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June 30, 2016

The Honorable Robert Califf, M.D.
Commissioner
United States Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Califf,

I am writing today to express my strong disappointment and objection to the announcement by FDA on June 1, 2016 regarding its voluntary standards for sodium in food. I find it quite disturbing that a public health issue would be handled in this manner.

process of the Dietary Reference Intake (DRI) for sodium.

As you probably know, my amendment was added to the House Agriculture Appropriations bill. It

be overturned. It seems like common sense to me

Because of the new research, I do not believe that the "totality of the scientific evidence supports sodium reduction from current intake levels" as the Center for Food Safety and Applied Nutrition's (CFSAN) Susan Mayne stated in the agency's press release.¹⁰ Rather, recently there have been significant studies published by the IOM (2013),¹¹ and in *NEJM*,¹² *JACC*,¹³ and most recently *Lancet*⁸ that have called into question along with accompanying editorials the current policy on sodium.^{3,5,6,9} As far as I can tell, the

the blood pressure impact with no regard for the IOM's stance that health outcomes and all-cause mortality should be the basis of all future guidelines.¹⁶⁻¹⁸ That finding has also been recently articulated in

the more recent publications that have called for or suggested that population-wide sodium restrictions

health outcomes need to be one of the strongest foundations of health policy.²¹

The FDA, CDC, and AHA have discredited all of the health outcomes reports of increased CVD events and deaths related to low-sodium diets on the basis that measures of business-to-business interactions.¹³

What needs to be explained is how these same critics then cite the "robust evidence"²² that sodium

sodium intake,^{14,16-18}

also noted with some interest a reply to a letter sent to you by Senator Roberts. In the reply sent to

memorandum that day. I do not believe such a statement was written in the 2013 document and

recommendation of the 2,300 mg intake level, and that it was not asked to determine a safe range, and no did not.¹⁰

A 44-page all-hands-on-deck response from the FDA, CDC, and AHA to the letter from Senator Roberts.

THANK YOU FOR YOUR INTEREST AND SUPPORT OF THE NATIONAL INSTITUTE OF MEDICINE AND THE NATIONAL ACADEMIES OF SCIENCES

Finally, you are highly respected for your work on the pharmacologic inhibition of the renin-angiotensin system and its implications for CVD.²⁵⁻²⁷ You found in your research and through drug trials that a stimulates renin-angiotensin system, lead to several CVD, and reduces progression of CVD in at risk patients. Further, we know from the work of Dr. John Laragh and colleagues from Columbia conducted in the early 1970s and published in *NEJM* that low-dose sodium intake acts as a stimulant that activates the renin-angiotensin system.²⁸ That seminal research also demonstrated that renin stimulation was associated with CVD events. Given these facts and your own published research in support of 25-27 that have demonstrated lower sodium levels in the food groups with

from the academic cardiology community have specifically urged for no lower recommending lower

sodium policy meet that long standing professional commitment of yours?

correct, and your assumptions are borne out in the requested review, so much the better for Americans.

References

1. Grassl N, Haines G, Beal D, Alderman MJ. Common salt, low sodium intake, low and high blood pressure, and cardiovascular mortality. *N Engl J Med*. 2014; 371:1129-1137.
2. O'Donnell M, Mente A, Rangarajan S, et al.; PURE Investigators. Urinary sodium and potassium excretion, mortality, and cardiovascular events. *N Engl J Med*. 2014; 371:620-30. doi:10.1056/NEJMoa1311889.
3. O'Donnell M, Mente A, Rangarajan S, et al.; PURE Investigators. Urinary sodium and potassium excretion, mortality, and cardiovascular events. *N Engl J Med*. 2014; 371:677-670.
4. Yancy CW. The uncertainty of sodium restriction in heart failure: we can do better than this. *JACC: Heart Failure* 2016; 4:39-41.
5. Hummel SL, Kanoson MC. Dietary sodium restriction in heart failure: a recommendation worth revisiting. *JACC: Heart Failure* 2016; 4:36-39.
6. Kieneker LM, Cresswell PT, de Roos DA, et al. Urinary potassium excretion and risk of cardiovascular events. *Am J Clin Nutr* 2016; 103:1204-1212.
7. Mente A, O'Donnell M, Rangarajan S, et al. Associations of urinary sodium excretion with cardiovascular mortality and morbidity: a population-based study. *Lancet* 2016; published online April 20, 2016.
8. U.S. Food and Drug Administration. FDA issues new guidance to food industry to reduce sodium in processed and commercialized food. FDA News Release, June 1, 2016. <http://www.fda.gov/oc/2016/06/01-fda-issues-new-guidance-to-food-industry-to-reduce-sodium-in-processed-and-commercialized-food>. FDA NEWS RELEASE, JUNE 1, 2016.
9. Institute of Medicine. Sodium intake in populations: Assessment of evidence. 2013. <http://www.nationalacademies.org/handbook/summary/11-sodium-intake-in-populations-assessment-of-evidence>.

15. Mertz W. The essential trace elements. Science 1981; 213:1332-1338.

16. Billing D, Davies K, Clifton GM, Gibson DG, et al. Dietary effects of calcium on blood pressure: a meta-analysis. Am J Clin Nutr 1998; 68:25-31.

17. Gibson DG, Clifton GM, Mertz W, et al. Calcium intake and blood pressure: a meta-analysis. Am J Clin Nutr 1998; 68:25-31.

18. Mozaffarian D, Fahimi S, Singh CM, et al. Global sodium consumption and death from cardiovascular diseases. N Engl J Med 2014; 371:629-638.

19. Porter ME, Larsson S, Lee C. Standardizing patient outcomes measurement. N Engl J Med 2016; 374:504-506. doi:10.1056/NEJMp1511701

20. U.S. DRI's. Dietary Reference Intakes for Calcium and Vitamin D. National Academies Press, 2011.

Chronic Disease Endpoints for Dietary Reference Intakes (DRI) Workshop

14. U.S. DRI's. Dietary Reference Intakes for Calcium and Vitamin D. National Academies Press, 2011.

21. U.S. DRI's. Dietary Reference Intakes for Calcium and Vitamin D. National Academies Press, 2011.

22. U.S. DRI's. Dietary Reference Intakes for Calcium and Vitamin D. National Academies Press, 2011.

23. U.S. DRI's. Dietary Reference Intakes for Calcium and Vitamin D. National Academies Press, 2011.

reduction intervention on BP and hypertension incidence in overweight people with high-normal

24. Department of Health, National Diet and Nutrition Survey: A representative cross-sectional study of adults (aged 19 to 64 years) in England.

25. Department of Health, National Diet and Nutrition Survey: A representative cross-sectional study of adults (aged 19 to 64 years) in England.

27. NAVIGATOR 6. J. G. M. M. H. H. J. D. D. J. E. C. C. J. G. M. M. H. H. J. D. D. J. E. C. C. J. G. M. M. H. H. J. D. D. J. E. C. C.

Prevalence of diabetes and cardiovascular events. N Engl J Med 2010; 362:1477-1486.