CENTER FOR
Science IN THE
Public Interest
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Dr. Janet Woodcock
Acting Commissioner of Food and Drugs
Food and Drug Administration
Department of Health and Human Services
Silver Spring, MD 20993

Re: FDA's Plans to Endorse a Voluntary Symbol Depicting the Nutrient Content Claim "Healthy" on Packaged Foods

Dear Acting Commissioner Woodcock,

The Center for Science in the Public Interest (CSPI)[1] writes to express our concerns about FDA's pursuit of a voluntary symbol depicting the nutrient content claim "healthy" as part of its Nutrition Innovation Strategy. Simple, standardized front-of-package nutrition labeling (FOPNL) that provides interpretive information about the healthfulness of foods has great potential to help improve consumers' food choices and diets. However, studies suggest that FOPNL schemes similar to a "healthy" symbol are not the most effective forms of FOPNL and may exacerbate inequitable access to healthy foods.

Dozens of countries are already using FOPNL to help improve consumers' food choices and diets.[2] FOPNL can take a wide variety of forms, such as endorsement logos that appear only on the healthiest packaged foods (a "healthy" symbol would fall in this category); traffic light labels, star ratings, and guideline daily amount (GDA) labels that appear on all foods; and warning signs that appear only on products with high levels of calories or unhealthful nutrients. Based on the experiences of its member states, the World Health Organization Regional Office for Europe (WHO Europe) cautions that endorsement logos alone can have unintended adverse effects and advises that countries adopt FOPNL systems that provide evaluations of product unhealthfulness, as opposed to systems that provide only positive judgments.[3]

This administration has the opportunity to establish its legacy as a champion of public health through FOPNL. Unfortunately, by taking a voluntary rather than mandatory approach and by failing to evaluate current evidence and select the FOPNL system with the greatest potential to improve diet quality, FDA is not taking full advantage of this opportunity.

We urge the FDA to take a more ambitious, evidence-based approach and adopt a mandatory FOPNL system with the aims of maximizing public health impact and avoiding any unintended harm.

I. FDA's Action on FOPNL and "Healthy" To Date

Consumers have been calling for FDA to develop a simple, interpretive FOPNL that applies systematically across all packaged foods for more than a decade. CSPI first petitioned FDA to develop such a system in 2006.[4] In 2007, FDA held its first public hearing to solicit information on the use of symbols to communicate nutrition information on food labels.[5] In 2009, Congress directed the Institute of Medicine (IOM) to conduct a study to examine FOPNL systems and provide recommendations for one or multiple systems that would best promote consumers' health.[6]

The IOM issued a two-phase report in 2010 and 2012 which concluded that FDA and the U.S. Department of Agriculture should develop, test, and implement a single, standardized FOPNL system to appear on all food and beverage products, and recommended several criteria for such a system.[7] Among these criteria were recommendations that the system display calories; assign zero to three nutritional "points" for saturated and trans fats, sodium, and added sugars; and appear on *all* grocery products, allowing consumers to compare food choices both across and within categories.

In the nine years since the issuance of this report in 2012, several countries (including Ecuador, Mexico, Iran, Chile, Sri Lanka, and Israel) have adopted mandatory FOPNL systems, and governments in more than a dozen countries have endorsed voluntary FOPNL systems.[8,9] However, the FDA has taken little further action on FOPNL and no government-endorsed FOPNL system exists in the United States today.

Meanwhile, FDA has undertaken efforts to update the definition of the nutrient content claim "healthy." CSPI has previously commented in support of a strong definition of "healthy" that would permit the claim only on the most nutrient-dense foods.[10]

FDA now seeks to develop a symbol that can act as a stylized representation of the "healthy" claim.[11] Former FDA Commissioner Scott Gottlieb announced the agency's interest in developing a "healthy" logo in March 2018,[12] and FDA published a "Healthy Symbol Literature Review" in February 2021.[13]

A "healthy" symbol would effectively be the first government-endorsement FOPNL system in the United States. FDA recognizes its approach as one among many different approaches to FOPNL, as its literature review included evidence supporting broadly-defined FOPNL (endorsement symbols similar to a "healthy" logo as well as other FOPNL formats, including traffic light, GDA, star ratings, warning signs, and more) to inform its development of the "healthy" symbol.[14] However, FDA did not systematically evaluate the relative efficacy of endorsement logos compared to other FOPNL options. The review was not conducted using systematic methods for evaluating quality of evidence (including assessment for risk of bias) or meta-analyzing study findings. Instead, it provided only a narrative summary of the evidence. And the table that summarizes the evidence and states the authors' conclusions does not consistently cite which studies informed each conclusion, raising issues of transparency and replicability.

Furthermore, FDA did not begin its literature review until after the agency already announced the "healthy" symbol as its intended approach to FOPNL.[15] Unlike most scientific literature reviews, this review had a preordained outcome (adoption of a "healthy" symbol), as reflected in the way FDA described the objective of its review:

> FDA is exploring options to standardize the presentation of "healthy" claims for voluntary use on the food label. To support that effort, FDA conducted a literature review to summarize what is currently known and understood about the effects of nutrition labeling schemes – referred to as front-of-pack (FOP) labels displaying a summary of the product's healthfulness or nutrient content.[16]

Given that FDA had already apparently decided on a "healthy" logo as its approach to FOPNL, it is unclear why other FOPNL systems were even included in the review.

In a Federal Register notice on May 6, 2021, FDA announced plans to conduct research about the use of the FDA-endorsed "healthy" symbols on food products.[17] If the agency proceeds with these studies as planned, it will be moving forward with an approach to FOPNL that was not decided upon based on a thorough review of the evidence.

II. Concerns about a Voluntary "Healthy" Logo as FDA's Approach to FOPNL

A. *Studies suggest that endorsement logos are less effective than other FOPNL schemes.*

Several peer-reviewed systematic reviews and meta-analyses published in recent years present more thorough assessments of FOPNL than FDA's "Healthy Symbol Literature Review."[18] Reviews of studies assessing how different FOPNL systems affect selection and consumption of foods are particularly useful in assessing the potential for FOPNL to impact consumer behavior and public health. A 2016 systematic review and meta-analysis of randomized controlled trials (RCTs) compared the effects of three FOPNL schemes (GDA, traffic light, and an "other labels" category that includes endorsement logos similar to a "healthy" logo) and found that traffic light labels increased the number of people that selected a healthier option by 29% (CI: 20-39%), "other labels" by 15% (CI: 4-26%), and GDA by 12% (5-18%).[19] The results of this review suggest that traffic light labels may be more effective than endorsement logos at encouraging selection of healthier choices.

Additionally, limited evidence from RCTs that tested endorsement logos head-to-head against other FOPNL schemes suggests that endorsement logos are not the most effective. Only one RCT included in the 2016 review tested an endorsement logo against other FOPNL schemes.[20] The study assigned participants to one of five label conditions (endorsement logo, multiple traffic light, monochrome GDA, colored GDA, or no-label control) and asked them to identify the healthier food item in 28 pairwise comparisons. All three other FOPNL conditions led to a significantly higher average number of correct identifications compared with the endorsement logo.[21]

Another RCT that was not included in the 2016 review, as it was published after the search period, also assigned participants to one of five label conditions (endorsement logo, multiple traffic light, GDA, five-color label, or no-label control) and assessed the overall nutritional quality of the contents of participants' shopping carts after a shopping task in a web-based supermarket.[22] The five-color label performed significantly better than the endorsement logo (and all other FOPNL systems tested).

In addition to encouraging *increased* selection of healthier options, studies have looked at how FOPNL may *decrease* selection of less healthy options. This is an important outcome given that overconsumption of calories and unhealthful nutrients are major drivers of obesity and related diseases.[23,24] One review looked at the effects of different FOPNL schemes on the sugar content of consumer food choices and found significant reductions from health warning messages, graphic depictions of sugar content, warning signs, and traffic light labels plus "high in sugar" disclosures, but no effect from traffic light labels alone, GDA, or star rating labels.[25] Another review meta-analyzed findings from experimental studies and found that "high in" warnings significantly decreased calories, sugar, and sodium purchased by participants; traffic light labels significantly decreased sodium only; and other labeling schemes including Nutriscore, star ratings, and Daily Intake Guide (similar to GDA) had no effect.[26]

Neither of these reviews included endorsement logos because such logos are intended to only appear on healthier products. Endorsement logos may be less likely to affect consumption of less healthy foods. Indeed, research suggests that purchase decisions are driven more by negative than positive evaluative judgments, and that negative judgments can reduce impulsivity towards less healthy foods.[27,28] This highlights the need for FOPNL systems that include not only indicators of product *healthfulness*, but also indicators of product *un*healthfulness. Based on the experiences of more than a dozen member states, the WHO Europe specifically advises that countries "utilize a system of interpretive FOPL that can provide evaluative judgements about product unhealthfulness, which appears to be a more effective way to support consumers to choose nutritionally favourable products."[29]

FDA should systematically consider the evidence on different FOPNL systems and learn from the experiences in other countries to select the system most likely to have the greatest impact on consumer choices and diet quality, with dual goals of increasing consumption of healthier foods and decreasing consumption of calories and overconsumed nutrients.

B. *Endorsement logos may lead to unintended adverse effects.*

Americans with low incomes face a multitude of structural barriers to achieving healthy diets.[30,31] As a result, on average, Americans with lower incomes have lower diet quality scores than higher-income Americans[32] and also experience higher rates of some diet-related chronic diseases.[33] Consumers with lower incomes and people with less education are significantly less likely to regularly use the Nutrition Facts label,[34] which can require a high level of literacy and numeracy. Therefore, well-designed FOPNL systems that communicate nutrition information in a quick and simple way have the potential to be particularly useful for low-income consumers and enhance access to information to promote healthier choices.

However, if FOPNL causes healthier products to become more expensive, this will negate the benefits of FOPNL for consumers with low incomes. Data suggest that endorsement logos including the Choices logo in the Netherlands and Keyhole logo in Denmark were associated with higher food prices,[35] raising concerns that a similar "healthy" logo could increase the price of healthier foods or be utilized primarily on higher-priced products. This may target the potential benefits of the policy towards higher-income Americans. Such effects would not be expected from systems such as warning labels that aim to make less healthy foods less appealing as opposed to making healthier foods more appealing.

The WHO Europe report on FOPNL explicitly cautions that the adoption of endorsement logos "may engender a price premium, which may have implications for low socioeconomic groups."[36] We urge FDA to consider alternative labeling schemes that are less likely to have such an effect.

C. *A voluntary "healthy" symbol will not do enough to change the food labeling landscape.*

Under current FDA regulations, foods must meet certain conditions in order to bear a "healthy" nutrient content claim including criteria for nutrients to limit in the diet, such as saturated fat, cholesterol, and sodium, and criteria for nutrients to encourage, including vitamin A, vitamin C, Vitamin D, calcium, iron, potassium, protein, and fiber.[37,38] This means only a limited subset of foods would qualify to bear an FDA "healthy" symbol.

Even among those foods that qualify, not all would actually bear an FDA "healthy" symbol on their labeling, because its use would be voluntary. Few foods are presently labeled with general "healthy" claims, as specific nutrient-content claims are more common.[39] Also, other countries that have implemented voluntary endorsement logos have seen variable penetration of these labels in the marketplace. According to WHO Europe:

> In countries applying an endorsement logo system, the absence of logos may be either a result of poor uptake to voluntary labelling policies or an indication that only a small number of products comply with nutritional standards. This means that consumers in such countries may find themselves in a situation where they (i) have no FOPL to guide their decisions for the majority of products on the market and (ii) cannot be certain of the reason behind its absence; evidence suggests that non-occurrences tend to be overlooked, with lack of a label not considered by customers as necessarily indicating a less healthful product.[40]

Based on the experiences of countries in the region, WHO Europe recommends that governments "explore ways to overcome issues with uptake of the FOPL system in the marketplace, including through mandatory implementation."[41]

Packaged foods are already saturated with claims emphasizing their healthful properties. Therefore, adoption of a "healthy" symbol would not represent a substantial shift in the food labeling landscape. Companies already have ample financial incentives for making positive nutrition claims, but not for identifying their products as relatively less healthy than others or disclosing high levels of nutrients to limit in the diet. Therefore, a gap exists in transparent disclosure regarding the unhealthful properties of foods which would be best addressed through regulatory or legal action.

If FDA wishes to optimize its resources and use its regulatory authority to promote diets lower in calories, saturated fat, sodium, and added sugars, the agency should adopt a mandatory FOPNL system.

III. FDA's Authority to Take Specific Actions on FOPNL

The Nutrition Labeling and Education Act (NLEA) provides the FDA with legal authority to authorize mandatory FOPNL. The NLEA states that a food is misbranded "unless its label . . . bears nutrition information that provides [certain nutrition information, such as calories]."[42] The NLEA does not dictate the placement and format of the required nutrition information and, importantly, does not prohibit placement on the front-of-package.[43] Instead, the NLEA gives the FDA considerable discretion in deciding where and how such information must be displayed.

To guide that discretion, the NLEA mandates that the nutrition information be conveyed "in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet."[44] This provision serves as the basis for the formatting and placement of Nutrition Facts label and could similarly authorize a mandatory FOPNL.

It provides the FDA the authority to require the placement of nutrition labeling in a "readily observ[able]" location, such as the front of package, and to require that such information be conveyed in a manner that is easily "underst[ood]" and "comprehend[ed]" by the public, including by use of images, symbols, and other interpretive aids.

In the House Report on the NLEA, Congress was explicit about the latter authority. It stated:

> In order to present nutrition information in a manner that facilitates the public's understanding, the Secretary may choose among a variety of options. . . . This could include the use of descriptive terms such as "high," medium," and "low" or use of universal symbols to indicate desirable or undesirable levels of particular nutrients.[45]

We urge the FDA to utilize this authority and consider all the available evidence in adopting a mandatory FOPNL system that provides the greatest benefit to consumers.

IV. FDA's Plans to Conduct Research About Use of "Healthy" Symbols

While there is sufficient evidence to support adoption of a comprehensive, mandatory FOPNL system without additional research,[46,47] to the extent that FDA continues the information collection activities described in its recent Federal Register notice,[48] we urge the agency to expand its studies to include additional FOPNL schemes beyond a "healthy" symbol endorsement logo. Also, if FDA proceeds with an experimental study using purchase/choice questions to assess consumer response to the labels, these questions should be designed to assess both increased selection of healthier choices as well as decreased selection of less healthy choices and should be adequately statistically powered to do so.

V. Conclusion

By underutilizing its regulatory authority and failing to follow the evidence, FDA is not taking full advantage of FOPNL as an opportunity to improve public health. We urge the agency to shift course towards a more impactful approach.

Rather than approaching FOPNL through the adoption of a voluntary "healthy" symbol, CSPI urges FDA to systematically evaluate the current evidence and select whichever FOPNL system will have the greatest effect on improving diet quality. This includes considering a mandatory approach that will maximize uptake across the food supply. We also urge the agency to ensure that such a system makes information accessible to people from all demographic groups (*e.g.*, lower literacy or non-English-speaking) without limiting accessibility in other ways (*e.g.*, through a price premium).

We welcome an opportunity to discuss this topic further and request a meeting with your office at your earliest availability.

Thank you for your time and attention.

Sincerely,

Peter Lurie
Executive Director and President

Sarah Sorscher
Deputy Director of Regulatory Affairs

Eva Greenthal
Senior Science Policy Associate

[1] *The Center for Science in the Public Interest ("CSPI") is a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public's health through better nutrition and safer food. The organization does not accept government or corporate grants and is supported by the roughly half million subscribers to its Nutrition Action Healthletter. CSPI provides nutrition and food safety information directly to consumers, and has long advocated for legislation, regulation, and judicial rulings to ensure that foods are safe and clearly labeled.*

[2] World Cancer Research Fund International. Building momentum: lessons on implementing a robust front-of-pack food label. 2019. https://www.wcrf.org/policy/our-publications/building-momentum-series/lessons-implementing-robust-front-of-pack-food-label/

[3] Kelly B & Jewell J. What is the evidence on the policy specifications, development processes and effectiveness of existing front-of-pack food labelling policies in the WHO European Region? *World Health Organization Europe Health Evidence Network Synthesis Report 61*. 2018. https://www.euro.who.int/__data/assets/pdf_file/0007/384460/Web-WHO-HEN-Report-61-on-FOPL.pdf

[4] Center for Science in the Public Interest. Petition for Advance Notice of Proposed Rulemaking on the Use of Symbols on the Principal Display Panel to Communicate the Healthfulness of Foods. November 30, 2016. https://cspinet.org/sites/default/files/attachment/healthy_symbol_petition.pdf

[5] U.S. Food and Drug Administration. Food labeling: Use of symbols to communicate nutrition information, consideration of consumer studies and nutritional criteria. Public hearing; request for comments. Fed Reg. 2007;72: 39815-39818.

[6] Explanatory statement submitted by Mr. Obey, Chairman of the House Committee on Appropriations, regarding H.R. 1105, Omnibus Appropriations Act, 2009; Congressional Record Vol. 155, No. 31.

[7] Institute of Medicine. Front-of-Package Nutrition Rating Systems and Symbols: Promoting Healthier Choices. 2012. Washington, DC: The National Academies Press.

[8] World Cancer Research Fund International (2019).

[9] Kelly & Jewell (2018).

[10] Center for Science in the Public Interest. Re: Use of the term "healthy" in the labeling of human food products; request for information and comments; Docket No. FDA-2016-D-2335. April 26, 2017. https://cspinet.org/sites/default/files/attachment/CSPI%20Healthy%20Comment%20%28002%29.pdf

[11] *Note: CSPI raised several concerns with respect to the adoption of a voluntary "healthy" logo in our comments on the Nutrition Innovation Strategy in 2018*: https://cspinet.org/sites/default/files/attachment/nis-cspi-comments-with-appendix_0.pdf

[12] U.S. Food and Drug Administration. Speech by Scott Gottlieb: Reducing the Burden of Chronic Disease. March 29, 2018. https://www.fda.gov/news-events/speeches-fda-officials/reducing-burden-chronic-disease-03292018

[13] Verrill L, et al. Healthy Symbol Literature Review. *U.S. Food and Drug Administration*. February 26, 2021.

[14] Verrill (2021).

[15] *The initial literature search included studies published through October 2018, several months after Commissioner Gottlieb announced FDA's plans to adopt a voluntary "healthy" logo in March 2018.*

[16] Verrill (2021).

[17] U.S. Food and Drug Administration. FDA In Brief: FDA issues procedural notice on potential plans to conduct research about use of 'healthy' symbols on food products. May 6, 2021. https://www.fda.gov/news-events/press-announcements/fda-brief-fda-issues-procedural-notice-potential-plans-conduct-research-about-use-healthy-symbols

[18] See, *e.g.*:

An R, et al. Effect of front-of-package nutrition labeling on food purchases: a systematic review. *Public Health.* 2021;191:59-67.

An R, et al. Impact of sugar-sweetened beverage warning labels on consumer behaviors: a systematic review and meta-analysis. *Am J Prev Med.* 2020;60(1):115-126.

Brown HM, et al. Influence of the nutrition and health information presented on food labels on portion size consumed: a systematic review. *Nutr Rev.* 2018;76(9):655-677.

Cecchini M and Warin L. Impact of food labelling systems on food choices and eating behaviours: a systematic review and meta-analysis of randomized studies. *Obesity Reviews.* 2016;17:201-210.

Clarke N, et al. Impact of health warning labels on selection and consumption of food and alcohol products: systematic review with meta-analysis. *Health Psych Rev.* 2020:1-24.

Crockett RA, et al. Nutritional labelling for healthier food or non-alcoholic drink purchasing and consumption. *Cochrane Database Syst Rev.* 2018;2(2):CD009315.

Crocker H, et al. Front of pack nutritional labelling schemes: a systematic review and meta-analysis of recent evidence relating to objectively measured consumption and purchasing. *J Hum Nutr Diet.* 2020;33:518-537.

Daley AJ, et al. Effects of physical activity calorie equivalent food labelling to reduce food selection and consumption: systematic review and meta-analysis of randomized controlled studies. *J Epidemiol Community Health.* 2020;74(3):269-275.

Feteira-Santos R, et al. Effectiveness of interpretive front-of-pack nutritional labelling schemes on the promotion of healthier food choices: a systematic review. *Int J Evid Based Healthc.* 2020;18(1):24-37.

Grummon A & Hall MG. Sugary drink warnings: a meta-analysis of experimental studies. *PLoS Med.* 2020;17(5):e1003120.

Gupta A, et al. The effect of front-of-package labels or point-of-sale signage on consumer knowledge, attitudes and behavior regarding sugar-sweetened beverages: a systematic review. *Nutr Rev.* 2020;1-17.

Scapin T, et al. Influence of sugar label formats on consumer understanding and amount of sugar in food choices: a systematic review and meta-analyses. *Nutr Rev.* 2021;79(7):788-801.

[19] Cecchini (2016).

[20] Borgmeier I & Westenhoefer J. Impact of different food label formats on healthiness evaluation and food choice of consumers: a randomized-controlled study. *BMC Public Health.* 2009;9:184.

[21] *Note that this significant finding may be attributable to lack of adjustment for multiple comparisons.*

[22] Ducrot P, et al. Impact of different front-of-pack nutrition labels on consumer purchasing intentions: a randomized controlled trial. *Am J Prev Med.* 2016;50(5):627-636.

[23] Wang, et al. Reaching the healthy people goals for reducing childhood obesity: closing the energy gap. Am J Prev Med. 2012;42(5):437-444.

[24] Hall K, et al. Quantification of the Effect of Energy Imbalance on Bodyweight. Lancet. 2011;378(9793): 826-37.

[25] Scapin (2021).

[26] Croker (2020).

[27] Scarborough P, et al. Reds are more important than greens: how UK supermarket shoppers use the different information on a traffic light nutrition label in a choice experiment. *Int J Behav Nutr Phys Act.* 2015;12(1):151.

[28] Rohr M, et al. The color red supports avoidance reactions to unhealthy food. *Exp Psychol.* 2015;62(5):335-45.

[29] Kelly & Jewell (2018).

[30] U.S. Department of Agriculture Food and Nutrition Service. Barriers that Constrain the Adequacy of Supplemental Nutrition Assistance Program (SNAP) Allotments. June 23, 2021. https://www.fns.usda.gov/snap/barriers-constrain-adequacy-snap-allotments

[31] Vilar-Compte M, et al. Urban poverty and nutrition challenges associated with accessibility to a healthy diet: a global systematic literature review. *International Journal for Equity in Health.* 2021;20:40.

[32] Rehm CD, et al. Dietary intake among US adults, 1999-2012. *JAMA.* 2016;315(23):2542-2553.

[33] Shaw KM, et al. Chronic disease disparities by county economic status and metropolitan classification, Behavioral Risk Factor Surveillance System, 2013. *Prev Chronic Dis.* 2016;13:160088.

[34] Christoph MJ, et al. Nutrition Facts Panels: who uses them, what do they use, and how does use relate to dietary intake? *J Acad Nutr Diet.* 2018;118(2):217-228.

[35] Edenbrandt AK, et al. A hedonic analysis of nutrition labels across product types and countries. *European Review of Agricultural Economics.* 2018;45(1):101-120.

[36] Kelly & Jewell (2018).

[37] 21 CFR 101.65

[38] U.S. Food and Drug Administration. Guidance for Industry: Use of the Term "Healthy" in the Labeling of Human Food Products. September 2016. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-use-term-healthy-labeling-human-food-products

[39] Cao Z & Yan R. Health creates wealth? The use of nutrition claims and firm financial performance. *Journal of Public Policy and Marketing.* 2015;34(3):1-9.

[40] Kelly & Jewell (2018).

[41] Kelly & Jewell (2018).

[42] 21 U.S.C. § 343(q)(1).

[43] *The NLEA mandates that the nutrition information appear on the "label," (21 U.S.C. § 343(q)(1)), which is broadly defined as the "display of written, printed, or graphic matter upon the immediate container of any article." (21 U.S.C. § 321(k)).*

[44] P.L. 101-535.

[45] H.R. Rep. 101-538, at 18 (1990).

[46] Research Triangle Institute. Front of Package Nutrition Labeling: Environmental Scan and Literature Review. *Report prepared for U.S. Food and Drug Administration.* 2016. https://aspe.hhs.gov/basic-report/policy-research-front-package-nutrition-labeling-environmental-scan-and-literature-review

[47] Verrill (2021).
[48] U.S. FDA (2021).