September 30, 2021

The Honorable Shalanda Young
Acting Director
Office of Management and Budget
Executive Office of the President
725 17th Street, NW
Washington, DC 20503

Dear Acting Director Young,

On September 1st, the U.S. Food and Drug Administration (FDA) sent a final version of the 2016 "Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods: Guidance for Industry" to the Office of Management and Budget for review. Approving these guidelines as soon as possible is critically important as they could save thousands of lives per year in the near term and tens of thousands of lives per year a decade from now.

The high-sodium content of the American diet increases blood pressure, ultimately causing as many as 100,000 premature deaths due to heart attacks, strokes, and kidney disease, and $24 billion in preventable health-care costs annually.[1] In 2020, the Surgeon General released a call to action highlighting hypertension as a major preventable risk factor for heart disease and stroke, which are the first and fifth leading causes of death in the United States, and establishing a goal of making hypertension control a national priority.[2] The burden of hypertension is not shared equally among Americans but disproportionately impacts Black Americans. Of the 32 million Black adults in the U.S. census, 14 million (45%) have hypertension, of whom only an estimated 2 million have it controlled.[3] Black Americans have higher rates of hypertension (57% of Black adults compared to 43% of non-Hispanic white adults and 43% of Hispanic adults)[4] and lower rates of hypertension control (48% compared to 56% among non-Hispanic whites)."[5] Further, Black Americans also have the highest mortality

[1] Bibbins-Domingo, K. et al. Projected effect of dietary salt reductions on future cardiovascular disease. N. Engl. J. Med. 362 https://www.nejm.org/doi/full/10.1056/NEJMoa0907355(2010).
[2] U.S. Department of Health and Human Services. The Surgeon General's Call to Action to Control Hypertension. Washington, DC: U.S. Department of Health and Human Services, Office of the Surgeon General; 2020.
[3] Frieden, T., Foti, K. (2021). National Initiatives to Prevent Myocardial Infarction and Stroke, *JAMA*.
[4] 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.
[5] Carnethon MR, Pu J, Howard G, Albert MA, Anderson CAM, Bertoni AG, Mujahid MS, Palaniappan L, Taylor HA Jr, Willis M, Yancy CW; on behalf of the American Heart Association Council on Epidemiology and Prevention; Council on Cardiovascular Disease in the Young; Council on Cardiovascular and Stroke Nursing; Council on Clinical Cardiology; Council on Functional Genomics and Translational Biology; and Stroke Council. Cardiovascular health in African Americans: a scientific statement from the American Heart Association. *Circulation*. 2017;136:e393–e423. doi: 10.1161/CIR.0000000000000534

rates due to heart attacks and strokes among any race/ethnic group in the United States – 20% higher for heart attacks and 40% higher for strokes than non-Hispanic whites.[6]

Salt reduction, therefore, is likely to have a greater impact on the health of Black Americans. A 2001 randomized control trial found that Black participants saw a greater reduction in systolic blood pressure compared to other races when exposed to a low sodium diet.[7] Similarly, a 2010 study estimated an almost two-fold higher decrease in mortality rates among Black Americans between 35 to 64 compared to other races in the same age range.[8] To effectively pursue health equity in this country we must ensure that we target diseases disproportionately burdening communities of color with interventions that have high potential for combating health disparities.

Approximately 75% of the sodium in the American diet comes from processed and restaurant foods and therefore it is very difficult for individuals to reduce sodium intake through their own actions. To address this, the Institute of Medicine's 2010 report recommended that the FDA set *mandatory* limits on sodium, with those limits declining every few years. The FDA guidance sent to the White House is *voluntary* and the targets were adjusted based on industry feedback, thus implementation should be eminently feasible. The guidance sets out 2-year and 10-year voluntary sodium limits by food category based on reductions from the state of the market at the time the guidance was released. The limits include both a target average sodium concentration level for the entire food category and a maximum sodium concentration level for individual food products. Ultimately these policies are designed to help Americans reach the current recommended sodium intake of 2,300 mg/day.

We encourage the immediate approval of this proposed guidance and encourage the following steps to protect the health of all Americans:

- Ensure the guidance is fast tracked to be implemented as quickly as possible. As implementation rolls out, the FDA could consider creating intermediate (such as 6-year) goals to encourage steady progress over the coming decade.
- Ensure the FDA is supported, including with appropriate budget levels, to track industry progress toward the targets. We encourage the appropriation of $5 million for each of the next five years to fund an FDA Office of Sodium Reduction, which would monitor progress in reducing sodium levels in the food supply, mount a public education campaign, press large companies to lower sodium, and advise smaller companies on how to lower sodium. The commissioner should appoint a "Sodium Czar" to vigorously implement the program.

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[6] Mensah GA. Cardiovascular Diseases in African Americans: Fostering Community Partnerships to Stem the Tide. *Am J Kidney Dis*. 2018;72(5 Suppl 1):S37-S42. doi:10.1053/j.ajkd.2018.06.026

[7] Sacks, F. M. *et al.* Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet. *N. Engl. J. Med.* **344** https://www.nejm.org/doi/full/10.1056/nejm200101043440101 (2001).

[8] Bibbins-Domingo, K. et al. Projected effect of dietary salt reductions on future cardiovascular disease. N. Engl. J. Med. 362 https://www.nejm.org/doi/full/10.1056/NEJMoa0907355(2010).

- If companies don't reduce sodium sufficiently to meet the 2-year goals, the FDA's "maximum" voluntary goals should be made mandatory and/or "high in sodium" icons on the fronts of food packages and chain-restaurant meals (as Mexico, Israel, and several other countries have done) should be required.

We look forward to seeing this guidance approved and working with the administration to ensure effective and equitable implementation.

Sincerely,

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