

January 27, 2012

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Docket Clerk
US Department of Agriculture, Food Safety and Inspection Service
FSIS Docket Room
1400 Independence Avenue, SW
Patriots Plaza 3, Mailstop 3782, Room 163A
Washington, DC 20250-3700

Re: U.S. Food and Drug Administration – docket number: FDA-2011-N-0400
U.S. Food Safety & Inspection Service – docket number: FSIS-2011-0014

Dear Ms. Kennard and Mr. Almanza:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments, data, and information on approaches to reducing sodium consumption. ASN represents more than 13,500 physicians, scientists, and other healthcare professionals dedicated to providing high-quality care to kidney patients and to developing cures for kidney diseases. The society appreciates the U.S. Food and Drug Administration (FDA) and U.S. Department of Agriculture Food Safety and Inspection Service's (FSIS) interest in the role of sodium consumption in hypertension and chronic diseases. Hypertension and diabetes are the leading causes of chronic kidney disease (CKD). ASN submits the following comments to the FDA and FSIS for consideration.

In general, ASN believes efforts to reduce sodium consumption, as well as the amount of sodium in processed foods, are commendable and have the potential to benefit patients with kidney disease or who are at risk for kidney disease. Studies have shown significant benefits to reducing sodium in certain subsets of the population, including patients with CKD. For example, in patients with CKD, increased sodium intake associates with future development of end stage renal disease (see Tabs #1-4). Increased sodium intake also appeared to mitigate the beneficial effect of standard therapy with ACE inhibitors, a pharmaceutical drug used primarily for the treatment of hypertension and congestive heart failure. Moreover, patients with glomerular disease are particularly sensitive to salt consumption, as are 60 percent of patients with high blood pressure. Both of these patient populations would likely benefit from reduced sodium consumption, as well as efforts to reduce sodium content in processed foods.

High-sodium processed or manufactured foods are known to contain relatively high amounts of unhealthful nutrients (e.g. saturated fats), lack nutrients considered beneficial (e.g. potassium), and contain preservatives (e.g. phosphates) that are detrimental to patients' health. Consequently, reducing sodium content alone may not necessarily have a substantial

effect on patient outcomes. As such, *ASN supports recommendations that discourage consumption of processed, high sodium foods—foods that commonly contain other unhealthful components—in the diet of persons with or at high risk for kidney disease.*

Because patients with CKD are disproportionately socioeconomically disadvantaged, they are more likely than the average American to live in “food deserts” and be less able to afford healthier, non-processed foods that are low in sodium. The association of sodium consumption on the progression of CKD is well-documented. Moreover, curtailing the amount of sodium in processed foods may have the potential to help ameliorate socioeconomic and racial/ethnic health disparities in kidney disease. Patients with CKD who are racial/ethnic minorities are more likely to live in poorer communities and 1.5 to 4 times more likely to have kidney failure than white CKD patients (see Tab #5).

It should be noted that given the preponderance of sodium in the processed foods that form the basis of many Americans’ diets, it would be extremely challenging to target sodium reduction only in populations where evidence of direct benefit exists. While evidence suggests a correlation between reduced sodium intake and mortality in some populations, to date no randomized clinical trial has demonstrated a direct relationship in the general U.S. population. Currently available evidence suggests, but does not confirm, that reducing sodium in the general patient population would be beneficial. As such, *the society supports the FDA and FSIS’s interest in sodium reduction, but suggests that the agencies gradually roll-out any population-wide initiatives, conduct ongoing research while doing so to identify any unintended consequences (such as excessive sodium reduction), and support randomized clinical trials on the effect of sodium reduction.*

In addition to sodium, alternative additives, such as phosphates or flavoring with potassium chloride, could have serious unintended adverse consequences for patients with CKD. Substantial inferential data exists regarding the relationship between serum phosphate and mortality in patients with kidney disease (see Tab #6). Often, phosphates added to foods such as deli meat and other meat products are not listed on the nutritional value labels, making it difficult for patients to identify their presence. Reducing sodium in processed foods—only to replace it with an alternative preservative such as phosphates—could have serious unintended adverse consequences for patients with CKD. *ASN suggests that FDA and FSIS bear this possibility in mind should the agencies proceed with developing sodium-reduction efforts. The society specifically recommends that FDA and FSIS study the influence of any sodium-reduction initiatives on consumption of other micro- and macronutrients—and the effect on patient outcomes—in various populations on a large public health scale.*

In light of conflicting evidence, ASN also recommends further study of the sodium intake estimate. The “What We Eat in America, National Health and Nutrition Examination Survey (NHANES) 2007-2008,” referenced in the FDA and FSIS Federal Register notice estimates the “average sodium intake from foods among persons in the US aged 2 years or older” at approximately 3,300 milligrams per day (mg/d). ASN suggests that the NHANES figure is likely an underestimate. Other studies indicate that the median daily intake of sodium is higher, including a study that showed an average sodium intake of 4.77 g/d based on an estimation of 24 hour sodium excretion from a spot morning fasting urine (see Tab #7).

Lastly, ASN welcomes the FDA’s continued efforts to establish voluntary guidelines for front-of-package labeling; especially labeling that emphasizes nutrients consumers may want to avoid, such as sodium and calories. However, the society notes that evidence suggests that such labeling does not necessarily correlate with behavior changes (see Tab #8). Lack of nutritional

knowledge may be a barrier to patients seeking to improve their diets, and public education could be an important component of a sodium-reduction campaign—particularly in socioeconomically disadvantaged areas.

Facilitating healthy food choices is a crucial part of a public health strategy to prevent and slow the progression of chronic disease. Based on the currently available evidence, the society supports efforts to reduce sodium consumption in patients with or at risk for kidney disease. ASN appreciates the opportunity to provide the FDA and FSIS these comments and welcomes the opportunity to discuss further if it would be helpful. Please contact ASN Manager of Policy and Government Affairs Rachel Shaffer at (202) 640-4659 with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Ronald J. Falk". The signature is written in a cursive style with a large initial "R" and "F".

Ronald J. Falk, MD, FASN
President