Tufts UNIVERSITY | Gerald J. and Dorothy R. Friedman School of Nutrition Science and Policy

February 16, 2023

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2016-D-2335, Proposed Rule on Food Labeling: Nutrient Content Claims; Definition of Term "Healthy"

Dear Food and Drug Administration:

As leading nutrition scientists and health professionals with substantial expertise in diets, health, and nutrition communication and translation, we are pleased that the Food and Drug Administration (FDA) has published a proposed rule to update the definition for the implied nutrient content claim, "healthy," with the goals of accurately representing the levels of nutrients in food that may help consumers maintain healthy dietary practices and being consistent with current nutrition science and Federal dietary guidance, especially the *Dietary Guidelines for Americans, 2020-2025 (DGA)*. Suboptimal diet is a leading cause of poor health in the United States and also contributes to health and economic inequity, preventable health care spending, and adverse effects on worker productivity and military readiness. These are compelling reasons for making it a major federal priority to improve the healthfulness of the food supply and help consumers make informed, healthful dietary choices.

Overall, it is our conclusion that the proposed rule represents a tremendous advance over the previous, outdated standards for use of the term "healthy" in food labeling. We applaud the FDA for issuing this proposed, much improved rule.

Two particular strengths of the new rule that we support are the:

Food-based focus. We applaud the framework's use of a sensible, evidence-based food group-based approach, in line with DGA recommendations, as its core foundation.

Omission of minimum nutrients. We support FDA's proposal to no longer include minimum amounts of nutrients to encourage as part of the "healthy" criteria. We share the Agency's stated concern that including criteria for nutrients to encourage could spur fortification efforts for the sole purpose of increasing food product eligibility to bear the "healthy claim" and increase sales, without actually improving healthfulness of products or the health of Americans.

In addition to this support, we offer five important recommendations for improvement to the proposed rule, based on current scientific evidence as well as some inconsistencies between the proposed rule and the DGA recommendations.

150 Harrison Avenue | Boston, MA 02111 | TEL: 617.636.0374 | TWITTER: @DMozaffarian | EMAIL: dariush.mozaffarian@tufts.edu

Our five major recommendations are as follows:

1. Calculation of Food Group Equivalents

We support the proposed method to calculate the food group equivalents by dividing the recommended daily food group amount (based on a 2,000 calorie diet and the "Healthy U.S.-Style Dietary Pattern as described in Table A3-2 of the DGA) by four eating occasions. There appear to be relevant inconsistencies, however, in how this was executed in the proposed rule. Specifically, Table A3-2 recommends 5 oz equivalent of nuts and seeds per week based on a 2,000-calorie diet. However, the proposed rule states that the food group equivalent for nuts and seeds would be a 1 oz equivalent per daily eating occasion (i.e., 4 oz per day), or 28 oz equivalents per week, which greatly exceeds the 5 oz equivalent per week recommended by the DGA. To be consistent with the Table A3-2 of the DGA and the Agency's proposed calculation of baseline amounts for other food group equivalent requirements, the food group equivalent for nuts and seeds would be ~0.18 oz (5 oz equivalents per week / 28 eating occasions per week). We appreciate that recommending such a small amount may not be feasible in practice. Thus, the FDA could instead change the equivalent amount to be ½ oz, rather than 1 oz, equivalent for nuts and seeds. The scientific evidence for health benefits of nuts is strong, and at a serving level even stronger than for other food groups like fruits and vegetables for which the minimum equivalent amounts for the healthy definition are proposed at less than 1 serving equivalent. Thus, to maintain consistency with the scientific evidence and DGA recommendations as much as possible when calculating the food group equivalents, and to support healthy products in the food supply, the minimum food group equivalent for nuts and seeds should be ½ oz equivalent per RACC.

2. Nutrient to Limit - Saturated Fat

We are pleased to see the removal of total fat in the list of nutrients to limit, consistent with the scientific evidence, recent Dietary Guidelines Advisory Committee (DGAC) reports, and the DGAs. As an alternative and/or an addition to FDA's proposal to focus solely on a threshold saturated fat limit, we recommend using a measure of overall fat quality, such as the ratio of saturated fat to unsaturated fat. This criterion of fat quality is more consistent with the scientific evidence and can be consistent across food groups that naturally or are reasonably expected to contain a minimum amount of fat. The Women's Health Initiative randomized clinical trial demonstrated that reducing saturated fat, in the context of reducing total fat, did not improve any major health outcomes.[i] In contrast, the PREDIMED randomized clinical trial demonstrated that increasing the abundance of unsaturated fats, relative to total fat or saturated fat, significantly reduced cardiovascular disease events and diabetes.[ii] The DGAs specifically state that "the best strategy is not just to limit saturated fats — it's also to replace them with healthier unsaturated fats."[iii] Prior DGAC reports have also concluded that there is "consistent evidence from prospective cohort studies that higher SFA intake as compared to total carbohydrates is not associated with CVD risk (DGAC Grade: Strong)."[iv] Thus, focusing on SFA alone does not achieve the DGA goals of optimizing fat quality and replacing saturated fat with unsaturated fats, and also penalizes foods that may be higher in saturated fat but also contain high amounts of unsaturated fats. For example, a product that contains 1 g of saturated fat will have very different effects on health if it also contains 0 g of unsaturated fat, or 5 g of unsaturated fat. A ratio approach operationalizes these DGAC conclusions and DGA recommendations. Recent published science supports the strong value of ratios for predicting better health in a national sample of Americans, including the ratio of saturated to unsaturated fat, carbohydrate to fiber, and sodium to potassium.[v] Specifically, assessment of individuals' diets based on these three factors alone was significantly associated with major health risk factors, prevalent health conditions, and all-cause mortality. An appropriate ratio threshold could be selected based on the DGA recommended intake of saturated fat (<10%) vs. the current DRI for total fat (<35% energy), or a saturated fat to total fat ratio of <1:3.5 for food or beverage groups that naturally or are reasonably

expected to contain a minimum amount of fat. Thus, a revised criterion for saturated fat could have different thresholds for saturated fat content depending on whether or not the product also had a favorable ratio of saturated fat to total fat. For example, a revised criterion could be <1 g of saturated fat per RACC *or* a saturated fat to total fat ratio of <1:3.5. Based on our analysis of products consumed by Americans in the National Health and Nutrition Examination Survey (NHANES), examples of food products that would not meet the current proposed FDA saturated fat criterion but would meet this revised criterion include soybeans, cooked; edamame, cooked; Peruvian beans, from dried; chickpeas, NFS; chickpeas, from dried, fat added; potato, boiled, from fresh, peel eaten, NS as to fat; potato, canned, fat added, NS as to fat type; sweet potato fries, from fresh, baked; crackers, wheat, reduced sodium; and bread, puri, wheat.

3. Nutrients to Limit - Sodium

We agree with the inclusion of sodium in the list of nutrients to limit. In contrast to FDA's proposal to focus solely on a baseline sodium limit, we recommend the FDA evaluate the possibility of further incorporating the ratio of sodium to potassium as an alternative criterion that would apply to products that exceed FDA's proposed threshold of 230 mg sodium per RACC. Well-established science demonstrates that these two nutrients biologically interact with each other and that their ratio is more predictive of both blood pressure and clinical risk of cardiovascular events than intake of either alone.[vi] [vii] [viii] Similar to the aforementioned recommendation regarding fat quality, evaluating "mineral quality" is relevant for understanding the positive health impacts of offsetting sodium with potassium intake. For example, a product that contains 200 mg of sodium will have very different effects on blood pressure and cardiovascular risk if it also contains 20 mg of potassium, or 400 mg of potassium. An appropriate ratio threshold consistent with federal guidelines could be selected based on the DRI recommended CDRR for sodium (<2300 mg/day for adults) and AI for potassium (3000 mg/day average for men and women), i.e., a ratio of sodium to potassium <2.3/3.0 (<0.77) for food or beverage groups that naturally or are reasonably expected to contain a minimum amount of sodium. Thus, a revised criterion for sodium could have different thresholds for sodium content depending on whether or not the product also had a favorable ratio of sodium to potassium. For example, a revised criterion could be <230 mg of sodium per RACC *or* a ratio of sodium to potassium <0.77. Based on our analysis of products consumed by Americans in NHANES, examples of food products that would not meet FDA's proposed sodium criterion, but would meet this revised criterion include tuna, fresh, baked or broiled, no added fat; sweet potato, canned, no added fat; sweet potato, baked, peel not eaten, made with margarine; potato, canned, no added fat; white beans, from canned, no added fat; black beans, from canned, no added fat; pinto beans, from canned, no added fat; and kidney beans, from canned, no added fat.

4. Nutrients to Limit - Added Sugars

We are pleased to see the inclusion of added sugars in the list of nutrients to limit. However, the threshold limit should be consistent across all food groups. For example, the evidence for healthfulness of fruits, vegetables, beans, nuts, and seeds is at least as strong as the evidence for healthfulness of whole grains or dairy. Yet, the proposed rule allows some added sugar for the latter food groups, but none for the former food groups. This position is not consistent with the science. Why would nuts sweetened with a bit of honey be excluded, but whole grain bread or milk sweetened with sugar be allowed? We appreciate and agree that the "healthy" claim should not be constructed in a fashion to encourage addition of added sugars to any products. However, different healthy food groups should be treated similarly and consistently based on the science, rather than based on expectations on use of added sugar that is "typical or expected" in the current food environment. Regardless of what threshold level the FDA selects, the FDA should consider setting the limit for added sugar at the same percentage energy value for all food groups and subgroups. This more consistent approach would also allow

consumers more ability to distinguish between those products within a category with only low amounts of added sugars and those with higher levels of added sugars. Based on our analysis of products consumed by Americans in NHANES, examples of food products that would meet a consistent added sugar criterion of <=2.5 g per RACC but would not be allowed under FDA's current proposal include fruit smoothie, with whole fruit, non-dairy; fruit and vegetable smoothie, non-dairy; fruit and vegetable smoothie, non-dairy, added protein; sunflower seeds, flavored; almond butter; cashew butter; and peanut butter. Examples of additional foods that would meet a consistent criterion of <=5 g per RACC but would not be allowed under the current proposed FDA criterion are mixed nuts, honey roasted; peanuts, honey roasted; trail mix with nuts and fruit; bread, multigrain; and bread, multigrain, with raisins.

5. Regularly Update Criteria Based on Evolving Nutrition Science

To ensure the FDA criteria for "healthy" continue to align with current nutrition science and Federal dietary guidance, we strongly urge the FDA to update the rule requirements in a timely manner. For example, the requirements should continue to be realigned with the DGA recommendations on a recurring basis (every five years).

In addition to the major recommendations above, other suggestions are as follows:

Individual Food Groups - Grain Products

The proposed algorithm based on whole grain content and added sugar content has merits. We recommend the FDA evaluate the possibility of further incorporating an additional, evidence-based criterion for carbohydrate quality, that should be evaluated in parallel. Research has shown that use of a ≤ 10:1 ratio of total carbohydrate to fiber (i.e., the presence per 10 g of carbohydrate of at least 1 g of fiber) is superior to other common metrics for identifying more healthful grain-rich foods, as it provides an overall measure of the content of whole grains, bran, and other sources of fiber (e.g., added seeds or fruit) relative to the content refined grains, starch, and sugar.[ix] In prior research, grain foods meeting the 10:1-ratio had less available carbohydrate, total sugar, added sugar, and saturated fat, and more dietary fiber and protein, among other nutrients.[x] This metric for identifying healthier grain products has been used by the American Heart Association for setting and evaluating its 2020 Strategic Impact Goals for a healthy diet.[xi] While federal guidance on the ratio of carbohydrates to fiber does not currently exist, we have recently recommended, in comments submitted during the 2020 DGA development cycle, that the DGAC evaluate how the carbohydrate to fiber ratio in food products and the overall diet influence major health outcomes. We recommend that, as part of implementation of the proposed rule, the FDA jointly evaluate the carbohydrate to fiber ratio of products meeting or not meeting the healthy criterion and use this information for potential future updates to the "healthy" rule. Thus, the FDA should evaluate a revised criterion for whole grain foods that incorporates the additional criterion of meeting a ≤ 10:1 ratio of total carbohydrate to fiber.

Individual Food Groups - Dairy Products

We appreciate that the criteria for dairy in the proposed rule were outlined to largely align with the 2020-2025 DGA recommendations. At the same time, we wish to highlight that a growing body of research from randomized trials, long-term prospective studies of self-reported dietary intake, and long-term prospective studies of circulating blood biomarkers suggests little evidence for meaningful differences in health outcomes for consuming reduced-fat vs. whole-fat dairy foods.[xii xiii xiv xv xvi xvii xviii xix] We are aware that the 2025-2030 Dietary Guidelines process is underway and hope that the scientific advisory committee will evaluate the separate relationships of distinct subtypes of dairy products

(including low-fat and whole-fat versions of milk, yogurts, and cheese) with major health outcomes through the following proposed scientific questions:

1) What is the relationship between beverage consumption (beverage patterns, dairy milk and milk alternatives, 100% juice, low- or no-calorie sweetened beverages, sugar-sweetened beverages, coffee, tea, water) and:
    a) growth, size, body composition, risk of overweight and obesity, and weight loss and maintenance?
    b) risk of type 2 diabetes?
2) What is the relationship between food sources of saturated fat consumed and risk of cardiovascular disease?

We recommend that the FDA follow this scientific review and consider timely updates to its "healthy" rule based on the findings and conclusions of the DGAC as well as additional published science.

Individual Food Groups - Fruit Products

We agree with the Agency's tentative decision to not consider fruit powders to be fruits for the purpose of calculating food group equivalents. We agree with FDA's rationale that "These products could be produced or used in a way that modifies the whole fruit to an extent that removes some essential characteristics that are beneficial when consuming the whole fruit, which could impact nutrient content." We are concerned that permitting fruit powders to quality as food group equivalents for the fruit group could lead to fortifying food products with fruit powders for the sole reason of qualifying for the "healthy" claim. Furthermore, we believe that "healthy" should be reserved for products composed predominantly of whole, intact foods.

In closing, we reiterate our overall support for FDA's decision and proposed rule to update the definition for the implied nutrient content claim, "healthy," to be consistent with current nutrition science and federal dietary guidance. As leading nutrition scientists and health professionals, we offer suggestions and recommendations for FDA to consider to further optimize these efforts to best align with current nutrition science. We emphasize our willingness to provide our efforts and expertise to work further with FDA in its quest to update and harmonize policies and rules related to diet and health. Several of us have served on major committees whose missions were to weigh scientific evidence in order to establish national and international nutrition policy guidelines. We would be glad to further share our experience and knowledge in this arena.

We thank FDA for the opportunity to submit this comment for consideration as it continues to refine the "healthy" criteria based on public comments.

Sincerely,

Dariush Mozaffarian, MD, DrPH
Special Advisor to the Provost, Dean for Policy
Jean Mayer Professor of Nutrition and Medicine

Sean B. Cash, Ph.D.
Bergstrom Foundation Professor in Global Nutrition
Doctoral and Postdoctoral Officer
Associate Professor, Friedman School of Nutrition Science and Policy

Timothy Griffin, PhD, Associate Professor
Teri and Barry Volpert Family Professorship in Nutrition, Agriculture and Sustainable Food Systems
Dean of Educational Affairs – *ad interim* – Jaharis 269G
Division Chair – Agriculture Food and Environment
Friedman School of Nutrition Science and Policy

Ronit Ridberg, PhD MS
Research Assistant Professor
Friedman School of Nutrition Science & Policy

Patrick Webb, Ph.D.
Alexander MacFarlane Professor
Friedman School of Nutrition Science and Policy

Fang Fang Zhang, MD, PhD
Associate Professor
Friedman School of Nutrition Science & Policy

These comments represent the recommendations of individual Tufts faculty members. 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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