President
725 Seventeenth Street NW
Washington, DC 20503

Dear Acting Director Young,

The Center for Science in the Public Interest (CSPI) writes today to advocate for the imminent release of the final voluntary sodium reduction targets. These targets were first issued in draft form in 2016 in response to 1978 and 2005 petitions CSPI filed with the Food and Drug Administration (FDA) and a lawsuit we brought in 2015 for failure to act on our 2005 petition. We are encouraged that the voluntary sodium reduction guidelines have moved to the OMB for final review. This promising development brings our nation one step closer to preventing thousands of deaths due to heart attacks and strokes and to saving billions of dollars in healthcare costs each year.[1]

Since the voluntary sodium reduction guidelines were proposed five years ago, new evidence-based recommendations have demonstrated, with increased certainty, that the FDA was right in taking at least a modest step to reduce sodium in commercially processed, packaged, and prepared foods. Americans are consuming an average of about 3,400 mg of sodium per day.[2] While all natural foods contain small amounts of sodium, more than 70 percent of the sodium that the average American consumes comes from packaged and restaurant foods.[3] In the authoritative 2019 National Academies of Science, Engineering, and Medicine's (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 to 1,200 to 2,300 mg per day for children, depending on their age.[4] 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 reduces the risk of the hard outcome of cardiovascular disease (CVD), largely based on randomized, controlled trials.

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[1] Dehmer SP, Cogswell ME, Ritchey MD, et al. Health and Budgetary Impact of Achieving 10-Year U.S. Sodium Reduction Targets. *Am J Prev Med*. 2020;59(2):211-218.
[2] U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015 – 2020 Dietary Guidelines for Americans*. 8th Edition. December 2015. Available at https://health.gov/our-work/food-nutrition/previous-dietary-guidelines/2015.
[3] Harnack LJ, Cogswell ME, Shikany JM, et al. Sources of Sodium in US Adults From 3 Geographic Regions. *Circulation*. 2017;135(19):1775-1783.
[4] National Academies of Sciences Engineering and Medicine 2019. *Dietary Reference Intakes for Sodium and Potassium*. Washington, DC: The National Academies Press.

Excess sodium consumption has critical public health and economic implications. We identified nine studies that weighed the costs and/or benefits of reducing sodium consumption. These are summarized in detail in the Appendix; here we only provide a brief summary. Two of these[5,6] 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.[7,8,9,10,11] Other than one study that modeled only limited sodium reduction,[8] 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.[12,13] In the first,[12] 100% compliance with FDA's 2-year targets prevented 120,000 CVD cases over 20 years at a net savings of $12 billion. Similar compliance with the 10-year target prevented 450,000 CVD cases and 35,000 deaths at a net savings of $41 billion. The second study[13] modeled the impact of the FDA guidelines on people working in the food system and the processed food industry itself. Complying with FDA's 2-year target prevented 500 to 10,400 CVD cases and 80 to 1,100 deaths over 20 years. Compliance with the 10-year target as well 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 compliance with the FDA guidelines could be substantial (in the $6 to $17 billion dollar range), in most scenarios the interventions were actually cost-saving.

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[5] Danaei G, Ding EL, Mozaffarian D, et al. The preventable causes of death in the United States: comparative risk assessment of dietary, lifestyle, and metabolic risk factors. *PLoS Med*. Apr 28 2009;6(4):e1000058.
[6] Mozaffarian D, Fahimi S, Singh GM, et al. Global sodium consumption and death from cardiovascular causes. *N Engl J Med*. Aug 14 2014;371(7):624-634.
[7] Palar K, Sturm R. Potential societal savings from reduced sodium consumption in the U.S. adult population. *Am J Health Promot*. Sep-Oct 2009;24(1):49-57.
[8] Smith-Spangler CM, Juusola JL, Enns EA, Owens DK, Garber AM. Population strategies to decrease sodium intake and the burden of cardiovascular disease: a cost-effectiveness analysis. *Ann Intern Med*. Apr 20 2010;152(8):481-487, w170-483.
[9] Bibbins-Domingo K, Chertow GM, Coxson PG, et al. Projected effect of dietary salt reductions on future cardiovascular disease. *N Engl J Med*. Feb 18 2010;362(7):590-599.
[10] Coxson PG, Cook NR, Joffres M, et al. Mortality benefits from US population-wide reduction in sodium consumption: projections from 3 modeling approaches. *Hypertension*. Mar 2013;61(3):564-570.
[11] Dehmer SP, Cogswell ME, Ritchey MD, et al. Health and budgetary impact of achieving 10-Year U.S. sodium reduction targets. *Am J Prev Med*. Aug 2020;59(2):211-218.
[12] Pearson-Stuttard J, Kypridemos C, Collins B, et al. Estimating the health and economic effects of the proposed US Food and Drug Administration voluntary sodium reformulation: Microsimulation cost-effectiveness analysis. *PLoS Med*. Apr 2018;15(4):e1002551.
[13] Collins B, Kypridemos C, Pearson-Stuttard J, et al. FDA sodium reduction targets and the food industry: are there incentives to reformulate? Microsimulation cost-effectiveness analysis. *Milbank Q*. Sep 2019;97(3):858-880.

One strategy that companies can use to reduce the sodium content in their foods is to replace traditional salt (sodium chloride) with a salty-tasting, yet sodium-free, alternative: potassium chloride. Notably, in December 2020, the FDA approved "potassium salt" as an alternative name for potassium chloride. The new term should be more recognizable on food labels (and less off-putting) and thus may spur more companies to use potassium salt to reduce sodium content in their foods. Interestingly, just weeks ago, the New England Journal of Medicine published a randomized, controlled trial in which the intervention group was randomized to a salt substitute (75% sodium chloride and 25% potassium chloride by mass) while the control used conventional salt (100% sodium chloride). The study reported a statistically significant reduction in rates of stroke (29.14 events in the salt substitute group vs. 33.65 events per 1000 person-years in the control group; rate ratio, 0.86; 95% CI, 0.77 to 0.96), major CVD events (rate ratio, 0.87; 95% CI, 0.80 to 0.94), and death from any cause (rate ratio, 0.88; 95% CI, 0.82 to 0.95) among participants with a history of stroke, high blood pressure or aged ≥60 years.[14] Although these findings may not be generalizable to healthy adults, they show promise as a viable strategy for improving health, especially given that 45% of U.S. adults have high blood pressure.[15]

We now have a unique opportunity to tackle one of the principal contributors to our national burden of diet-related disease. It is critical that the OMB move expeditiously to release the final voluntary sodium reduction targets, including the 10-year targets, to support nation-wide sodium reduction. Thank you again for your efforts to promote policies that will prevent chronic disease, promote population health, and save lives.

Sincerely,

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Center for Science in the Public Interest

Peter Lurie, MD, MPH
President and Executive Director
Center for Science in the Public Interest

CC:
Acting Commissioner Janet Woodcock, Food and Drug Administration
Ambassador Susan Rice, Assistant to the President for Domestic Policy, Domestic Policy Council, Executive Office of the President
Director Susan T. Mayne, Center for Food Safety and Applied Nutrition, Food and Drug Administration
Kelliann Blazek, Special Assistant to the President for Agriculture and Rural Policy, Domestic Policy Council, Executive Office of the President
Secretary Xavier Becerra, Health and Human Services

[14] Neal B, Wu Y, Feng X, et al. Effect of Salt Substitution on Cardiovascular Events and Death [published online ahead of print, 2021 Aug 29]. *N Engl J Med*. 2021;10.1056/NEJMoa2105675. doi:10.1056/NEJMoa2105675
[15] Ostchega Y, Fryar CD, Nwankwo T, Nguyen DT. Hypertension prevalence among adults aged 18 and over: United States, 2017–2018. NCHS Data Brief, no 364. Hyattsville, MD: National Center for Health Statistics. 2020.

Appendix: Cost/Benefit Studies Related to Sodium Reduction

| Author, Year | Design, Duration | Intervention | Reduction in CVD | Reduction in Mortality/QALYs | Total Costs | Direct Savings | Net Savings |
|---|---|---|---|---|---|---|---|
| Palar, 2009 | Cross-sectional simulation | Mean sodium consumption = 2,300 mg/d | 11M cases of hypertension | 312,000 QALYs/y | | $18B/y in health care<br>From QALYs: $32B/y | |
| Danaei, 2009 | Burden of usual dietary sodium exposure | N/A | | 102,000 deaths/y, mostly CVD | | | |
| Smith-Spangler, 2010 | Markov model<br><br>Lifetime of 40-85 year-olds | 1. Industry collaboration (mean Na decrease 9.5%)<br>2. Sodium tax (mean Na decrease 6%) | 1. 514K strokes; 480K MIs<br>2. 328K strokes; 306K MIs | 1. 1.3M life-years; 2.1M QALYs<br>2. 840K life-years; 1.3M QALYs | | 1. $32B<br>2. $22B | |
| Bibbins-Domingo, 2010 | Markov model<br><br>10 years | 1. Reduction in average sodium by 400 mg/d<br>2. Reduction in average sodium by 1,200 mg/d | 1. 20-40K CHD cases/y; 11-23K strokes/y; 18-35K MIs/y<br>2. 60-120K CHD cases/y; 32K-66K strokes/y; 54-99K MIs/y | 1. 15-32K deaths/y<br>2. 44-92K deaths/y; 194-392K QALYs/y | 1. Phase-in over 10 years: $0.3B<br>2. Phase-in over 10 years: $0.3B | 1. N/A<br>2. $10-24B/y | 1. $15-26 per dollar spent<br>2. $45-76 per dollar spent |
| Coxson, 2013 | Computer simulations<br><br>10 years | Reduction to mean Na 2,200 mg/d | 383K CHD deaths<br>145K stroke deaths | 505K deaths;<br>1.8M person-years | | | |

| Author, Year | Design, Duration | Intervention | Reduction in CVD | Reduction in Mortality/QALYs | Total Costs | Direct Savings | Net Savings |
|---|---|---|---|---|---|---|---|
| Mozaffarian, 2014 | Burden of Na > 2000 mg/d | N/A | 35K CHD deaths/y;<br>10K stroke deaths/y;<br>12K other CVD deaths/y;<br>57K all CVD deaths/y | | | | |
| Pearson-Stuttard, 2018 | Micro-simulation<br><br>20 years | 1. 100% compliance with 10y FDA target<br>2. 50% compliance with 10y FDA target<br>3. 100% compliance with 2y FDA target | 1. 450K CVD cases; 35K deaths<br>2. 220K CVD cases<br>3. 120K CVD cases | 1. 2.1M QALYs<br>2. 1.1M QALYs<br>3. 0.7M QALYs | 1. $17B<br>2. $10B<br>3. $7B | | 1. $41B<br>2. $19B<br>3. $12B |
| Collins, 2019 | Micro-simulation<br><br>20 years<br><br>People working in the food system and processed food industry | 1. 100% compliance with both 2y and 10y FDA targets<br>a. Food system ever workers<br>b. Food system current workers<br>c. Processed food industry ever workers<br>d. Processed food industry current workers | 1. a. 38.7K CVD cases; 3.0K deaths<br>b. 10.1K CVD cases; 1.2K deaths<br>c. 7.1K CVD cases; 0.6K deaths<br>d. 2.0K CVD cases; 0.2K deaths | 1. a. 180K QALYs<br>b. 67K QALYs<br>c. 32K QALYs<br>d. 12K QALYs | 1. a. $11.2B<br>b. $15.1B<br>c. $15.6B<br>d. $16.4B | 1. a. $5.2B<br>b. $1.4B<br>c. $1.0B<br>d. $0.3B | 1. a. $6.8B<br>b. -$8.3B<br>c. -$12.4B<br>d. -$15.1B |

| Author, Year | Design, Duration | Intervention | Reduction in CVD | Reduction in Mortality/QALYs | Total Costs | Direct Savings | Net Savings |
|---|---|---|---|---|---|---|---|
| Collins, 2019 (ctd.) | | 2. 100% compliance with 2y target but with no further reformulation<br>a. Food system ever workers<br>b. Food system current workers<br>c. Processed food industry ever workers<br>d. Processed food industry current workers | 2. a. 10.4K CVD cases; 1.1K deaths<br>b. 2.6K CVD cases; 0.5K deaths<br>c. 1.9K CVD cases; 0.2K deaths<br>d. 0.5K CVD cases; 0.08K deaths | 2. a. 62K QALYs<br>b. 25K QALYs<br>c. 11K QALYs<br>d. 4K QALYs | 2. a. $5.5B<br>b. $6.8B<br>c. $7.0B<br>d. $7.3B | 2. a. $1.8B<br>b. $0.5B<br>c. $0.3B<br>d. $0.1B | 2. a. $0.7B<br>b. -$4.4B<br>c. -$5.9B<br>d. -$6.8B |
| Dehmer, 2020 | Micro-simulation<br><br>10 years | Reduction to mean Na 2,300 mg/d | 895.2K CVD events; 252.5K deaths | | | $36.9B in medical costs<br>$18.2B societal productivity gains | |