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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 agency would take action before a specific review of the relevant science - even though other parts of the government are asking for and, in fact, the National Academy of Medicine is beginning the review process of the Dietary Reference Intake (DRI) for sodium.

As you probably know, my amendment was added to the House Agriculture Appropriations bill. It directed FDA to consider the updated NAM DRI review before publishing the voluntary standards. I don't know what a new standard should be, or even whether there should be a population-wide standard. However, I have been intrigued by the newer published articles indicating there might be an issue with lowering sodium intake in healthy individuals.[1-9] Because public health institutions such as FDA are responsible for the health of all individuals, healthy and sick, I believe it is prudent to allow experts to review all of the data before the agency expends scarce resources to embark on a policy that might later 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*,[2] *JACC*,[4] 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 response of the agency[12] and its activist surrogates has been to merely dismiss the studies as flawed.[13,14] It is interesting to me that the arguments as to why the studies are flawed range from reverse causality to residual confounding and preexisting disease. However, these factors were specifically addressed and accounted for in the publications at issue.[2,4,7,8] Even more interesting is the continued denial of the existence of a J-shaped curve for sodium (a graphic phenomenon that shows that consuming too little or too much can have negative consequences for humans), a curve that exists for virtually all essential nutrients.[15] From a scientific point of view, to suggest that sodium is the one anomaly is quite novel.

With regard to the published articles calling for salt reduction, these have tended to focus exclusively on 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 "Categories of Quality Measures Listed in the National Quality Measures Clearinghouse."[19]The IOM's position is also in line with those of NIH and Health Canada which have stated that new modeling on sodium should focus on all-cause mortality.[20]

You are also likely aware that there have been substantive challenges to the methodology used in some of the more recent publications that have called for or suggested that population-wide sodium restrictions save lives. These publications are all built upon the assumption that sodium's effects on BP translate into a reduced incidence of CVD.[16-18] That assumption is not universally correct, and, as you have written, 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 lower sodium intake on the basis that measures of urinary sodium are inaccurate.[13] What needs to be explained is how these same critics then cite the "robust evidence"[22] that sodium restriction lowers BP in randomized trials when those very same trials most often employed the same approach to measuring sodium intake, and in many of the trials employed less rigorous measures of sodium intake.[14,16-18]

I also noted with some interest a reply to a letter sent to you by Senator Roberts. In the reply sent to Senator Roberts, Dayle Cristinzio stated "the 2013 (IOM) report (a study paid for by the CDC) reaffirmed the conclusion that dietary sodium consumption levels are too high and should be reduced to 2,300 milligrams (mg) per day." I do not believe such a statement was written in the 2013 document, and unless you can show me the passage, I would expect a retraction is in order. The IOM report was notable because it specifically said the committee could find no evidence to support a population-wide recommendation of the 2,300 mg intake level, and that it was not asked to determine a safe range, and so did not.[10]

Additionally, just several weeks ago former FDA official Mike Taylor stated in an interview with Politico that "Some people question the science from the vantage point of well, there's a good chunk of the population that's not necessarily going to be benefited by the reduction – it's not that they're going to be hurt, but they're not going to be benefited."[12] That statement suggests to me that the recent studies have not been read and reviewed by Mr. Taylor and FDA, as the most recent studies (mentioned above) specifically find that healthy individuals have increased all-cause mortality at sodium intake below 3,000 mg/day. This daily requirement is considerably above the targets established under the voluntary guidelines, so not only is that population not likely to be benefited, it may actually be harmed under the proposal.

Mr. Taylor's statement also raises the question: can a sodium restriction policy of FDA actually change the population's intake? The National Heart, Lung, and Blood Institute (NHLBI) studies TOHP I and II, which have been cited repeatedly by the activist supporters of sodium reduction, clearly documented that the FDA goal is not achievable.[23] Not surprisingly that aspect of the TOHP results is never discussed. As documented in the summary publication in *JAMA* 1997, the NHLBI goal was to reduce the sodium intake of high-risk persons to 1,955 mg/d. The authors, including some of the most vehement supporters of reducing sodium, acknowledge failure to achieve long-term sodium intake reduction in the *JAMA* paper.

Specifically, in spite of providing reduced sodium foods and intense nutritional counseling, the participants failed to lower intake below 2,645 mg/d. After 36 months, even with the availability of free low sodium foods and continued counseling, mean sodium intake of the several thousand participants had regressed to 3,335 mg/d. The government's carefully designed and monitored RCT failed to document that the FDA target is feasible. Sodium restriction advocates have cited, as evidence of feasibility, the UK experiment.[24] I encourage you to go to the UK government site that records the actual data on the change in sodium intake over the time frame of that population-wide experiment. It states the change in urinary sodium excretion as a measure of intake was non-significant.[24]

Finally, you are highly regarded for your work on the pharmacologic inhibition of the renin-angiotensive system and its implications for CVD.[25-27] You found in your research and through drug trials that a stimulated renin-angiotensive system leads to greater CVD issues, and inhibiting that system saves lives 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 lower sodium intake acts to stimulate that same 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 it,[25-27] then how does proposing lower sodium levels in the food supply, without research showing the FDA proposed consumption levels are safe, makes any medical sense? Colleagues of yours from the academic cardiology community have specifically called for no longer recommending lower sodium to heart failure patients.[5,6] If such experts believe sodium restriction is unsafe for heart patients what rationale could possibly justify it is safe for the general population?

If a series of published large-scale trials revealed that a drug increased all-cause mortality for healthy individuals, as is the case with sodium restriction, FDA would quickly and thoroughly review the science; and withhold approval from a new drug or quickly pull an existing drug from the market. How does that reality square with the sodium restriction policy now proposed by FDA? You have argued cogently in the past of the role of health outcomes to "moving quality to a national level."[21] Does the proposed FDA sodium policy meet that long-standing professional commitment of yours?

I stand by my position that the prudent, cautious action of any public health agency is to make sure they have their science right before proceeding, in this case, with a one-size-fits-all sodium policy. If you are correct, and your assumptions are borne out in the requested review, so much the better for Americans. However, if your assumptions are wrong, the actions taken by the Agency are potentially dangerous for significant segments of the American population.

Sincerely,



Andy Harris, M.D.
Member of Congress

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