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

Re: Docket No. FDA-2023-N-0155, [Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Quantitative Research on Front of Package Labeling on Packaged Foods](#)

Dear Food and Drug Administration:

As leading scientists, health professionals, and consumer behavior experts with unique expertise in nutrition, consumer communication and behavior, food labeling research, health and nutrition policy, and policy translation, we submit this letter in response to the Food and Drug Administration's Agency Information Collection on Quantitative Research on Front of Package Labeling on Packaged Foods. We applaud the FDA for its continued efforts to prioritize activities to help empower consumers with nutrition information to make healthier choices more easily and to encourage industry innovation by providing flexibility to facilitate production of healthier foods.

In March 2023, four signatories of this letter submitted a [comment](#) to Docket No. FDA-2023-N-0155, "Agency Information Collection Activities; Proposed Collection; Comment Request; Quantitative Research on Front of Package Labeling on Packaged Foods." In that comment, we encouraged FDA to consider "not only assessing the trustworthiness of the logo but also investigating measures of respondents' trust in both government institutions and the food industry." We are pleased that our recommendation was considered, and FDA has now included measures of trustworthiness of the schemes to be considered along with the other outcome measures.

In addition, we share the following concern and subsequent recommendation regarding the proposed experimental study to further explore consumer responses to various front-of-pack (FOP) schemes.

Concern - We do not support FDA's approach to test only the specific listed nutrient-based criteria in a prospective FOP label (i.e., saturated fat, added sugar, sodium, and total calories). We strongly recommend that FDA not proceed with testing of labels using these nutrient-based criteria alone.

Focusing solely on these nutrient-based targets for this FOP research is a return to the now-outdated approaches used in the definition of "healthy" established by FDA in 1993. In response to a petition noting that these nutrient-targets are outdated and do not define a healthy diet or healthy foods, the FDA acknowledged their limitations, leading to FDA's much improved new proposed rule on defining "healthy." These nutrients in the proposed FOP research are inconsistent with FDA's current approach to food labeling as set forth in its proposed rule, ["Food Labeling: Nutrient Content Claims; Definition of Term "Healthy,"](#) which states that in order to be labeled with the "healthy" claim on food packaging, a product needs to not only adhere to specific limits for certain nutrients, but also contain a certain

meaningful amount of food from at least one of the food groups or subgroups recommended by the *Dietary Guidelines for Americans*. Several faculty members from the Friedman School of Nutrition Science and Policy at Tufts University submitted a [comment](#) in February 2023 to Docket No. FDA-2016-D-2335, [Proposed Rule on Food Labeling: Nutrient Content Claims; Definition of Term “Healthy”](#) and concluded “that the proposed rule represents a tremendous advance over the previous, outdated standards for use of the term ‘healthy’ in food labeling.”

We believe that returning to the outdated approach of sole use of these nutrient-based criteria for the FOP labels under consideration would not meet these labels’ stated goals of empowering consumers with nutrition information to more easily make healthier choices and to facilitate industry’s production of healthier foods and could lead to likely harms for the public. In particular, a focus on calories - which are not a predictor of the health effects of a food product, including for weight gain¹ - will likely lead to industry reformulation that reduces healthy fats and protein, as seen with the industry response to calorie menu labeling.² Consumers will mistakenly believe that a product with lower calories is healthier than another, when there is no evidence that calorie content per se relates to health outcomes.

A focus on saturated fat, without specifying replacement with polyunsaturated fat, is based on a 21 year-old Dietary Reference Intake (DRI) and is inconsistent with the evidence-based conclusions of the 2020 USDA Dietary Guidelines Advisory Committee (DGAC) systematic reviews,³ which concluded that:

- Strong evidence demonstrates that replacing saturated fatty acids with polyunsaturated fatty acids in adults reduces the risk of coronary heart disease events and cardiovascular disease mortality. (Grade: Strong)
- Insufficient evidence is available to determine whether replacing saturated fatty acids with different types of carbohydrates (e.g., complex, simple) in adults affects the risk of cardiovascular disease. (Grade: Grade not assignable)
- Limited evidence is available regarding whether replacing saturated fatty acids with monounsaturated fatty acids in adults confers overall cardiovascular disease endpoint health benefits. (Grade: Limited)

Consequently, a focus on saturated fat reduction, without specifying the replacement nutrient of polyunsaturated fat, is inconsistent with this consensus science. Several faculty members from the Friedman School of Nutrition Science and Policy at Tufts University have previously recommended in a [comment](#) submitted in February 2023 to Docket No. FDA-2016-D-2335, [Proposed Rule on Food Labeling: Nutrient Content Claims; Definition of Term “Healthy”](#) that the ratio of saturated to polyunsaturated fat can be utilized, in place of the outdated, non-consensus based focus on saturated fat alone. That recommendation is also valid here. It is highly appropriate and timely as part of this important FDA research effort on FOP labeling on packaged foods to test evidence-based metrics like the ratio of saturated to polyunsaturated fat in the planned studies of consumer understanding and influence.

¹ Mozaffarian D, Hao T, Rimm EB, Willett WC, Hu FB. Changes in diet and lifestyle and long-term weight gain in women and men. *N Engl J Med*. 2011;364(25):2392-2404. doi:10.1056/NEJMoa1014296

² Grummon AH, Petimar J, Soto MJ, et al. Changes in calorie content of menu items at large chain restaurants after implementation of calorie labels. *JAMA Netw Open*. 2021;4(12):e2141353. doi:10.1001/jamanetworkopen.2021.41353

³ Sneltselaar L, Bailey R, Sabaté J, Van Horn L, Schneeman B, Bahnfleth C, Kim JH, Spahn J, Butera G, Terry N, Obbagy J. Types of Dietary Fat and Cardiovascular Disease: A Systematic Review. July 2020. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://doi.org/10.52570/NESR.DGAC2020.SR0501>

In addition, the USDA and HHS have recognized the uncertainties and controversies around use of total saturated fat content as a metric to help define healthy foods and products in the [proposed scientific questions](#) to the 2025 DGAC. Recognizing the lack of scientific consensus, the proposed scientific questions include an assessment of the heterogeneity between different food sources of saturated fat consumed and relevant health outcomes. The lack of scientific consensus is clearly demonstrated by the broad range of reputable, expert scientists who disagree with the utility and evidence for focusing on total saturated fat.^{4 5 6 7 8 9}

In sum, a focus on total saturated fat in FOP labeling is inconsistent with the results of the USDA Nutrition Evidence Systematic Reviews, with the DGAC conclusions on the evidence around health effects of total saturated fat, the USDA and HHS recognition of the potential heterogeneity between different food sources of saturated fat and relevant health outcomes, and with the tremendous scientific controversy and uncertainty around total saturated fat. The FDA research and other efforts around FOP labeling should focus on evidence-based, consensus-derived, and noncontroversial metrics. Total saturated fat does not meet these criteria.

A focus on added sugar and sodium is more reasonably evidence-based than total calories or saturated fat. However, these two metrics alone cannot help consumers identify healthier foods. There are many food products with zero added sugars that are unhealthy, and many with higher added sugars that are healthy. Similarly, knowing the sodium content of a product is helpful, but not sufficient to make healthier choices without knowing the potassium content and, more importantly, the contents of healthful food-based ingredients.

A critical need exists to inform consumers about the contents of healthful food-based ingredients. In contrast to the nutrients discussed above, and as recognized by the FDA proposed rule on “healthy,” the most important, consensus-based, noncontroversial way to help identify healthier food products is through healthful, food-based ingredients. These include the contents of fruits, vegetables, whole grains, nuts, and other components included in the FDA proposed rule on “healthy.” Today, consumers are terribly confused about which food products contain or do not contain these ingredients, and how much of each ingredient they may contain. While the current Nutrition Facts panel already includes clear information on contents of total calories, saturated fat, added sugar, and sodium (making the addition of these to FOP labeling highly redundant), there is currently no required information in Nutrition Facts or the ingredients list on contents of fruits, vegetables, whole grains, nuts, and other healthful food components included in the FDA proposed rule on “healthy.” Industry readily

⁴ Astrup A, Magkos F, Bier DM, et al. Saturated Fats and Health: A reassessment and proposal for food-based recommendations: JACC State-of-the-Art Review. *J Am Coll Cardiol.* 2020;76(7):844-857. doi:10.1016/j.jacc.2020.05.077

⁵ Astrup A, Bertram HC, Bonjour JP, et al. WHO draft guidelines on dietary saturated and trans fatty acids: Time for a new approach? *BMJ.* 2019;366:l4137. doi:10.1136/bmj.l4137

⁶ Hirahatake KM, Astrup A, Hill JO, Slavin JL, Allison DB, Maki KC. Potential cardiometabolic health benefits of full-fat dairy: The evidence base. *Adv Nutr.* 2020;11(3):533-547. doi:10.1093/advances/nmz132

⁷ Wu JHY, Micha R, Mozaffarian D. Dietary fats and cardiometabolic disease: Mechanisms and effects on risk factors and outcomes. *Nat Rev Cardiol.* 2019;16(10):581-601. doi:10.1038/s41569-019-0206-1

⁸ Imamura F, Fretts A, Marklund M, et al. Fatty acid biomarkers of dairy fat consumption and incidence of type 2 diabetes: A pooled analysis of prospective cohort studies. *PLoS Med.* 2018;15(10):e1002670. doi:10.1371/journal.pmed.1002670

⁹ Imamura F, Micha R, Wu JH, et al. Effects of saturated fat, polyunsaturated fat, monounsaturated fat, and carbohydrate on glucose-insulin homeostasis: A systematic review and meta-analysis of randomised controlled feeding trials. *PLoS Med.* 2016;13(7):e1002087. doi:10.1371/journal.pmed.1002087

manipulates this information gap, e.g., by using misleading product names or images of fruits or vegetables on products with very little content of these ingredients; or misleading marketing terms like “multigrain” on products containing little or no whole grains.¹⁰

The lack of any required information on the contents of these healthful food-based ingredients, combined with the frequent use of misleading product names, images, and marketing terms implying the inclusion of these food-based ingredients, creates major challenges for consumers to identify and choose more healthful food products. The FDA proposed rule on “healthy” is a step in the right direction but will only address a small part of these challenges. First, by our and other calculations, fewer than 3-5% of U.S. products will qualify to meet the FDA proposed “healthy” definition. Even for those products meeting the definition, consumers will not know which food-based ingredients are present, or how much of each, that led to the qualification. And, for the vast majority of U.S. products that do not meet the definition, there will remain no readily visible information for consumers to understand and identify which healthful food ingredients, if any, are present in the products; and how much of each of these food ingredients. For example, products that contain some of these healthful food ingredients, but not enough to qualify for the “healthy” definition, will not be recognized by consumers; while products that contain very little or none of these healthful food ingredients can continue to be misleadingly marketed.

In addition to providing critically important information to consumers, the inclusion of objective, quantitative contents of key healthful food ingredients on a FOP label - for example, serving-equivalents of fruits, vegetables (including legumes), whole grains, and nuts, potentially with other food categories included in the proposed FDA “healthy” definition rule - would incentivize positive industry reformulation. For many products, meeting the relatively strict criteria for “healthy” will be challenging, and when a binary “yes/no” target like that cannot be met, there is little motivation for industry to make incremental change. In contrast, with a quantitative FOP label that lists the actual contents of these healthful food-based ingredients, any increase would result in a positive labeling change, incentivizing industry to make stepwise progress as practical for each product.

A critical need exists for consistency across different government nutrition messaging. Numerous studies of U.S. consumers demonstrate substantial confusion around identifying and choosing healthier food products. One of the contributors to this confusion is the seemingly inconsistent and heterogeneous government messaging around nutrition. For example, the DGAs have strongly shifted toward food-based dietary guidelines. At the same time, the Nutrition Facts panel and DRIs remain focused on isolated nutrients. Calorie menu labeling focuses only on a single metric: the energy contained in a food. The previous FDA standards for “healthy” focused on selected isolated nutrients like total fat, saturated fat, and others. School meal standards focus on a combination of food-based guidelines and a few key nutrients.

The more consistency that can be achieved across these different sources of messaging for U.S. consumers, the better. FDA can play a key leadership role to help achieve this. The clear direction of scientific consensus is toward healthful, food-based dietary patterns. This is evident in the DGAs, the Healthy Hunger-Free Kids Act, and the FDA’s proposed definition of “healthy.” Instead of a backwards-looking, non-consensus-based focus on calories, saturated fat, added sugar, and sodium that is also

¹⁰ Wilde P, Pomeranz JL, Lizewski LJ, Zhang FF. Consumer confusion about wholegrain content and healthfulness in product labels: A discrete choice experiment and comprehension assessment. *Public Health Nutr.* 2020;23(18):3324-3331. doi:10.1017/S1368980020001688

inconsistent with these other government messages, the FDA research on FOP labeling should move toward a consistent, evidence-based, consensus focus on healthful food-based ingredients.

Recommendation - We recommend the use and testing of a FOP label that quantifies the types and amounts of healthful food groups in the product. The absence of healthful food groups in U.S. diets is associated with much of the diet-related disease burden in our country.¹¹ Therefore, we recommend that the FOP label show a product's content of the food groups/subgroups referenced in FDA's September 2022 proposed definition of "healthy" (e.g., fruits, vegetables, nuts, etc.). This approach would also align with the current DGA and its food group-based recommendations, upon which the proposed "healthy" definition is founded. A food-group based approach would also support FDA in its efforts to proceed with a harmonized set of criteria and definitions to be used in consumer nutrition efforts and communications. The use of widely varying criteria and definitions by government entities would be both confusing to consumers and make food industry compliance more difficult. By standardizing labels to provide food group/subgroup amounts, consumers will be empowered to identify deceitful marketing practices (e.g., products called "multigrain" or claiming to be "made with real fruit" despite containing no whole grains nor meaningful proportion of fruit, respectively) and more easily make healthier choices. Such labeling requirements would also be a compelling incentive for industry to reformulate and/or develop new products to contain meaningful amounts of these food groups, instead of simply reformulating products to meet a few nutrient-based targets. The use of nutrient-based FOP metrics will also have the unintended consequence of many products (e.g., highly processed products rich in refined grains) to score positively for contents of saturated fat, sodium, added sugars, and even sodium, while containing no meaningful amount of any food from at least one of the food groups or subgroups recommended by the DGAs. The use of nutrient-based FOP metrics will likewise have the unintended consequence of negative scoring for many products that are relatively healthful, such as many whole grain or nut-based products that also contain added sugars, or products that are very high in healthful unsaturated fats but also contain saturated fat.

Alternatively, we recommend that FDA may consider moving forward with testing and comparing both its planned approach and our recommended approach. This will allow the empiric research to determine which approach is superior for helping consumers identify more healthful food products. We understand the importance of following recommendations set forth by the DGAs, which aim to represent the best consensus science. As such, the DGAs emphasize food-based dietary patterns as the primary approach to identifying and eating a healthful diet.

In closing, we reiterate that we do not support FDA's approach to test only the proposed, limited nutrient-based criteria in a prospective FOP label, and we recommend that FDA not proceed with testing of labels based on these nutrient-based criteria alone. Rather, we recommend that FDA use and test FOP label options that include food-based targets in alignment with its proposed rule on "healthy." Alternatively, FDA may consider moving forward with testing and comparing both approaches.

We share these comments to further optimize efforts to best align with current nutrition science and advance healthier eating and better health for all Americans. We emphasize our willingness to leverage our expertise to work further with FDA in its quest to empower consumers with nutrition information to make healthier choices more easily. We thank FDA for the opportunity to submit this comment for

¹¹ GBD 2017 Diet Collaborators. Health effects of dietary risks in 195 countries, 1990-2017: A systematic analysis for the Global Burden of Disease Study 2017. *Lancet*. 2019;393(10184):1958-1972. doi:10.1016/S0140-6736(19)30041-8

consideration as it continues to explore the establishment of a standardized, science-based FOP scheme that helps consumers, particularly those with lower nutrition literacy, quickly and easily identify foods that are part of a healthy, food-based dietary pattern.

Sincerely,

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