



October 11, 2018  
Division of Dockets Management  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: FDA-2018-N-238; The Food and Drug Administration's Comprehensive, Multi-Year Nutrition Innovation Strategy; Public Meeting; Request for Comments**

The American Cancer Society (ACS) and the American Cancer Society Cancer Action Network (ACS CAN) respectfully submit the following comments on the Food and Drug Administration's (FDA's) comprehensive, multi-year Nutrition Innovation Strategy. The ACS is the nation's largest voluntary health organization, dedicated to eliminating cancer as a major health outcome through research, education, and service. ACS CAN is the non-profit, non-partisan advocacy affiliate of ACS. ACS CAN advocates for legislative, regulatory, and policy solutions that will make cancer a national priority. Overall, we appreciate the agency's commitment to align food labels with dietary advice. The agenda offers a critical opportunity to create greater transparency for consumers in the service of public health and to foster innovation that drives reformulation and the availability of healthier foods.

Contrary to the sound recommendations of the 2015 Dietary Guidelines for Americans, Americans under-consume healthful foods: fruits and vegetables, low-fat dairy, and whole grains. We also over-consume unhealthy added sugars, saturated fats, and sodium. Labeling transparency is a valuable tool for assisting consumers in making healthful choices and should assist consumers in following dietary advice, as the Nutrition Labeling Education Act directs.

Consumers should be confident that foods marketed as better for them are indeed more healthful choices. The stakes are high: seventy percent of adults and 33 percent of children and teens are now overweight or obese.<sup>1,2</sup> Approximately 45 percent of adults have diabetes or prediabetes.<sup>3</sup> Every time a

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<sup>1</sup> Fryar CD, Carroll MD, Ogden CL. Prevalence of Overweight, Obesity, and Extreme Obesity Among Adults Aged 20 and Over: United States, 1960–1962 Through 2013–2014. National Center for Health Statistics, July 2016. Accessed at: <[https://www.cdc.gov/nchs/data/hestat/obesity\\_adult\\_13\\_14/obesity\\_adult\\_13\\_14.pdf](https://www.cdc.gov/nchs/data/hestat/obesity_adult_13_14/obesity_adult_13_14.pdf)>.

<sup>2</sup> Fryar CD, Carroll MD, Ogden CL. Prevalence of Overweight and Obesity Among Children and Adolescents Aged 2–19 Years: United States, 1963–1965 Through 2013–2014. National Center for Health Statistics, July 2016. Accessed at: <[https://www.cdc.gov/nchs/data/hestat/obesity\\_child\\_13\\_14/obesity\\_child\\_13\\_14.htm](https://www.cdc.gov/nchs/data/hestat/obesity_child_13_14/obesity_child_13_14.htm)>.

<sup>3</sup> National Center for Chronic Disease Prevention and Health Promotion. *National Diabetes Statistics Report, 2017: Estimates of Diabetes and Its Burden in the United States*. 2017. Accessed at: <<https://www.cdc.gov/diabetes/data/statistics/statistics-report.html>>.

consumer goes looking for healthier food and is sold a food or beverage that undermines their health, that is a missed opportunity to reduce diet-related disease.

### ***Diet and Cancer***

Poor diet, physical inactivity, excess weight, and excess alcohol consumption are major risk factors for cancer, second only to tobacco use. In fact, a recent study led by ACS scientists estimated that 18 percent of cancer cases and 16 percent of cancer deaths in 2014 were attributable to the combined effects of excess body weight, physical inactivity, and an unhealthy diet (including excess alcohol).<sup>4</sup> Excess weight is clearly associated with an increased risk of developing cancers of the breast (postmenopausal), colon and rectum, uterus, kidney, pancreas, ovary, liver, gastric cardia, gall bladder, and thyroid, and adenocarcinoma of the esophagus, meningioma, and multiple myeloma.<sup>5</sup>

As a result of the clear relationship diet and body weight have with many types of cancer, ACS guidelines for cancer prevention and cancer survivorship recommend eating a healthy diet, with an emphasis on plant foods.<sup>6,7</sup> Specific dietary recommendations include choosing foods and beverages in amounts that help achieve and maintain a healthy weight, limiting processed meats and red meats, consuming fruits and vegetables and whole grains instead of refined grain products, and limiting alcohol intake for those who drink alcoholic beverages.<sup>8</sup> Recent research has found that non-smoking adults who followed ACS guidelines for weight control, diet, physical activity, and alcohol consumption lived longer and had a lower risk of dying from cancer and cardiovascular disease.<sup>9, 10</sup>

### **Recommendations**

As the FDA designs its program, the agency should consider whether its labeling strategy will help to clarify what is both *in* products and *not* in them, and whether the labeling strategy will effectively encourage consumers to fill grocery carts with fresh fruits and vegetables that bear no labels at all. For these reasons, we believe that the FDA should focus on the following topics as part of the Nutrition Innovation Strategy:

- **The agency should strengthen the definition of “healthy” and review a full range of options for front-of-package nutrition labeling programs.**
- **The FDA should improve labeling of whole grains to improve transparency for consumers and encourage healthful reformulation of grain-containing foods.**
- **The FDA should complete its critical work on nutrition education and sodium reduction.**

Below, we address each of these areas in more detail.

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<sup>4</sup> Islami F, Sauer AG, Miller KD, et al. Proportion and number of cancer cases and deaths attributable to potentially modifiable risk factors in the United States. *CA Cancer J Clin*. 2017; published online November 21.

<sup>5</sup> Lauby-Secretan B, Scoccianti C, Loomis D, et al. Body Fatness and Cancer – Viewpoint of the IARC Working Group. *N Engl J Med* 2016; 375: 8.

<sup>6</sup> Kushi LH, Doyle C, McCullough M, et al. American Cancer Society Guidelines on Nutrition and Physical Activity for Cancer Prevention. *CA Cancer J Clin* 2012; 62:30-67.

<sup>7</sup> Rock CL, Doyle C, Demark-Wahnefried W, et al. Nutrition and Physical Activity Guidelines for Cancer Survivors. *CA Cancer J Clin* 2012; doi: 10.3322/caac.21142.

<sup>8</sup> Kushi, 2012.

<sup>9</sup> Kohler LN, Garcia DO, and Harris RB. Adherence to Diet and Physical Activity Cancer Prevention Guidelines and Cancer Outcomes: A Systematic Review. *Cancer Epidemiol Biomarkers Prev* 2016; 25(7): 1018-28.

<sup>10</sup> McCullough ML, Patel AV, Kushi LH, et al. Following Cancer Prevention Guidelines Reduces Risk of Cancer, Cardiovascular Disease, and All-Cause Mortality. *Cancer Epidemiol Biomarkers Prev* 2011; 20(6): 1089-97.

***The agency should strengthen the definition of “healthy” and review a full range of options for front-of-package nutrition labeling programs.***

As part of its interest in “modernizing claims,” the FDA seeks public comment on the possibility of using an easy-to-find symbol to denote the claim “healthy” on food labels. We support an effort to create a national, standardized, front-of-package symbol system to help consumers quickly identify healthier foods.

While an FDA-defined healthy logo holds potential to be useful for consumers, we are concerned that a standardized “healthy” symbol, available to manufacturers for voluntary use, would be less helpful than a more comprehensive symbol system that conveys information about both the healthier and unhealthier attributes of foods. While a “healthy” logo may guide consumers to a few healthier choices within a food category, it would not allow them to discern which foods should be avoided or eaten less often — information that is critical to people’s ability to follow the advice in the Dietary Guidelines for Americans, such as to eat less saturated fat, added sugars, and sodium. Moreover, a “healthy” symbol that is primarily available for packaged foods would have the potential to make these foods appear more attractive relative to unpackaged alternatives, such as fresh fruits and vegetables, which are significantly under-consumed.

This problem would be exacerbated if the standard for “healthy” is too lax, allowing products high in refined grains or added sugars to be mislabeled as healthy. Red meats, processed meats, and sugar-sweetened beverages should not be labeled “healthy” because regular consumption of these products directly increases the risk for cancer or for obesity, which, in turn, increases the risk of several cancers.<sup>11,12,13</sup>

Should the FDA proceed with a healthy logo, we encourage the agency to consider ways to integrate the effort with existing labeling systems and provide additional information to consumers about the nutrition content of foods. This could include guidance on integrating the healthy logo with additional front-of-package elements, such as the information about calories, saturated fat, sodium, and added sugars, which are provided through the industry’s “Facts Up Front” initiative.

We note that the Healthy Star Rating in use in Australia and New Zealand combines normative advice (a star rating score) with nutrition information for calories, saturated fat, sodium, and sugars (the same macronutrients used for the industry’s Facts Up Front program in the United States). The FDA should consider whether a healthy logo could similarly combine both normative advice and nutrition information into one standardized logo. Presenting both types of elements in combination may also help to distinguish the logo from other packaging symbols and clarify its connection to nutrition. Consumer testing of a range of systems, as well as existing research and labeling rules on front-of-package systems around the globe, should guide the FDA’s review, and should include an evaluation of their impact on both consumer choices and reformulation.

We encourage the FDA to begin by strengthening the definition of “healthy” as it has already proposed. The revised “healthy” definition should include limits on added sugars and require that grain-containing foods be nearly 100% whole grain.

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<sup>11</sup> World Cancer Research Fund (WCRF) and American Institute for Cancer Research (AICR). *Diet, Nutrition, Physical Activity and Cancer: A Global Perspective*. 2018. Available at: <https://www.wcrf.org/sites/default/files/Summary-third-expert-report.pdf>

<sup>12</sup> 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;364:2392-404.

<sup>13</sup> Malik VS, Pan A, Willett WC, and Hu FB. Sugar-sweetened beverages and weight gain in children and adults: a systematic review and meta-analysis. *Am J Clin Nutr*. 2013 Oct; 98(4): 1084–1102.

Whole grains are grain products in their most nutrient-dense forms and typically provide fiber, which is under consumed in the population. Additionally, while research shows that Americans are eating enough grain products overall, consumption of whole grains is low.<sup>14</sup> This means that for people to eat enough whole grains, they must shift some of their consumption of refined grains to whole grains. For products that provide foods from multiple food groups, the nearly 100 percent whole grain requirement should apply to the portion of the food that is grain-based.

We do not support requiring “healthy” foods to provide a minimum absolute amount of whole grains (e.g., 8 grams of whole grain, the minimum amount required by the Whole Grains Council for a whole grain stamp), because while these foods provide a small amount of whole grain, they may provide an even larger amount of refined grains.<sup>15</sup> Consumption of these foods would do little to reduce overconsumption of refined grains. Similarly, we believe that a 50 percent whole grain standard for “healthy” foods would also be too low.

The definition of “healthy” should also consider both food and nutrient criteria but maintain maxima for saturated fat (with exemptions for some foods like avocados and nuts which are naturally high in fats, including some saturated fat), sodium, and added sugar in “healthy foods.”

If the FDA makes additional changes as to the healthful ingredients permitted on labels using the term “healthy,” it should consider only the foods that make up the core of a healthy eating pattern in their nutrient-dense forms. For example, should the agency consider exempting certain fruits and vegetables from the minimum requirements that apply to certain beneficial nutrients, any such exemption should only apply to fruits and vegetables that are present in a food in a whole or cut-up form, and *not* when they are merely a concentrate, powder, paste, isolate, juice, or puree. We are concerned that if “healthy” is not carefully defined, the claim could encourage consumers to select unhealthy foods rather than under-consumed whole fruits and vegetables.

### ***The FDA should improve labeling of whole grains to improve transparency for consumers and encourage healthful reformulation of grain-containing foods***

Virtually everyone eats packaged bread, crackers, pasta, and cereals, rather than preparing them from scratch at home, so clearer labeling of grains on processed foods is an important and promising area that could create new clarity for consumers and revitalize incentives to improve the healthfulness of these foods.

The FDA should consider, as part of its Nutrition Innovation Strategy, how better to support consumers in following the Dietary Guidelines advice for consumption of whole grains. The Dietary Guidelines recommend that Americans “make at least half of your grains whole.”<sup>16</sup> The ACS also recommends that individuals consume whole grain products in place of refined grains.<sup>17</sup> The evidence that whole grains lower colorectal cancer risk was ranked as “probable” in the 2018 WCRF/AICR report.<sup>18</sup>

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<sup>14</sup> U.S. Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA). *2015–2020 Dietary Guidelines for Americans*. 8th Edition. December 2015. Available at: [https://health.gov/dietaryguidelines/2015/resources/2015-2020\\_Dietary\\_Guidelines.pdf](https://health.gov/dietaryguidelines/2015/resources/2015-2020_Dietary_Guidelines.pdf)

<sup>15</sup> Oldways Whole Grain Council. Whole Grain Stamp. Available at <https://wholegrainscouncil.org/whole-grain-stamp>. Accessed September 28, 2018.

<sup>16</sup> 2015–2020 Dietary Guidelines for Americans. 8th Edition. Washington, D.C.: U.S. Department of Health and Human Services and U.S. Department of Agriculture: December 2015. Accessed at: [https://health.gov/dietaryguidelines/2015/resources/2015-2020\\_Dietary\\_Guidelines.pdf](https://health.gov/dietaryguidelines/2015/resources/2015-2020_Dietary_Guidelines.pdf).

<sup>17</sup> Kushi et al, 2012.

<sup>18</sup> WCRF and AICR, 2018.

Some consumers have responded to that advice by seeking out products with names that tout their whole grain or multi-grain content. Yet, many of these products are misleadingly made with white flour as the first ingredient and contain little whole grain. As with added sugars, additional information is required as a fundamental first step in assuring that consumers can easily follow science-based dietary recommendations that reduce their risk of cancer and other chronic diseases.

Along with whole fruit, vegetables, legumes and nuts, whole grains are a natural source of dietary fiber, and dietary fiber is also related to lower risk of colorectal cancer according to recent reviews.<sup>19</sup> As fiber claims proliferate, consumers have no way of knowing how much of the “Dietary Fiber” listed on the Nutrition Facts Panel is intact, versus isolated or synthetic fiber. Given that foods with isolated fibers may not provide the same benefits as the mix of intact fibers in a healthy diet and that consumers may be employing them as substitutes for fiber-rich foods, we ask that FDA require foods that make fiber claims and contain synthetic or isolated fibers clearly disclose on the front of a package that a food “Includes X grams of processed fiber per serving.”

A result of this confusion is that while some companies are innovating in the marketplace to offer products with whole grains that appeal to consumers, incentives for these innovations are blunted by the fact that consumers often cannot tell which grain products are whole grain, and which are refined grains. Hearty-looking (and sometimes artificially colored) “wheat” breads and “multigrain” breads add to the confusion by containing labeling claims and images that suggest they contain whole grains when they may include none or negligible amounts. Whole grain content is not disclosed in the Nutrition Facts panel, and even the ingredient list may not be informative if it contains confusing names, fails to specify which grains are whole grains, or lists multiple refined grains after whole grain, which together could add up to make refined grain the predominant ingredient.

We therefore urge the agency to prioritize the issue of whole grain labeling. To prevent misleading claims and encourage healthful innovation, we request that the FDA:

- Define “whole grain claims” to clearly include use of the terms “whole wheat,” “whole grain,” “made with whole grain,” “multigrain,” as well as a declaration of the whole grain content by weight;
- Also include in “whole grain claims” use of the term “wheat” on a wheat-based bread, pasta, or other product that is typically made from wheat, use of depictions of wheat or grains, or any similar descriptive phrases, terms, or representations suggesting the product contains whole grains; and
- Require that foods making such whole grain claims prominently and uniformly disclose the percentage of whole grains and refined grains.

***FDA should complete its critical work on nutrition education and sodium reduction.***

*Implementing Menu Labeling and the Nutrition Facts Label Education Campaigns*

We support the agency conducting consumer-awareness education campaigns for menu labeling and the updated Nutrition Facts Panel and urge the agency to dedicate adequate funding and resources towards these efforts. Such campaigns will maximize these consumer education tools and assist consumers in making informed choices about what they eat, support healthier eating, and increase healthier food options.

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<sup>19</sup> WCRF and AICR, 2018.

For menu labeling, we were pleased that the FDA conducted focus groups and found the learnings helpful for developing consumer education materials. For instance, the FDA found that simple swaps are effective messages, such as “getting your sandwich with grilled chicken instead of fried helps cut the calories.” We encourage the FDA to finalize and release its menu labeling materials. Other materials that would be useful could highlight the succinct statement on menus and menu boards providing context about calories in a daily diet to educate the public on the average target for 2,000 calories per day. The FDA should also highlight the additional nutrition information that is available upon request, including information that can be of importance for people with diet-related diseases.

For both menu labeling and Nutrition Facts efforts, we encourage the agency to collaborate with major public health coalitions and organizations that represent constituencies such as education, nutrition, and other health professionals. We encourage the FDA to hold a meeting with these stakeholders and present at key conferences and coalitions to widely disseminate its menu labeling materials.

For Nutrition Facts Panel public education efforts, we support the focus on calories, serving sizes, and added sugars, and encourage the agency to include sodium. We also encourage the FDA to conduct message testing through focus groups and/or polling to determine best practices for educating consumers about the updated Nutrition Facts label, as it has done with menu labeling. We recommend low-income mothers as a priority population given their influence over child and family health in purchasing decisions.

In addition, given the agency’s public health progress on requiring a Daily Value for added sugars on the Nutrition Facts Panel, it is critical that consumers continue to perceive the added sugars from single-ingredient sweeteners such as table sugar, honey, and maple syrup as part of their overall daily “budget” for sugars. The declaration of added sugars on the Nutrition Facts label is of great public health importance: two out of three adults and one out of three children are overweight or have obesity, and one of three adults is diagnosed with prediabetes. Small amounts of single-ingredient sweeteners significantly contribute to daily added sugars intake. For example, a one-tablespoon serving of honey contains about one-third of a day’s worth of added sugars, and a two-tablespoon serving of maple syrup has half a day’s added sugars.

We urge the FDA to ensure that the percentage “Daily Value” of sugars remains listed for these single-ingredient sweeteners regardless of whether the word “added” is retained on the label. To facilitate consumer understanding, we urge the FDA to issue guidance that maintains clear and specific labeling requirements that apply only to single-ingredient sweeteners. Such guidance should require that the percentage “Daily Value” for added sugars be provided as part of the current line for “Total Sugars” and permit substitution of the term “Sugars” in lieu of “Total Sugars” to alleviate any consumer confusion.

#### *Sodium Reductions*

We strongly support inclusion of sodium reduction included in the FDA’s Nutrition Innovation Strategy. The typical sodium intake—about 4,000 milligrams per day—is a major cause of high blood pressure, or hypertension.<sup>20</sup> An estimated 46 percent of U.S. adults suffer from that condition, which increases the

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<sup>20</sup> Cogswell ME, Loria CM, Terry AL, Zhao L, Wang CY, Chen TC, Wright JD, Pfeiffer CM, Merritt R, Moy CS, Appel LJ. Estimated 24-Hour Urinary Sodium and Potassium Excretion in US Adults. *JAMA*. 2018; 319(12):1209–1220. Accessed at <<https://www.ncbi.nlm.nih.gov/pubmed/29516104>>.

risk of heart disease and stroke.<sup>21</sup> Together, coronary heart disease and stroke kill about 500,000 people annually in the United States.<sup>22</sup>

Given successful population-wide sodium-reduction efforts in several other countries and the variation in sodium concentration within similar types of foods, the FDA's proposed sodium-reduction targets are eminently feasible and could even be strengthened. The agency's modest two-year sodium-reduction targets should be finalized, as promised, by 2019 given the urgent need to start reducing the harm from excessive sodium in the food supply. The FDA should also continue its work toward finalizing the ten-year sodium-reduction targets as soon as possible, since far more significant reductions could be accomplished, and ten years gives industry ample time to plan and reformulate its products.

## Conclusion

We appreciate the opportunity to comment and look forward to working with the agency on solutions to advance public health. If you have any questions or we can provide any additional information, please contact Katie McMahon, Principal, Policy Development – Prevention at [katie.mcmahon@cancer.org](mailto:katie.mcmahon@cancer.org) or 202.585.3245 or Kristen Sullivan, Director, Nutrition and Physical Activity at [kristen.sullivan@cancer.org](mailto:kristen.sullivan@cancer.org) or 404.417.5897.

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<sup>21</sup> Whelton PK, Carey RM, Aronow WS, Casey DE Jr, Collins KJ, Dennison Himmelfarb C, DePalma SM, Gidding S, Jamerson KA, Jones DW, MacLaughlin EJ, Muntner P, Ovbigele B, Smith SC Jr, Spencer CC, Stafford RS, Taler SJ, Thomas RJ, Williams KA Sr, Williamson JD, Wright JT. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2018; 71(19):e127-e248. Accessed at: <<https://www.ncbi.nlm.nih.gov/pubmed/29146535>>.

<sup>22</sup> Benjamin EJ, Blaha MJ, Chiuve SE, Cushman M, Das SR, Deo R, de Ferranti SD, Floyd J, Fornage M, Gillespie C, Isasi CR, Jimenez MC, Jordan LC, Judd SE, Lackland D, Lichtman JH, Lisabeth L, Liu S, Longenecker CT, Mackey RH, Matsushita K, Mozaffarian D, Mussolino ME, Nasir K, Neumar RW, Palaniappan L, Pandey DK, Thiagarajan RR, Reeves MJ, Ritchey M, Rodriguez CJ, Roth GA, Rosamond WD, Sasson C, Towfighi A, Tsao CW, Turner MB, Virani SS, Voeks JH, Willey JZ, Wilkins JT, Wu JHY, Alger HM, Wong SS, Muntner P. Heart Disease and Stroke Statistics—2017 Update: A Report from the American Heart Association. *Circulation*. 2017; 135(10):e146-e603. Accessed at: <<https://www.ncbi.nlm.nih.gov/pubmed/28122885>>.