

October 11, 2018

Scott Gottlieb, MD
Commissioner
U.S. Food and Drug Administration
Division of Dockets Management
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**

Dear Commissioner Gottlieb:

The American Institute for Cancer Research (AICR) appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) comprehensive, multi-year Nutrition Innovation Strategy. AICR is the leading authority on the links between diet, weight and physical activity, and cancer prevention and survival. A healthy pattern of eating and drinking is strongly correlated with a lower risk of cancer, as well as reducing the risk of weight gain and having overweight or obesity¹. With this in mind, we recognize that cancer prevention depends not only on individual choices, but on governments creating an environment that encourages lifelong healthy eating. The creation of such an environment depends heavily on promoting an informed consumer base, an initiative we believe that the FDA can achieve through its Nutrition Innovation Strategy.

Overall, we appreciate the agency's commitment to aligning food labels with evidence-based dietary recommendations. 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. We encourage the FDA to use this opportunity to both promote healthful foods and to prevent misleading labeling that hampers Americans' ability to make healthful dietary choices.

Summary of AICR's Comments on FDA's Nutrition Innovation Strategy

AICR strongly supports the FDA using its authority to make it easier for Americans to make informed dietary choices that reduce their risk of cancer and other chronic diseases. As part of this strategy, the FDA should make changes that both empower consumers to make educated decisions on their food choices through the provision of accurate and easily accessible information and fostering of an environment that will make it more appealing to companies to

¹ World Cancer Research Fund/American Institute for Cancer Research. *Diet Nutrition, Physical Activity and Cancer: A Global Perspective*. Continuous Update Project Expert Report 2018. Available at dietandcancerreport.org

develop healthful food options. We make the following recommendations with respect to the Nutrition Innovation Strategy:

- 1) The FDA should continue its critical work on nutrition education that supports consumer use of nutrition information to improve individual choices.
- 2) The FDA should strengthen the definition of “healthy” and review a full range of options for front-of-package nutrition labeling programs.
- 3) The FDA should improve labeling of whole grains to improve transparency for consumers and encourage healthful reformulation of grain-containing foods.
- 4) The FDA should support health and transparency by addressing deceptive labeling, updating standards of identity, and improving ingredient lists.

Our comments and recommendations are discussed in more detail in the sections that follow.

General Comments on FDA’s Strategic Policy Roadmap

In January 2018, the FDA released a strategic policy roadmap that included as one of its pillars: “Empower consumers to make better and more informed decisions about their diets and health; and expand the opportunities to use nutrition to reduce morbidity and mortality from disease.”²

We applaud the FDA for making it a priority to use its authority to make it easier for Americans to make more informed dietary choices, and for their recognition of the link between diet and disease. We believe that this was an important step forward in educating the public about the link between their lifestyle choices and their risk for chronic, non-communicable diseases, including cancer. In fact, cancer is the second leading cause of death in the U.S., accounting for nearly a quarter of all deaths in 2015.³ Yet, between 30 and 50 percent of all cancer cases are estimated to be preventable through a healthy lifestyle coupled with avoiding other known carcinogens.¹

Further, we commend the FDA on one of the key initiatives of its Nutrition Action Plan: the empowerment of consumers to make educated decisions on their food choices through the provision of accurate and easily accessible information, as well as the fostering of an environment that will make it more appealing to producers to develop healthful food options. This two-pronged approach takes into account both the supplier and the consumer, a tactic that we believe is vital to ensuring an impact on the health behaviors of Americans.

² U.S. Food & Drug Administration. Healthy innovation, safer families: FDA’s 2018 strategic policy roadmap. <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM592001.pdf>. Updated January 2018. Accessed October 9, 2018.

³ Centers for Disease Control. National vital statistics reports: Deaths: Final data for 2015. Updated November 27, 2017. https://www.cdc.gov/nchs/data/nvsr/nvsr66/nvsr66_06.pdf

General Principles that Connect Sound Labeling Policy to Public Health Goals

Contrary to the sound recommendations of the 2015-2020 *Dietary Guidelines for Americans*, Americans under consume healthful foods: in particular, fruits and vegetables, low-fat dairy, and whole grains. We also overconsume unhealthful added sugars, saturated fats, and sodium.⁴ 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.^{5,6} Our new findings show strong evidence linking overweight or obesity to 12 cancers, and in a few decades, having overweight and obesity is likely to overtake smoking as the most important cause of cancer globally.^{7,8} Every time a consumer seeks to purchase a healthier food or beverage and is sold one that undermines their health, it is a missed opportunity to reduce cancer risk.

Many consumers who try to follow dietary advice struggle with excess weight gain and other preventable diet-related health problems, including one of 12 types of cancer.⁴ Data from the International Food Information Council show that health, as well as weight loss, are core considerations for most consumers in making food choices. Consumers pay attention to labels: more than half of consumers look at the Nutrition Facts Panel or ingredient list “often” or “always” when making a purchasing decision, and approximately 40% say they consider other labeling statements about health or nutrition benefits.⁹

Labels provide actionable information at the point of decision, connecting dietary choices to health. Yet products across the marketplace attempt “permission” marketing, in which a health halo is intentionally created to make foods and beverages appear more healthful than they are. Specifically, consumers should not be misled that processed foods touting images of fruits and vegetables are adequate dietary substitutes for fresh fruits and vegetables. For this reason, it is critical that the FDA’s initiative should seek to correct misleading or inaccurate labeling claims

⁴ U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015-2020 Dietary Guidelines for Americans*. 8th Edition. December 2015. Available at <https://health.gov/dietaryguidelines/2015/guidelines/>.

⁵ 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>.

⁶ 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>.

⁷ World Cancer Research Fund/American Institute for Cancer Research. *Diet Nutrition, Physical Activity and Cancer: a Global Perspective*. Continuous Update Project Expert Report 2018. Available at dietandcancerreport.org

⁸ Ligibel JA, Alfano CM, Courneya KS et al. American Society of Clinical Oncology position statement on obesity and cancer. *Journal of Clinical Oncology*. 2014; 32 (31): 3568-3574. doi: 10.1200/jco.2014.58.4680.

⁹ International Food Information Council Foundation. *2018 Food and Health Survey*. Washington, DC: International Food Information Council Foundation, 2018. Accessed at: <<https://www.foodinsight.org/2018-food-and-health-survey>>.

and should not enable unhealthy foods to unfairly compete with fresh fruits and vegetables, which occupy too little space in Americans' diets.

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 it will effectively encourage consumers to fill grocery carts with fresh fruits and vegetables that bear no labels at all.

1) The FDA should continue its critical work on nutrition education that supports consumer use of nutrition information to improve individual choices.

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.

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 as a way to educate the public on the ballpark target for 2,000 calories per day. The FDA should also highlight the additional nutrition information that is available upon request, which information 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, such as AICR. As an organization dedicated to preventing cancer and increasing survivorship, AICR's most important job is interpreting our evidence so that our large base of health professionals and other health-focused individuals can translate it into actionable steps to reduce the risk of cancer. We do this through numerous programs, such as our New American Plate Challenge, which is a 12-week web-based lifestyle intervention designed to lower risk of both cancer and other chronic diseases. As a primary stakeholder in the nutrition education space, we feel that it would be mutually beneficial to meet with the FDA to discuss how our organizations can work together to help more Americans live a cancer-protective lifestyle.

For Nutrition Facts Panel public education efforts, we support the focus on calories, serving sizes, and added sugars. 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.

2) The FDA should strengthen the definition of "healthy" and review a full range of options for front-of-package nutrition labeling programs.

We encourage the FDA to strengthen the definition of "healthy" as it has already begun to consider. The revised "healthy" definition should include both food and nutrient criteria,

including a requirement that grain-containing foods be 100% whole grain, and limits on saturated fat, sodium, and added sugar in “healthy foods.” Further, FDA should consider only allowing use of the term “healthy” on foods that make up the core of a healthy eating pattern in their nutrient-dense forms. 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 consider the available research and conduct additional research, as needed, to determine the best design for a symbol or rating system for “healthy” that makes it easy for consumers to make choices that align with the *Dietary Guidelines for Americans*. A national standardized, front-of-package symbol system should help consumers quickly identify healthier foods both within and across categories. Development of such a symbol or system should be informed by consumer testing of a range of systems, existing research and rules on front-of-package systems around the globe, and an evaluation of their impact on consumer choices and reformulation.

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

There is strong evidence that incorporating whole grains into one’s diet can reduce the risk of colorectal cancer by 17 percent.¹ However, misleading label claims can make it difficult for consumers to verify whether or not what they are eating is a whole grain. Since the majority of the population eat packaged bread, crackers, pasta, and cereals, rather than preparing them from scratch at home, 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.”¹⁰ Yet Americans in every age group are not following this advice, under consuming whole grains and overconsuming refined grains.⁹ Cancer survivors, in particular, consume refined grains at a rate much higher than their unaffected counterparts. According to a 2015 study, cancer survivors had particularly poor adherence to Dietary Guidelines regarding their intake of whole grains, despite this population’s interest in how food choices can affect their health.¹¹ This situation is further worsened by the fact that higher whole grain intake has been found to lower mortality

¹⁰ 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; 2:41-43. Accessed at: https://health.gov/dietaryguidelines/2015/resources/2015-2020_Dietary_Guidelines.pdf

¹¹ Zhang FF Liu S John EM Must A & Demark-Wahnefried W. Diet quality of cancer survivors and noncancer individuals: Results from a national survey. *Cancer*. 2015; 121 (23). doi: 10.1002/cncr.29488

rates in those diagnosed with colorectal cancer, which remains the second deadliest cancer in America.^{12,13}

Research shows that consumers are often confused by whole grain labels. A study published in 2016 by the FDA in collaboration with several academic institutions showed that older adults are confused by package information about whole grain products. The study used a structured interview protocol to determine whether older adults (n = 89, age ≥ 65 years) were able to accurately identify whether three common food items were whole grain. The study found that approximately 35 percent of participants were not able to correctly identify the two whole grain products tested (cereal and crackers) as whole grain, and 80 percent of participants could not correctly identify that the refined grain product (bread) was not whole grain; nearly half of participants mis-identified the refined grain bread as whole grain.¹⁴ Participants also did not know where to look on labels for information about whole grains and consulted the Nutrition Facts label almost as often as they did ingredient lists.

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 the difference between primarily whole grain and refined grain products. 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. We would welcome an opportunity to work with FDA to ensure updates to whole grain labeling requirements incentivize manufacturers to develop and market whole grain products and support consumers in choosing grain products that help them meet the Dietary Guidelines recommendations and reduce their colorectal cancer risk.

4) The FDA should support health and transparency by addressing deceptive labeling, updating standards of identity, and improving ingredient lists.

We support the FDA using its authority to update requirements for label claims, modify certain standards of identity, and modernize ingredient lists in a manner that would benefit the public health. These updates should improve transparency and address deceptive labeling for consumers and incentivize companies to develop and reformulate products that support consumers following the *Dietary Guidelines for Americans*. We also support efforts to

¹² Song M Wu K Meyerhardt JA et al. Fiber intake and survival after colorectal cancer diagnosis. *Journal of American Medical Association Oncology*. 2018; 4(1):71-79. doi: 10.1001/jamaoncol.2017.3684.

¹³ American Cancer Society: Cancer Facts and Figures 2018. Atlanta, Ga: American Cancer Society, 2018. Accessed at: <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2018.html>. Last accessed October 9, 2018.

¹⁴ Violette C Kantor MA Ferguson K et al. Package information used by older adults to identify whole grain foods. *Journal of Nutrition in Gerontology and Geriatrics*. 2016; 35(2):146-160. doi: 10.1080/21551197.2016.1168759

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modernize ingredient lists to make them more readable and consumer-friendly. We urge the agency to take regulatory and enforcement action to achieve these goals.

Conclusion

We appreciate the opportunity to comment, are invigorated by the possibilities, and look forward to working with the agency on solutions and public education efforts that generate greater transparency on food labels in the service of health. Should you have any questions about this letter or AICR, please contact Deirdre McGinley-Gieser, Senior Vice President of Programs, at d.mcginley-gieser@aicr.org.

Sincerely,



Kelly B. Browning
Chief Executive Officer