Tufts UNIVERSITY | GERALD J. AND DOROTHY R. FRIEDMAN SCHOOL OF NUTRITION SCIENCE AND POLICY

October 11, 2018

RE: **The Food and Drug Administration's Comprehensive, Multi-Year Nutrition Innovation Strategy; Public Meeting; Request for Comments**
Docket ID. FDA-2018-N-2381

Dear Commissioner Gottlieb:

As one of the leading institutions for nutrition science and policy in the world, the Friedman School's mission is to produce trusted science, future leaders, and real-world impact. The undersigned faculty, experts in the field of nutrition science and policy, are pleased to provide these suggestions for the FDA's Nutrition Innovation Strategy (NIS).

We recommend that the FDA, as part of its NIS, should:

1. **Add limitations on conditions of use to particular foods to address a current lack of limitations on salt's status as a "generally recognized as safe," or GRAS.**
    - Nearly nine out of ten Americans consume more sodium than what's recommended in the Dietary Guidelines for Americans.[i] Over seventy percent of that sodium comes from restaurant and packaged foods.[ii] There is a global scientific consensus that excess sodium intake contributes to high blood pressure, and leads to death from stroke and heart attack. Scientists agree that lowering sodium intake lowers blood pressure, and American sodium consumption is not near the hypothesized "threshold" below which risk for stroke or heart attack would plateau.[iii] Therefore, sodium is not "generally recognized as safe…under the [current] conditions of its intended use" and should be subject to specific limitations on conditions of use that contribute to excessive sodium consumption within the diet (including soups, breads, and other categories of food that contribute to excessive sodium intake) within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act. The goal of these conditions of use limitations would be to reduce sodium intake from 3600mg per day to 2400 mg per day – about half a teaspoon of salt – which would save 44,000-92,000 lives and $10 billion - $24 billion in health-care costs annually.[iv]
2. **Institute front-of-pack labeling that makes it easier for consumers to eat according to the Dietary Guidelines.**
    - Historically, the FDA has studied and recommended front-of-pack labeling schemes that rely upon the percent Daily Values of nutrients and the Nutrition Facts Panel as the primary means of judging the healthfulness of food products. However, while most front-of-pack labeling schemes advertise nutrients, daily value percentages, and rankings, Americans are simultaneously being encouraged, in the government's nutrition education programs, to eat according to the Dietary

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Guidelines, which emphasize dietary patterns rather than nutrients (focus on whole fruits, vary your veggies, make half your grains whole grains, etc.). As part of its NIS, the FDA should develop and study front-of-pack labeling that makes it easier for consumers to look at the front of a food product, quickly understand its contents, and determine how it aligns with the Dietary Guidelines.

- Any new front-of-pack labeling scheme should preempt potentially misleading and conflicting industry sponsored information that may not be in the best interest of consumer health. Furthermore, any recommendations should consider the Institute of Medicine's comprehensive, two-stage report on front-of-pack labeling. Priority information to consider for a front-of-package label could include the top three ingredients, the calorie count, type and number of additional ingredients, the carbohydrate to fiber ratio, the polyunsaturated fat to saturated fat ratio, and the sodium level.

3. **Review whether products made to meet the current definition of 'whole grain' are delivering the purported health benefits, specifically those products made with reconstituted wheat flour.**
    - We recommend the FDA evaluate the definition of "whole grain" products with the goal of eliminating consumer confusion and ensuring Americans are reaping nutritional benefits from foods marketed as whole grain products. According to current FDA guidance, any food labeled whole grain must contain the main components of the grain – germ, bran, and endosperm – in approximately the same proportion as an intact grain. However, still unclear are the relative health effects of eating various combinations of reconstituted grain types versus eating grains that include the original proportions of germ, bran, and endosperm or, more importantly, the health effects of some minimally processed grains. We encourage the FDA to investigate the health effects of – e.g., the effects on metabolic parameters, body composition, brain chemistry, GI tract, gut hormones, and microbiome – and improve the whole grain definition based on its findings.
    - Any new definition of whole grain should be evaluated for its effects on consumer behavior.
4. **Update ingredient lists on food packages for readability and ease of consumer understanding.**
    - Consumers are increasingly looking to ingredient labels to determine the healthfulness of packaged foods. However, while the Nutrition Facts Panel has received several updates over the years, the ingredient label is virtually unchanged from its origin seventy years ago. We recommend grouping or aggregating similar ingredients (like added sugars) into a single list and disclosing the percentage contribution of each ingredient or aggregated ingredient to the total weight (or calories) of the product. Additional updates include bringing the ingredient label regulations into alignment with the requirements set forth by the Nutrition Facts Panel – ingredients should use a single, easy-to read type style, use upper and lower-case letters, letters should never touch, required information should be in at least 8-point type, etc.
5. **Streamline the process for authorized health claims and qualified health claims and establish a process for regularly scheduled review and renewal of health claims, considering both nutrients and foods of public health concern.**

- We applaud the FDA's stated agenda to improve the efficiency of the health claims review process. We encourage the agency to prioritize the most meaningful and evidence-based health claims for categories for which the American diet typically falls short of recommendations, including both nutrients and food types as recommended to be consumed in the Dietary Guidelines for Americans. In addition to streamlining the review process, we strongly recommend the FDA establish a practice for re-reviewing health claims once they are approved, to ensure the claims keep pace with forthcoming discoveries in nutrition science, which is a relatively young and rapidly growing field of research.

6. **Review and update the Nutrition Facts Panel based on modernized nutrients of public health significance.**
    - We acknowledge that the Nutrition Facts Panel recently underwent a redesign, which is still in the midst of implementation. However, the fundamental nutrition recommendations underlying the panel remain vastly out of date. The Daily Values (DVs) declared on the Nutrition Facts Panel are formulated based on Recommendation Dietary Allowances (RDAs) which have not been updated since 1968. The Institute of Medicine should update the RDAs, the DVs should be recalculated, and the FDA should update the Nutrition Facts Panel in-kind. This process should be undertaken on a regular basis, to allow for new advancements in nutrition science, at least every ten years. Furthermore, any Nutrition Facts Panel update should include consumer testing to determine how the redesign is interpreted by consumers and how it affects consumer behavior.
7. **Request additional resources for nutrition and establish an external advisory committee to support specific Nutrition Innovation Strategy projects.**
    - We recognize that our aforementioned recommendations are not insignificant in the time and energy required for their implementation. For this reason, we support an increase in the FDA's budget for nutrition. Even with a budget increase, these projects will be difficult to undertake without the requisite nutritional expertise; therefore, we also recommend the FDA establish an external advisory committee, composed of scientists and nutrition experts. This committee would support and advise the Nutrition Innovation Strategy work and oversee specific projects such as front-of-pack labeling, ingredient labeling, whole grain definition, etc.

Thank you for the opportunity to provide comments on the proposed topics for the Nutrition Innovation Strategy. This initiative could not come at a more critical time for public health and we strongly encourage the Agency to pursue our recommendations to better serve Americans with more robust, evidence-based, and meaningful nutrition guidance.

Sincerely,

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These comments represent the recommendations of individual Tufts faculty members, compiled with staff support. The opinions expressed in this document do not necessarily represent the views or opinions of the Friedman School of Nutrition Science and Policy, Tufts University, or its affiliates.

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[i] Centers for Disease Control and Prevention, Prevalence of Excess Sodium Intake in the United States – NHANES, 2009-2012. January 8, 2016; 64(52);1393-7.
[ii] Harnack, Lisa, et al., Sources of Sodium in US Adults from 3 Geographic Regions. *Circulation*. 2017;135:1775-1783.
[iii] Prospective Studies Collaboration. Age-specific relevance of usual blood pressure to vascular mortality: a meta-analysis of individual data for one million adults in 61 prospective studies. Lancet. 2002; 360:1903–13.
[iv] Bibbins-Domingo, et al., Projected effect of dietary salt reductions on future cardiovascular disease. *New England Journal of Medicine*. 2010;362(7),590-599.