Comments of the Competitive Enterprise Institute regarding the Food and Drug Administration's Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods;

Draft Guidance for Industry, Docket Number: FDA-2014-D-0055

Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Draft Guidance for Industry.
By Electronic Mail [http://www.regulations.gov]
Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
Re: Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Draft Guidance for Industry. Docket No. FDA-2014-D-0055-0001

The Competitive Enterprise Institute (CEI) appreciates the opportunity to comment on the Food and Drug Administration's Draft Guidance on sodium reduction goals. CEI is a 501(c)(3) non-profit public interest organization dedicated to promoting rational risk regulation and consumer choice. CEI has a long history of research and advocacy regarding the regulation of health and safety risks, with a particular emphasis on food and drug safety. We have frequently observed that attempts to limit exposure to certain risks unintentionally increase exposure to other, potentially more hazardous risks. In the case of sodium reduction, we believe the continued focus on reducing dietary salt for the population is not scientifically based and may be obscuring other, more effective, approaches to improving public health.

Although the FDA requested comments on eight specific questions, the Federal Register notice (FDA-2014-D-0055-0001) welcomed "comment on any issues related to the methods for developing the sodium targets." In particular, CEI wishes to address the FDA's stated goal of implementing the voluntary sodium reduction targets in order to "support the 2015-2020 Dietary Guidelines and the Healthy People 2020 recommendations of sodium intake of less than 2,300 mg per day for many individuals." FDA states that, as noted by the Institutes of Medicine 2010 report, four decades of sodium reduction efforts by health agencies has failed.[1]

Furthermore, the draft guidance document notes that Americans consume the vast majority of their sodium in the form of prepared meals and snacks. Both of these assertions are true. However, we take issue with the subsequent logical leap that reducing sodium in processed, packaged, and prepared foods will:

1. Reduce consumers overall sodium intake; and

[1] Draft guidance for industry: voluntary sodium reduction goals: target for mean and upper bound concentrations for sodium in commercially processed, packaged, and prepared foods. U.S. Food and Drug Administration. July 1, 2016.
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm494732.htm. Accessed October 16, 2016.

2. Result in lower rates of hypertension.

After conducting an extensive review of the scientific literature, available in our forthcoming paper on the efficacy of various public policy approaches to managing hypertension, we find that the overwhelming weight of evidence does not support the view that reducing sodium consumption to the level recommended in the Dietary Guidelines would improve public health. The paper concludes that to date, there is no evidence that, for the average normotensive individual (having normal blood pressure), lowering sodium intake from the average 3,400 mg per day to the recommended 2,300 mg per day, results in better health outcomes.

The current body of research on the effect of dietary sodium and sodium restriction on health yields conflicted results, at best. There has not been a single randomized control trial (RCT) performed examining how sodium reduction to the current recommended maximum affects health outcomes. Of the RCTs that have examined sodium restriction to under 3,000 mg a day, all performed on already hypertensive and/or obese patients. While they found small changes in blood pressure, they also found no benefit for all-cause mortality risk.[2] Furthermore, an increasing body of observational research indicates that not only is lowering sodium below the average intake unhelpful for the majority of individuals, it may end up *increasing* their risk for negative health consequences for some.[3]

In addition to questioning the benefits of sodium reduction, we believe it is a mistake to assume that simply lowering the amount of sodium in prepared foods would lead consumers to lower their total sodium intake. Much research demonstrates that, outside of a controlled clinical setting, consumers unconsciously alter their dietary choices and behavior in an effort to maintain a constant level of sodium intake.[4] Reduced sodium consumption affects different individuals in different ways. Only an estimated 17 to 25 percent of the population is "salt sensitive"—they experience higher blood pressure with increased dietary sodium—while 75 percent are considered salt resistant and will experience no change in blood pressure with altered dietary sodium. However, an estimated 11 to 16 percent of the population are *inverse* salt sensitive, which means reduced dietary sodium can *increase* their blood pressure. With this heterogeneity in response to salt, trying to force a population-wide reduction in sodium availability in order to reduce incidences of hypertension would be ineffective at best and counterproductive at worst.

Lastly, while we believe that control of elevated blood pressure is vital to improving the heart health of our nation, the continued focus on sodium shifts the focus away from demonstrably more effective means of improving population blood pressure and health. Thus, we respectfully request the FDA to refocus its efforts toward approaches more likely to improve Americans' health, such as the correction of nutrient deficiencies in the diet.

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[2] Niels Graudal, "A radical sodium reduction policy is not supported by randomized controlled trials or observational studies: grading the evidence," *American Journal of Hypertension,* May 2016 Vol. 29, No. 5. doi: 10.1093/ajh/hpw006

[3] Ibid

[4] [4] McCarron D.A., Weder A.B., Egan B.M., et al., "Blood Pressure and Metabolic Responses to Moderate Sodium Restriction in Isradipine-Treated Hypertensive Patients," *American Journal of Hypertension,* Vol. 10, No. 1 (1997), pp. 68-76. https://www.ncbi.nlm.nih.gov/pubmed/9008250

Voluntary Sodium Limits

Salt is a necessary component of the human diet. Without it our bodies cease to operate on a cellular level. In addition to transmitting electrical impulses to control sympathetic nervous system and muscle function, sodium—along with potassium—is the means by which our bodies create a balance of fluid in and around our cells and maintain stable blood pressure. When blood pressure dips, cells, primarily in the kidneys, trigger the release of a hormones and enzymes that cause the body to retain sodium and water. Since water follows sodium, this retention results in an increase in blood volume. These enzymes also cause blood vessels to constrict, reducing the space through which blood flows. Combined with the increased blood volume, that constriction results in a rise in blood pressure, which allows the kidneys to maintain an adequate supply of clean blood. Once pressure increases, it stretches the vessels in the heart, triggering the release of hormones that reverse the processes activated by low pressure by ending the retention of sodium and water and releasing vessel constriction to bring blood pressure back down. Throughout both of these processes, hormones trigger or curtail our desire to drink and consume salt in order to increase or decrease our intake of the ingredients necessary for the body to force our blood pressure upward.

Sodium in the diet should never result in long-term blood pressure imbalance in a properly functioning body able to retain or excrete sodium and water when needed and with properly functioning triggers for thirst and salt appetite. Yet, hypertension, a known risk factor for numerous cardiovascular conditions, is unacceptably prevalent in Western societies.

The number of Americans with hypertension or on hypertensive drugs (with "controlled hypertension") has been steadily climbing since at least the 1980s.[5] Among health advocates, the proposed explanations are numerous. One of the most popular is that as a nation, we consume an average of 1,000 more milligrams of sodium a day than we should. More and more, the blame has been laid at the feed of prepared foods, from which Americans reportedly get about 80 percent or more of their daily sodium intake.[6]

The rise of hypertension has occurred during a time when government and other health agencies have effectively pushed the idea that too much dietary sodium inexorably leads to elevated blood pressure. Much of the general public now believes that to be unequivocally true. Still, recent research indicates that, despite this belief and increasing consumption of highly salted processed foods, sodium intake has remained stable since at least the 1950s.[7] And it is not just Americans. As David McCarron of the University of California, Davis and his colleagues found in 2013, human populations around the globe appear to consume an average level of sodium within a relatively narrow range.[8] Despite variations in culture, ethnicity, and even age, the average intake of very different populations fell between 2,600 and

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[5] Cutler JA, Sorlie PD, Wolz M, Thom T, Fields LE, Roccella EJ. Trends in hypertension prevalence, awareness, treatment, and control rates in United States adults between 1988–1994 and 1999–2004. *Hypertension*. 2008;52:818–827

[6] U.S. Food and Drug Administration "Lowering Salt in Your Diet," March 9, 2016, http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm181577.htm. Accessed October 16, 2016.

[7] Bernstein M, Willett W. Trends in 24-h urinary sodium excretion in the United States 1957-2003: a systematic review. *American Journal of Clinical Nutrition.* 2010; 92(5): 1172-1180. doi: 10.3945/ajcn.2010.29367

[8] McCarron D.A., Kazaks A.G., Geerling J.C., et al., "Normal range of human dietary sodium intake: a perspective based on 24-hour urinary sodium excretion worldwide. *American Journal of Hypertension* 10 (2013): 1218-1223. doi: 10.1093/ajh/hpt139

4,800 mg per day.[9] The Average American, consuming about 3,400 mg of sodium a day, falls in the middle of this range.

Sodium intake is Unconscious and Physiologically Driven

An important question the FDA should consider prior to implementation of its sodium reduction proposal is *how* consumers will respond to decreased sodium in their prepared meals.

There is some evidence that, given a salt shaker, people will not add as much salt back to their food as was removed, but this has only been observed in clinical settings where dietary options are limited.[10] In the real world, people have virtually unlimited options. It is unclear whether reducing sodium in prepared foods will result in consumers re-salting foods or in altering their diet so that more of their choices are salted.

There is some evidence indicating that sodium appetite—the amount of sodium a person's body craves—is unconscious and when sodium in the diet is altered, even without people's knowledge, they will shift their dietary choices so they end up taking in the same amount of sodium as before.[11] More robust evidence in the general population demonstrates that individuals with higher levels of sodium excretion, such as athletes or construction workers, generally have a higher sodium diet compared to others, which indicates there is a physiological balancing act occurring.[12] However, the reason *why* we are driven to maintain this high level of sodium is not well-understood.

Some researchers have theorized we are driven to consume high levels of sodium because of maladaptation,[13] learned-behavior, or even addiction.[14] Other evidence indicates that higher sodium intake serves some protective functions, such as promoting growth, lessening the effects of stress, and reducing depression.[15]

Does Lower Sodium Result in Better Health?

Without understanding why humans are driven to consume sodium at their current levels, it is difficult to predict the net health effect of restricting the amount of sodium in various food products available to the general population. However, emerging evidence indicates that in the general population, low

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[9] McCarron DA, Kazaks A, Geerling J, Stern J, Graudal N. Normal range of human dietary sodium intake: a perspective based on 240hour urinary sodium excretion worldwide. *American Journal of Hypertension.* 2013; 26(10): 1218-1223. doi: 10.1093/ajh/hpt139

[10] Beauchamp GK, Bertino M, Engelman K. Failure to compensate decreased dietary sodium with increased table salt usage. *Journal of the American Medical Association*. 1987;258(22):3275–3278

[11] McCarron D, Weder A, Egan B, Krishna G, et al. Blood Pressure and Metabolic Responses to Moderate Sodium Restriction in Isradipine-Treated Hypertensive Patients. *American Journal of Hypertension.* 1997; 10(1): 68-76. doi: 10.1016/S0895-7061(96)00295-6

[12] Leshem M. Biobehavior of the human love of salt. *Neuroscience and Biobehavioral Reviews.* 2009; 33(1): 1-17. doi: 10.1016/j.neubiorev.2008.07.007

[13] Crystal SR, Bernstein IL. Morning sickness: impact on offspring salt preference. *Appetite*. 1995; 25(3):231-40. doi: 10.1006/appe.1995.0058

[14] Cocores JA, Gold MS. The salted food addiction hypothesis may explain overeating and the obesity epidemic. *Medical Hypotheses*. 2009; 73(6):892-9. doi: 10.1016/j.mehy.2009.06.049.

[15] Goldstein P, Leshem M. Dietary sodium, added salt, and serum sodium associations with growth and depression in the U.S. general population. *Appetite.* 2014;79(1): 83-90. doi: 10.1016/j.appet.2014.04.008.

sodium intake at the level currently recommended by the Dietary Guidelines is related to worse health outcomes.[16]

Though vigorous debate within the research community remains, a growing number of large population studies find that, among the general population—as opposed to those with existing illnesses including hypertension—there is a U- or J-shaped curve charting the relationship between dietary sodium and mortality. That is, they find that intake at the very lowest and very highest levels correlates with higher rates of death while those in the middle have the best outcomes.

For example, one of the highest quality population studies, conducted by Katarzyna Stolarz-Skrzypek of the University of Leuven in Belgium and colleagues, analyzed 24-hour urine samples[17] for 3,600 European adults and tracked their health for an average of eight years.[18] In 2011 when they published their results, they concluded that, while higher sodium (> 5,000 mg for women or >6,000 mg for men per day) was independently associated with higher systolic blood pressure, "this association did not translate into a higher risk of hypertension or [cardiovascular disease] complications."[19] Instead, they found that lower sodium intake (<2,700 mg for men and <2,200 for women) correlated with higher rates of cardiovascular events leading to death.

Three years later, Graudal and his colleagues analyzed the result of 27 studies, including Stolarz-Skrzypek's and concluded that risk of death appeared to be lowest among individuals consuming between 2,565mg and 4,796 mg of sodium a day with higher rates of death in the upper and lower range.[20]

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[16] Alderman M.H., Cohen H.W., "Dietary sodium intake and cardiovascular mortality: controversy resolved?" *American Journal of Hypertension*, Vol. 25, No. 7 (2012), pp. 727-34. doi:10.1038/ajh.2012.52

[17] Researchers estimate sodium by a variety of methods: dietary recall or surveys, diet diaries kept by participants, "spot" urine tests which take a single urine sample and test sodium excretion, 24-hour urine in which participants collect all or most of their urine output over a day, and the gold standard of repeated 24-hour urine collection which gives researchers the most accurate way to assess a person's average daily sodium intake.

[18] Stolarz-Skrzypek K, Kuznetsova T, Thijs L, et al. Fatal and nonfatal outcomes, incidences of hypertension, and blood pressure changes in relation to urinary sodium excretion. *Journal of the American Medical Association.* 2011; 305(17): 1777-85. doi: 10.1001/jama.2011.574.

[19] Low sodium mean 120mmol for men (~2762 mg) and 95.1 (~2187mg)for women. Medium sodium was mean 188.8 (4342 mg) for men and 150.2 (3454 mg) for women. High sodium was mean 290.5 (6681mg) for men and 231.7 (5329 mg) for women.

[20] Graudal N, Alderman MH. Response to "Salt Intake and Mortality." *American Journal of Hypertension*. 2014;27(11): 1425. doi: 10.1093/ajh/hpu176.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4263952. Accessed October 15, 2016.

While some research has found that higher sodium is associated with poor outcomes in certain groups, such as those who are overweight,[2122], obese,[23] and smokers,[24] other studies have found that sodium restriction is also linked to worse health in certain groups. Particularly important are studies linking sodium restriction with higher mortality among type I[25] and type II[26] diabetics—groups representing nearly 30 million Americans and 10 percent of the population.[27]

Furthermore, in non-hypertensive people, modest sodium restriction (to around 2,700 mg of sodium a day) results in potentially harmful changes in blood lipid profile. For example, studies have found that while non-hypotensive individuals experienced a 1 percent reduction in systolic blood pressure (1 or 2 points) they had a 2.5 percent increase in cholesterol and a 7 percent increase in triglycerides.[28] Other studies have found that sodium reduction can also increase levels of insulin[29] and may increase insulin resistance, which has been implicated in the development of diabetes and cardiovascular disease.[30]

Sodium Response is Heterogeneous

While the theory that excess salt leads to hypertension seems like long-settled science, in reality researchers have known for decades that not everyone responds the same to increases or decreases in

[21] He J, Ogden LG, Vupputuri S, et al. Bazzano LA, Loria C, Whelton PK. Dietary sodium intake and subsequent risk of cardiovascular disease in overweight adults. *Journal of the American Medical Association.* 1999; 282:2027–2034. https://www.ncbi.nlm.nih.gov/pubmed/10591385. Accessed October 15, 2016.

[22] Cook NR, Cutler JA, Obarzanek E. Long term effects of dietary sodium reduction on cardiovascular disease outcomes: observational follow-up of the trials of hypertension prevention (TOHP). *British Medical Journal.* 2007. 28;334(7599):885-8 doi:10.1136/bmj.39147.604896.55

[23] Tuomilehto J, Jousilahti P, Rastenyte D, et al. Urinary sodium excretion and cardiovascular mortality in Finland: a prospective study. *Lancet.* 2001 March 17;357(9259):848–851. doi: 10.1016/S0140-6736(00)04199-4

[24] Larsson SC, Virtanen MJ, Monica M, et al. Magnesium, calcium, potassium, and sodium intakes and risk of stroke in male smokers. *Archives of Internal Medicine.* 2008;*168(5):459-465.* 2008;168(5):459-465. doi:10.1001/archinte.168.5.459

[25] Thomas MC, Moran J, Forsblom C, et al. The association between dietary sodium intake, ESRD, and all-cause mortality in patients with type 1 diabetes. *Diabetes Care* 2011; 34: 861-866. doi: 10.2337/dc10-1722. https://www.ncbi.nlm.nih.gov/pubmed/21307382

[26] Ekinci EL, Clarke S, Thomas MC, et al. Dietary salt intake and mortality in patients with type 2 diabetes. *Diabetes Care.* 2011; 34: 703-709. doi: 10.2337/dc10-1723
https://www.ncbi.nlm.nih.gov/pubmed/21289228

[27] Centers for Disease Control and Prevention. 2014 National Diabetes Statistics Report. Centers for Disease Control and Prevention. Published October 24, 2014.
http://www.cdc.gov/diabetes/data/statistics/2014statisticsreport.html. Accessed September 30, 2016.

[28] Graudal NA, Hubeck-Graudal T, Jurgens G. Effects of low sodium diet versus high sodium diet on blood pressure, renin, aldosterone, catecholamines, cholesterol, and triglyceride (review). Cochrane review. 2011

[29] Ruppert M, Diehl J, Kolloch R, et al. Short-term dietary sodium restriction increases serum lipids and insulin in salt-sensitive and salt-resistant normotensive adults. *Klinische Wochenschrift.* 1991;69 Suppl 25:51-7.http://www.ncbi.nlm.nih.gov/pubmed/1921253

[30] Garg R, Williams GH, Hurwitz S, Brown NJ, Hopkins PN, Adler GK. Low salt diet increases insulin resistance in healthy subjects. *Metabolism*. 2011; 60(7): 965–968. doi: 10.1016/j.metabol.2010.09.005. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3036792/

dietary salt. Only an estimated 17[31] to 25[32] percent of the population is considered "salt sensitive" and will experience a drop in blood pressure with sodium restriction. However, even for this small group, salt may not be the primary factor in developing hypertension. Alcohol consumption, vitamin and mineral deficiencies, and particularly being overweight all seem to be as important in the development of high blood pressure.[33] However, most people (upwards of 75 percent) are salt resistant and have no change in blood pressure even as a result of massive increases in sodium intake.

On the other hand, a smaller percentage of the population—perhaps 11 to 16 percent—are *inverse* salt sensitive, for whom sodium restriction causes blood pressure to *increase.*[34] Why some individuals might be salt sensitive versus resistant or inverse sensitive is not yet clear, although genetic factors may explain why certain populations, like those of African descent, are more sensitive to blood pressure changes due to dietary salt and more likely to develop hypertension.[35] Regardless of the cause, it is clear that we do not know enough to confidently assert that lowering sodium intake for the general population will have a net positive effect on health.

Research Supports Approaches to Hypertension unrelated to Sodium

While recommendations that some individuals reduce their salt consumption can certainly be one aspect of hypertension control, research indicates that other approaches might be more effective for a wider range of individuals. Emerging evidence indicates that simply increasing a person's potassium intake may be a potent way to combat hypertension (and have other health benefits):

- One 2014 meta-analysis found that high sodium intake was more strongly associated with high blood pressure when potassium intake was lower.[36]
- A 2014 study found sodium consumption was not statistically significant in relation to blood pressure, but did find that greater consumption of fruits and vegetables, which are high in vitamins and nutrients like potassium, was shown to significantly lower blood pressure.[37]

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[31] Ruppert M, Diehl J, Kolloch R, et al. Short-term dietary sodium restriction increases serum lipids and insulin in salt-sensitive and salt-resistant normotensive adults. *Klinische Wochenschrift.* 1991;69 Suppl 25:51-7.http://www.ncbi.nlm.nih.gov/pubmed/1921253

[32] U.Va. Researchers' New Diagnostic Test Can Identify Each Person's Optimal Salt Intake [press release]. UVA Health System. University of Virginia, April 30, 2013 https://news.virginia.edu/content/uva-researchers-new-diagnostic-test-can-identify-each-person-s-optimal-salt-intake. Accessed September 15, 2016.

[33] Helene Lelong, Pilar Galan, Emmanuelle Kesse-Guyot, et al. Relationship between nutrition and blood pressure: a cross-sectional analysis from the NutriNet-Sante study, a French web-based cohort study. *American Journal of Hypertension.* Vol28 (3) p 362-371 http://ajh.oxfordjournals.org.une.idm.oclc.org/content/28/3/362

[34] Felder RA, White MJ, Williams SM, Jose PA. Diagnostic tools for hypertension and salt sensitivity testing. *Current Opinion in Nephrology and Hypertension*. 2013;22(1):65-76. doi: 10.1097/MNH.0b013e32835b3693.

[35] Lackland, DT. Racial Difference in hypertension: implications for high blood pressure management. *American Journal of the Medical Sciences*. 2014;348(2):135-8. doi: 10.1097/MAJ.0000000000000308

[36] O'Donnell et al. Urinary Sodium and Potassium Excretion, Mortality, and Cardiovascular Events. *New England Journal of Medicine*. 2014; 27(9): 1129-37. Doi: 10.1093/ajh/hpu028 http://www.ncbi.nlm.nih.gov/pubmed/24651634

[37] Sodium's influence on blood pressure statistically insignificant: New research in the American journal of hypertension suggests sodium has less pervasive influence on health than once though [news release]. Oxford University Press. September 8, 2014. http://www.eurekalert.org/pub_releases/2014-09/oupu-sio090814.php Accessed September 30, 2016.

- Finally, a 2003 study found that increasing potassium by about 2,000 mg a day—roughly the amount found in two and half cups of cooked spinach—reduced blood pressure almost as much as cutting sodium in half.[38]

For almost as long as researchers have been investigating sodium's role in increased blood pressure, they have observed the connection between higher potassium intake and decreased blood pressure. Subsequently, studies have found that increasing potassium in the diet is effective at lowering blood pressure among the elderly,[39] African Americans,[40] and individuals who are not hypertensive.[41] According to the U.S. Centers for Disease Control and Prevention, 98 percent of Americans suffer from potassium deficiency.[42] Thus, addressing that deficiency presents a viable and possibly more palatable approach to lowering population blood pressure and reducing health risks associated with hypertension.[43] Furthermore, evidence indicates that potassium deficiency may play a role not only in the development of hypertension, but also that of other diseases, like diabetes and metabolic syndrome.[44] So, while sodium restriction may put millions at *increased* risk, an increase in potassium consumption has the potential for beneficial unintended consequences.

Body mass is another strong predictor of hypertension.[45] This is especially important for those of African heritage who are at a higher risk of being overweight, obese, and hypertensive compared with non-Hispanic whites.[46] In fact, studies looking at weight, sodium intake, and blood pressure have found that

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[38] Geleijnse JM, Kok FJ, Grobbee DE. Blood pressure response to changes in sodium and potassium intake: a metaregression analysis of randomised trials. *Journal of Human Hypertension*. 2003;17(7): 471-80. Doi: 10.1038/sj.jhh.1001575.

[39] Smith SR, Klotman PE, Svetkey LP. Potassium chloride lowers blood pressure and causes natriuresis in older patients with hypertension. *Journal of the American Society of Nephrology*. 1992;2(8):1302-9. http://www.ncbi.nlm.nih.gov/pubmed/1627756. Accessed September 23, 2016.

[40] Krishna GG. Effect of potassium intake on blood pressure. *Journal of the American Society of Nephrology.* 1990; 1(1):43-52 http://jasn.asnjournals.org/content/1/1/43.full.pdf+html?sid=50b8d7ad-a7b5-47e0-a7e7-1b1fd8f7e287. Accessed September 23, 2016

[41] Sacks FM, Willett WC, Smith A, Brown LE, Rosner B, Moore TJ. Effect on blood pressure of potassium, calcium and magnesium in women with low habitual intake. *Hypertension.* 1998; 31(1):131-8. doi: http://dx.doi.org/10.1161/01.HYP.31.1.131

[42] Mary E. Cogswel, Zefeng Zhang, Alicia L. Carriquiry, Janelle P. Gunn, Elena V. Kuklina, Sharon H. Saydah, Quanhe Yang, Alanna J. Moshfegh AJ, "Sodium and potassium intakes among US adults: NHANES 2003-2008," *American Journal of Clinical Nutrition* 96 (2012): 647-57. doi: 10.3945/ajcn.112.034413

[43] Cogswell ME, Zhang Z, Carriquiry AL, et al. Sodium and potassium intakes among US adults: NHANES 2003-2008. *American Journal of Clinical Nutrition.* 2012;96(3):647-57. doi: 10.3945/ajcn.112.034413.

[44] Lee H, Lee J, Hwang SS et al. Potassium intake and the prevalence of metabolic syndrome: The Korean National Health and Nutrition Examination Survey 2008–2010. *PLoS One.* 2013;8(1):e55106. doi: 10.1371/journal.pone.0055106.

[45] Shuger SL, Sui X, Church TS, Meriwether RA, Blair SN. Body mass index as a predictor of hypertension incidence among initially healthy normotensive women. *American Journal of Hypertension*. 2008;21(6):613-9. doi: 10.1038/ajh.2008.169

[46] Lackland, DT. Racial Difference in hypertension: implications for high blood pressure management. *American Journal of the Medical Sciences*. 2014;348(2):135-8. doi: 10.1097/MAJ.0000000000000308.

weight loss had a more significant effect on blood pressure over time than did sodium reduction, though a combination of both had the greatest effect.[47]

Conclusion

In a recent *Wall Street Journal* interview, Susan Mayne, director of the FDA's Center for Food Safety and Applied Nutrition, indicated that the FDA has a big "public health mission," and exists to not only to prevent food-borne illnesses and food contamination, but to address chronic illnesses related to diet.[48] If that is the case, then the FDA must consider the entirety of the evidence and the total effect of its actions. We respectfully assert it has not done with regard to its sodium reduction proposal. Nutrition is a multifaceted and rapidly developing science, with plenty of conflict in the literature on most topics.

For a minority of the population, reducing dietary sodium can be an effective means of lowering cardiovascular and hypertension risk. But identifying for whom sodium restriction may be beneficial and by how much is something that individuals and their doctors must determine. For the general population, sodium reduction is, by no means, a silver bullet to reducing hypertension and has the potential to increase risks for a large portion of the population. On the other hand, robust evidence points to effective and, in many respects, more effective methods of hypertension risk reduction. Yet, while health agencies certainly advise people to consume more vitamin-rich fruits and vegetables, the general public is unaware that doing so may be an effective way to lower their blood pressure. This is, in part, due to the myopic sodium-only approach that health agencies have pushed, without success, for nearly 40 years. Rather than perpetuate a demonstrably ineffective policy, we ask that the FDA abandon its sodium reduction targets, focus on protecting the food supply from real threats, and allow health agencies to advise the general public on nutritional issues.

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[47] The trials of hypertension prevention collaborative research group. Effects of weight loss and sodium reduction intervention on blood pressure and hypertension incidence in overweight people with high-normal blood pressure: the trials of hypertension prevention, phase II. *Archives of Internal Medicine.* 1997;157(6):657-667.

[48] The nutrition mission at the FDA: Robert Califf and Susan Mayne say the agency can—and should—give consumers incentives to eat healthier. *The Wall Street Journal.* October 16, 2016. http://www.wsj.com/articles/the-nutrition-mission-at-the-fda-1476670141. Accessed October 15, 2016.