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

Comment on FDA's 30-day Notice Regarding Quantitative Research on Front of Package Labeling (FDA-2023-N-0155)

The undersigned organizations and individuals strongly support FDA's pursuit of research to help select a front-of-package (FOP) labeling scheme that will help consumers quickly and easily identify foods that can help them build healthy eating patterns. We appreciate the additional information on FDA's proposed research on FOP labeling provided in this 30-day notice.[1] In this comment, we summarize our understanding of FDA's present research proposal, share our assessment of how the study design has improved since the previous notice, and provide requests for additional improvements.

I. Summary of FDA's Research Proposal

In this 30-day notice, FDA describes its plans to conduct a controlled, randomized experiment in which 9,000 U.S. adults will respond to a 15-minute questionnaire. The experiment will have two main parts:

a. *Comparison Task:* participants will see three versions of the same type of FOP labeling scheme at the same time, each with a different nutrient profile—one healthiest, one least healthy, and one medium healthy. Participants will be asked to identify the healthiest and least healthy scheme in the set of three. The task will be timed and each participant will complete the task three times, each time with a different scheme type. The FOP schemes will be displayed alone, as opposed to being shown as adhered to a food product/label, and participants will have the option to access the Nutrition Facts label by clicking a link.
b. *Single Product Evaluation:* participants will be randomized to view a single food product (breakfast cereal, frozen meal, or canned soup) with a single FOP label and one of three levels of healthfulness (healthiest, medium, or least healthy). Participants will respond to questions assessing perceptions of product healthfulness, healthfulness believability, scheme efficacy, and attitude toward the scheme.

FDA states that the study will have three primary outcomes:

1. Participants' ability to correctly interpret the nutritional profile of the product
2. The speed at which participants make their decisions
3. Whether or not participants search for more information to answer the question (*i.e.*, whether they click a link to view the Nutrition Facts label)

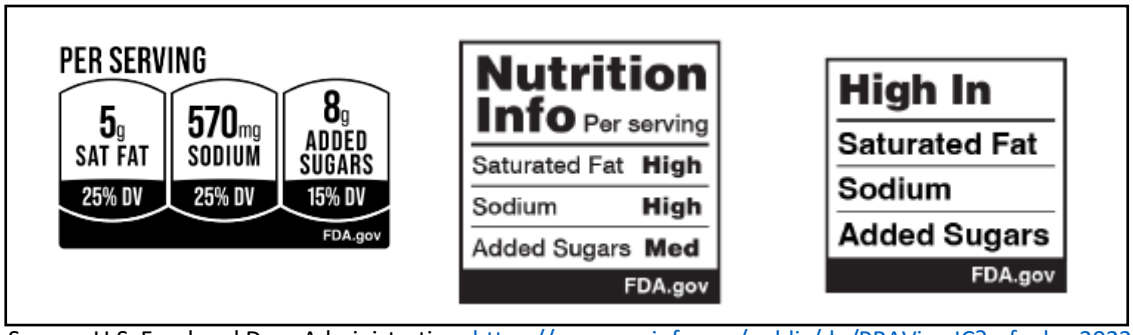
Each of the FOP labeling schemes to be examined focuses on the nutrients that the Dietary Guidelines for Americans have identified as nutrients to limit (*i.e.,* sodium, saturated fat, and added sugars), with certain schemes identifying levels of nutrients as "high," "medium," or "low" based on FDA's established criteria for interpreting the percent Daily Value (DV) of a nutrient (*i.e.,* under 5% DV is low, over 20% DV is high, everything in between is medium).[2]

FDA has provided images of the labels it plans to test,[3] which include eight variations of three main types (*see* Figure 1, left to right):

- Guideline Daily Amount (GDA) label, similar to Facts Up Front,[4] which provides no interpretive component to aid nutrition comprehension beyond the percent DV
- Nutrition Info label, which rates the amounts of saturated fat, sodium, and added sugars per serving as "low," "med," or "high"
- High In label which indicates if a food is high in saturated fat, sodium, and/or added sugars

The variations include Nutrition Info and High In labels with and without the percent DV, and additional versions of the Nutrition Info label with a magnifying glass icon and a green-yellow-red color scheme (as opposed to black and white). For the Comparison Task, participants will be randomized to view three of these eight schemes, and for the Single Product Evaluation Task, participants will be randomized to view just one.

Figure 1. The three main types of front-of-package labeling schemes FDA plans to test in its randomized experiment



Source: U.S. Food and Drug Administration. https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=202306-0910-004&icID=260638

II. Improvements to FDA's Updated Research Proposal

We appreciate that the agency has made several improvements to the design of this proposed study. Since the previous notice, the agency tripled the sample size from 3,000 to 9,000 participants. This will substantially improve the ability of this study to detect differences in the effect of different FOP labeling schemes on the study's primary outcomes. Based on estimates from a previous study testing FOP labeling, sample sizes of 3,375 people per label scheme in the Comparison Task (which we expect if the 9,000 participants are randomized to three of eight FOP scheme conditions) should be appropriately powered to detect differences in the effect of different schemes on participants' ability to select the healthiest/least healthy product in a set.[5]

The agency also decided, based on insights from its focus groups, to only test FOP schemes that highlight nutrients to limit (*e.g.,* sodium, saturated fat, and added sugars), and not schemes that combine nutrients to limit and nutrients to encourage (*e.g.,* fiber and calcium). We believe this has led to a selection of schemes that are easier to understand and better aligned with most FOP schemes adopted by other countries in the Americas.[6]

FDA adapted one of the Nutrition Info labeling schemes to include a magnifying glass icon (see Figure 2). In comments on the previous research notice, public health advocates and researchers recommended that designing labels to include attention-grabbing features such as icons or imagery could increase their efficacy. We appreciate that FDA incorporated this feedback into one of its designs.

Finally, we appreciate that FDA opted to incorporate a measure of caregiver status *(e.g.*, parent, carer for a sick/elderly person) into its survey. Use and understanding of FOP labeling by caregivers is essential, as they are likely making decisions about food for others in their household. A national survey of 3,010 U.S. adults in March 2023 found higher support for a mandatory front-of-package labeling policy in the United States among adults with children in their households (80% strongly or somewhat support, compared to 73% among people without children in their households).[7]

Figure 2. Variation of the Nutrition Info label that FDA plans to test in its controlled, randomized experiment

Source: U.S. Food and Drug Administration. https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=202306-0910-004&icID=260638

III. **Additional Requests**

a. Clarify the presence or absence of control conditions

The document titled "Appendix B—FOP Study Power Analysis…" indicates that the Comparison Task (referred to in Appendix B as Section 1) will include a no-scheme control.[8] Given that the task involves viewing standalone label schemes with no food/product images, we recommend that FDA eliminate the control condition and replace it with the Nutrition Info label with the magnifying glass icon or one of the variations of the High In label that we suggest in section d below.

Appendix B does not clearly indicate whether the Single Product Evaluation Task (referred to as Section 2) will include a no-scheme control condition. For this task, we recommend that FDA include a no-scheme control to allow for comparisons of the effects of the FOP schemes to the status quo.

b. Use correct interpretation of the healthiest/least healthy nutrient profiles as the sole primary outcome

As previously mentioned, FDA has indicated that its study will have three primary outcomes: 1) participants' ability to correctly interpret the nutritional profile of the product; 2) the speed at which participants make their decisions; and 3) whether participants search for more information (*i.e.*, click a link to view the Nutrition Facts label). We strongly recommend that FDA select the first of these three outcomes as its sole primary outcome, making the other two secondary outcomes of the study.

Of the three outcomes, we believe that participants' ability to correctly interpret the nutritional profile of the product is the most important because it is the only one that is independently and objectively desirable. In contrast, the desirability of faster decision-making is dependent on whether the decision is correct, and it is unclear what would be the more desirable outcome with respect to searching for the Nutrition Facts label. Searching for the Nutrition Facts label could be positive (if the labeling scheme spurs consumers to learn more about the product's nutrition information and ingredients) or negative (if the labeling scheme is not noticeable or confusing and thus participants need to seek more information).

c. Consider testing additional High In scheme designs with attention-grabbing features

The document titled "Appendix F—FOP Schemes and Mock Product Labels for FDA FOP Experiments" displays eight different FOP schemes that FDA will test in this experiment. One of these is a GDA scheme, five are Nutrition Info schemes, and two are High In schemes. We recommend that the agency test additional High In schemes, including High In schemes with additional features—such as icons or imagery— to draw the consumer's attention (see Figure 3). Schemes that are similar to FDA's High In designs have been adopted in both Canada and Brazil, and both include a magnifying glass icon. It is unclear why FDA would opt to test a Nutrition Info design with a magnifying glass icon, but not a High In label with a magnifying glass icon.

Icons and attention-grabbing features other than the magnifying glass should also be tested. In response to our previous request to test a label that includes the word "warning," FDA stated: "[W]e will not test the word 'warning' or a warning icon because doing so would not align with our research goals of learning how to provide consumers with additional factual context for food choices." We understand that the agency is not considering a warning label or icon in this study, but we encourage the agency to consider testing an exclamation point icon, "ATTENTION!" label, or a High In label with white text on a black background. These attention-grabbing features would contribute toward the study's goals of identifying a scheme that allows consumers to quickly evaluate the healthfulness of products. Even though FDA has opted to test FOP schemes on mock packages with fewer competing labeling claims than are found on many products in the marketplace, the agency should still be identifying which designs would be most attention-grabbing to be noticeable in the presence of additional nutrition-related claims.

Figure 3. Variations of FDA's High In Schemes with Additional Features to Draw Attention

Source: Center for Science in the Public Interest

d. Use the same nutrient profiles for healthiest, middle, and least healthy products across FOP schemes

The document titled "Appendix E—Front of Pack Nutrition Labeling Experiment and Pretests 1 & 2 Questionnaire" includes the Nutrition Facts labels that will be linked to the healthiest, middle, and least healthy versions of each FOP scheme during the Comparison Task (Figure 4).[9] Under the present proposal, the GDA and Nutrition Info schemes will be associated with one set of Nutrition Facts labels and the High In schemes will be associated with a different set. There are important differences between the two sets of Nutrition Facts labels that could affect the results of this study. For example, for the High In schemes, the amount of Total Sugars increases from least healthy (12 grams) to middle (15 grams) to healthiest (18 grams). However, for the GDA and Nutrition Info schemes, the middle product has the highest amount of Total Sugars (15 grams) while the healthiest and least healthy products each have 12 grams. These inconsistencies could result in the Comparison Task having different levels of difficulty for participants in the GDA and Nutrition Info scheme compared to participants in the High In

scheme, making it impossible to accurately assess the relative usefulness of GDA or Nutrition Info schemes compared to High In schemes in supporting consumers' understanding of product healthfulness. We recommend using a single set of Nutrition Facts labels across all three types of FOP schemes.

Figure 4. Nutrition Facts Labels for the Healthiest, Middle, and Least Healthy Versions of GDA and Nutrition Info Schemes (top) and High In Schemes (bottom), with colors added to demonstrate differences

Source: U.S. Food and Drug Administration. https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=202306-0910-004&icID=260638. Adapted by Center for Science in the Public Interest.

We also recommend using a consistent definition of healthiest, middle, and least healthy across all three types of FOP schemes. Based on the Nutrition Facts labels in Figure 4, the definitions appear to be inconsistent. For the High In schemes, healthiest is high in one nutrient and low in two, middle is high in two nutrients and low in one, and least healthy is high in three nutrients. For GDA and Nutrition Info, healthiest is low in two nutrients, medium in one, and high in none; middle is low in one nutrient, medium in two, and high in none; and least healthy is low in one nutrient and high in two. We recommend that you apply the definition used for the High In schemes to all schemes.

In Figure 5, we propose a new set of Nutrition Facts labels that could be used across all types of FOP schemes using consistent definitions of healthiest, middle, and least healthy. We recommend using these Nutrition Facts labels/nutrient profiles rather than the ones FDA developed for its High In schemes because our recommended nutrient profiles will require Nutrition Info labels to display combinations of "highs," "mediums," and "lows" (as opposed to just "highs" and "lows"), which is likely to better reflect what consumers would see in the marketplace.

Figure 5. Nutrition Facts Labels Recommended for the Healthiest, Middle, and Least Healthy Versions Across All FOP Schemes, with colors added to demonstrate differences

Source: Center for Science in the Public Interest

e. Consider testing label placement for either all schemes or no schemes

In the Single Product Evaluation Task, we are concerned that the addition of a new condition varying the placement of a single FOP scheme (the black and white Nutrition Info scheme) will reduce power and may not be very helpful, given that it is solely testing placement for a single scheme. We recommend that FDA either remove this condition from the study and review the existing literature to examine optimal placement of FOP schemes, or alternatively randomize participants within each scheme to either see the label placed on the top right or bottom right of the front of pack, which would allow FDA to compare the effects of placement across all label schemes. Existing research suggests that top right placement of nutrition information is optimal for capturing consumers' attention,[10,11] and other countries including Canada and Peru require their FOP labels to be placed on the upper right part of the food package.[12,13]

f. Ensure the survey operates consistently across different screen sizes

We recommend that FDA ensure that the survey is properly formatted to be viewed on all screen sizes of the different devices that participants may be using, including computers, tablets, and smartphones. This may involve allowing participants to zoom in to view each scheme. We also recommend conducting sensitivity analyses additionally controlling for device used if the distribution is uneven across conditions.

Thank you for considering these recommendations, and for your commitment to work expeditiously to develop an evidence-based FOP system.

Sincerely,

Center for Science in the Public Interest

American Heart Association

Association of State Public Health Nutritionists

International Fresh Produce Association

Prevention Institute

The Sumner M. Redstone Global Center for Prevention and Wellness at the George Washington University Milken Institute School of Public Health

Jennifer Falbe, ScD, MPH
Associate Professor of Nutrition and Human Development, Department of Human Ecology
University of California, Davis

Marissa G. Hall, PhD
Assistant Professor, Department of Health Behavior
University of North Carolina Gillings School of Global Public Health

Alyssa Moran, ScD, MPH, RD
Adjunct Assistant Professor, Department of Health Policy and Management
Johns Hopkins Bloomberg School of Public Health

Marion Nestle, PhD, MPH
Paulette Goddard Professor and Professor Emerita, Nutrition and Food Studies
New York University

P. Christopher Palmedo, PhD, MBA
Clinical Professor, Department of Community Health & Social Sciences
CUNY Graduate School of Public Health

Christina A. Roberto, PhD
Mitchell J. Blutt & Margo Krody Blutt Presidential Associate Professor of Health Policy, Department of Medical Ethics & Health Policy
University of Pennsylvania

Lynn Silver, MD, MPH, FAAP
Senior Advisor, Public Health Institute
Clinical Professor, University of California San Francisco

Marlene Schwartz, PhD
Professor and Director, Rudd Center for Food Policy and Health
University of Connecticut

Mary Story, PhD, RD
Professor, Global Health and Family Medicine and Community Health, Duke University
Director, Healthy Eating Research National Program, Robert Wood Johnson Foundation

Allison Sylvetsky, PhD
Associate Professor
George Washington University, Milken Institute School of Public Health

Lisa R. Young, PhD, RDN
Adjunct Professor of Nutrition
New York University

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