November 22, 2023

Submitted electronically via FOP@reagnudall.org

The Reagan Udall Foundation
1333 New Hampshire Ave, NW
Suite 420
Washington, DC 20036

Re: Front-of-Package Nutrition Labeling: *Virtual Public Meeting*

Dear Sir or Madam:

Thank you for the opportunity to provide written comments to supplement our oral comments delivered during the Reagan Udall Foundation virtual public meeting addressing front-of-package labeling. As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services — to amplify the collective work of the industry. More information about our organization is available at www.FMI.org.

In its Federal Register notices, FDA reiterated concerns related to diet-related chronic diseases and the continued prioritization of nutrition activities and empowering consumers with nutrition information to make healthier choices. FMI and our members share these important goals and appreciate FDA's use of quantitative research to guide the Agency's work and understanding related to this labeling initiative; however, we have a number of concerns related to the current approach, which we highlighted in our March 2023 and July 2023 comments. We discuss a number of these concerns below, specifically addressing two of the key topics set forth by the Reagan Udall Foundation:

- Potential intersection with other nutrition-related policies, such as other labeling efforts and nutrition assistance programs
- Design considerations, such as placement and color

Potential intersection with other nutrition-related policies, such as other labeling efforts and nutrition assistance programs

FMI is a co-creator of the Facts Up Front (FUF) program, a voluntary labeling program launched in 2011 designed to facilitate consumer transparency and empower informed choices. FMI believes that many characteristics of the FUF program make it the best suited front-of-package

(FOP) scheme for providing consumers with clear factual information. In particular, the FUF icons highlight quantitative values of calories, saturated fat, sodium, and added sugars on the front of the package. These values are taken directly from the existing Nutrition Facts Label (NFL), and do not conflict with the NFL, Dietary Guidelines, or other nutrition-related policies in any way. Although some of the schemes to be tested by FDA loosely resemble the FUF icons, there are important distinctions between the actual schemes to be tested that we think will miss the intended goals of the research and create confusing inconsistencies with other FDA rules, guidance, and nutrition related policies. We discuss these in greater detail below.

The Schemes Tested Should Include Calories

In our comments submitted to FDA, FMI urged the Agency to include calories in the FOP schemes to be tested. The Agency explained in its response to comment 32[1] that it is not testing any schemes that display calories because the revised NFL format gives greater prominence to calories. FDA concludes that consumers have "adequate access to calorie information, while the purpose of our research on FOP is to determine the usefulness of providing consumers with additional factual context for making healthy food selections."

Respectfully, we do not believe any meaningful discussion of providing additional nutrition information to ameliorate the "epidemic of diet-related chronic disease" – the stated goal of the research – can take place without including calories. Calories is the *only* nutrient that Congress sought fit to require to be declared at the point of purchase for both menu labeling and vending machine labeling, reflecting its importance in relation to obesity. It would be a missed opportunity if this nutrient was left off the most conspicuous position of packaged food labeling, while being featured prominently for restaurant and vending machine foods.

The Agency explains that the FOP labeling scheme is intended to complement the NFL. If that is the case, we question why the scheme would not include calories. Given the increased type size and bolding of calories in the NFL, it would be fully consistent and complementary to also highlight this information again on the front of pack. The information on calories provides a clearer picture of its contribution to the daily diet.

Including calories in any scheme tested is, in our view, necessary from a public health perspective. The changes to the NFL to increase the prominence of the calorie information were based on a 2004 FDA report finding that caloric balance is the single most important factor in weight control.[2] At the time the report was issued, FDA cited statistics finding that 64% of U.S. adults were overweight or obese. This number has only gone up in the past 20 years. According to 2017-2018 data from the National Health and Nutrition Examination Survey (NHANES), 73% of adults are overweight or obese. FDA has continued to make obesity a

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1 Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Quantitative Research on Front of Package Labeling on Packaged Foods, 88 Fed. Reg. 39257 (June 15, 2023).

2 FDA, Calories Count: Report of the Working Group on Obesity (2004).

priority of its nutrition initiatives, citing obesity rates at historic levels.[3] Likewise, the 2023 National Strategy on Hunger, Nutrition, and Health focuses significantly on obesity in its recommendations. Simply, obesity cannot be addressed without the inclusion of calories, and we think the failure to include even one scheme with calories is inconsistent with FDA's position in the menu labeling/vending rules, NFL, and other research.

The Schemes Tested Should Include Nutrients to Encourage

In our comments to the various dockets, we also encourage FDA to test schemes that include positive attributes/nutrients to encourage. For some consumers, these positive elements may be the more important factor in selecting healthful foods. Products that are "high" in the three nutrients FDA plans to test may still provide substantial positive nutrition overall. Consumers not only overconsume nutrients to limits, they also underconsume the positive nutrients listed on the Nutrition Facts panel, several of which are identified as nutrients of public health concern by the Dietary Guidelines for Americans (fiber, calcium, vitamin D and potassium).

It is just as important for consumers to increase consumption of these nutrients as it is for them to decrease consumption of nutrients to limit. For these reasons, including positive nutrients provides a more complete picture of the food's nutritional contribution. Indeed, FDA explains that the goal of the schemes is to help consumers "put a food, as a whole, into the context of their daily (or longer-term) diets." Information on the positive elements of nutrients would do just this, while helping consumers make healthful choices and is more consistent with both the Dietary Guidelines for Americans and FDA goals for more nutritious long-term patterns of eating.

Schemes including "High/Medium/Low" Designations are Oversimplified and Confusing to Consumers

Many of the proposed schemes go beyond a strictly factual disclosure and involve a subjective characterization ("high/medium/low" or "high in") of foods based on only three highlighted nutrients. Reducing a food's entire contribution to the diet to whether it is "high in" or "high", "medium," or "low" in one to three nutrients is overly simplistic and does not help educate consumers on how to improve their dietary pattern. This will likely result in perceiving many foods as "bad" even when they are healthful food choices recommended by the Dietary Guidelines for Americans and MyPlate resources. There are many examples of healthful nutrient dense foods, such as whole grain cereals and breads, that would be vilified under these subjective systems and would provide inconsistent messaging as compared to Dietary Guideline and MyPlate recommendations.

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[3] See https://www.fda.gov/news-events/fda-voices/improving-nutrition-turn-tide-diet-related-chronic-disease.

Additionally, the term medium has never been defined by regulation, nor has it been used in general FDA guidance regarding nutrition labeling.[4] Sudden use of previously undefined terms will be confusing to consumers, particularly those of lower nutrition literacy, who will struggle to know how to a "medium", especially when paired with a "low/high" designation, should impact their purchasing decision. A purely quantitative system, such as the FUF program, provides the same information on the levels of these nutrients without additional confusion.

The Schemes Tested Should Align with FDA's Regulatory and Claims Framework

Based on the consumer testing information and graphics that have been shared, the agency is basing the FOP labeling schemes to be tested on a "per serving" basis, which aligns with the Nutrition Facts Panel – an approach FMI supports. However, nutrient content claims, including "low" and "high" are based on the RACC, creating a significant discrepancy in the agency's application of these terms, compared to how they are defined under FDA regulations.[5] As highlighted in the marketplace assessment of four different breads below, there are considerable differences in the labeled serving sizes and the RACC. With the recently expanded definition of a single serving container as one with less than two times the RACC, these differences can be significant.

As noted below, the serving size for bread ranges from 25g to 49g, while the RACC for sliced bread is 50g. The chart illustrates how the product's assessment under the FOP scheme is impacted by variations in serving size. Importantly, based on only the three nutrients to limit included in the FOP schemes to be tested (added sugars, sodium, and saturated fat), white bread and 100% wheat whole bread appear to be equivalent nutritional choices. Further, a 100% whole wheat bread with a different serving size would rate differently even though it might be nutritionally identical to the first whole wheat bread on a per RACC basis.

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[4] Although FDA's How to Understand and Use the Nutrition Facts Label guidance, available at https://www.fda.gov/food/nutrition-facts-label/how-understand-and-use-nutrition-facts-label, at least discusses the meaning of "low" and "high" as it relates to the DV, the term "medium" is not mentioned.

[5] 21 CFR 101.13(p).

Low (per serving): ≤5% DV	Medium (per serving): 6-19% DV	High (per serving): ≥20% DV

Product	***Labeled Serving Size / Weight***	**Added Sugar / Serving**	**Sodium / Serving**	**Saturated Fat / Serving**
White Bread	1 slice 26g	2%DV 1g	5%DV 120mg	0%DV 0g
100% Whole Wheat Bread	1 slice 26 g	2%DV 1g	5%DV 110mg	0%DV 0g
100% Whole Wheat Bread	1 slice 43 g	6%DV 3g	5%DV 110mg	0%DV 0g
Hearty White Bread	1 slice 49g	8%DV 4g	10%DV 230mg	0%DV 0g

These significant differences between the RACC and serving size could result in confusion for consumers when trying to compare the same food product across various slice or pack sizes. To avoid consumer/stakeholder confusion and align with the FDA's own regulatory framework, the best practical solution is to avoid using nutrient content claim language in FOP labeling schemes. Strictly informational schemes like FUF do not raise this discrepancy.

Additionally, FDA continues to update the definition for the implied nutrient content claim "healthy" on a parallel path without discussion of how this will interact with potential FOP labeling updates. There are numerous potential conflicts that could cause consumer confusion unless these are considered in unison. As an example, unless FDA similarly adjusts the FOP scheme values to align with the use of individual, mixed product, main dish, and meal categorizations in the proposed definition of "healthy," there will be confusing inconsistencies between the two. For example, to be eligible to use the nutrient content claim "healthy" the sodium content in a meal product must be no greater than 30% of the daily value (DV); however, the interpretive FOP labeling schemes being tested would trigger a "high" designation if the sodium in the same meal was 20% of the DV or above. This means that meal products containing between 20% and 30% of the DV of sodium could potentially simultaneously carry a "high" in designation and a "healthy" claim. We urge the Agency to consider these in tandem to avoid policies that might allow for contradictory labeling and cause consumer confusion.

<u>The Schemes to be Tested May be Inconsistent with FDA's Existing Legal Authority and First Amendment Protections</u>

Legal Authority

As noted in both our March and July of 2023 comments, FMI believes that FDA should carefully assess whether its statutory authority before pursuing mandatory FOP labeling. The notices indicate that FDA may be considering both factual and interpretive schemes for FOP labeling (such as a "high", "medium", or "low" label; or labels that identify nutrients of concern that are "high in" the product). We also understand the planned consumer research is only a first step in exploring FOP labeling schemes and that FDA has not stated whether any standardized scheme it might adopt would be mandatory or voluntary. Before moving forward with a proposed mandatory approach, however, FMI has urged FDA to carefully assess whether Congress has

given the Agency the legal authority to enact a mandatory FOP scheme of the type under consideration.

The Federal Food, Drug, and Cosmetic Act (FFDCA) does not include express authority to mandate interpretive information about a selection of nutrients outside of the mandatory Nutrition Facts Panel. To the contrary, Congress was quite precise about the specific information FDA was authorized to require related to nutrition labeling.[6] And importantly, all of the regulatory authority provided to FDA related to mandatory nutrition information refers to factual information, rather than interpretation of it. FDA must carefully consider the limitations imposed by the current statutory framework when conducting research or proceeding with any FOP scheme.

The U.S. Supreme Court has recently made clear that Congress must provide *clear direction* to regulatory agencies – rather than a broad delegation of power – if the case implicates the "major question doctrine". The doctrine, invoked by a majority of justices in *West Virginia v. Environmental Protection Agency* (EPA) (2022), holds that courts should not defer to agencies on matters of "vast economic or political significance" unless Congress has explicitly given the agencies the authority to act in those situations. The doctrine is triggered here given the political significance that would be involved in moving from an approach that is information and education-based, as provided for under the FFDCA, to one that effectively characterizing foods as "good" or bad" based on specific nutrient levels.

In light of this precedent, a court could conclude that FDA's authority to mandate nutrition labeling and to regulate voluntary nutrient content claims does not provide a broad, never-before-exercised authority to mandate separate front-of-pack nutrient labeling, particularly in an interpretive format. Essentially, a court could hold that if Congress had intended for FDA to have such unusual and broad authority it would have clearly provided it. In sum, as FDA considers various FOP schemes, including interpretive ones, it should critically assess its legal authority to mandate the use of FOP labeling given that a requirement for such labeling has not been clearly provided for in the statute.

First Amendment Considerations

It is also critical that FDA assess First Amendment considerations in weighing the potential for a mandatory FOPNL scheme. Commercial speech is entitled to First Amendment protections. *Central Hudson Gas & Elec. Corp. v. Public Service Comm'n of New York*, 447 U.S. 557 (1980). Corporations cannot be compelled to speak except when that mandatory information is necessary to *avoid consumer deception*. There is a strong argument that, to the extent FDA were to impose the schemes it is testing as mandatory labeling requirements, they would be vulnerable to a constitutional challenge.

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[6] In terms of mandatory nutrition information, FDA is authorized to require nutrition labeling that includes the following complete set of information: the serving size, the number of servings per container, calories, total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, total protein, and vitamins and minerals.

Under *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), the Supreme Court upheld a compelled disclosure under the First Amendment when it was "reasonably related to the State's interest in preventing deception of consumers." 471 U.S.at 651. However, *Zauderer* involved compelled speech that is "strictly factual and uncontroversial." Many of the FOP labeling schemes that FDA intends to test are not "strictly factual *and* uncontroversial." The test is phrased in the conjunctive; the speech sought to be compelled must be *both* "strictly factual" *and* "uncontroversial."

A number of the proposed schemes go beyond a strictly factual disclosure of the number of calories or other nutrients. Several of the schemes involve a subjective characterization of the perceived virtuousness ("high/medium/low" or "high in") of foods based on only three highlighted nutrients—and some would mandate that foods bear color-coded symbols (red/yellow/green, like a stoplight) in order to signal which foods are deemed to be preferred and which are not. Reducing a food's entire contribution to the diet to whether it is "high in" or "high", "medium," or "low" in one to three nutrients is overly simplistic and does not help educate consumers on how to improve their dietary pattern. And consumers have varying dietary requirements and preferences; purporting to assign foods a one-size-fits all characterization to a food very well could prove confusing or even dangerous to consumers in such circumstances. None of this is "factual and uncontroversial."

Zauderer also suggests that it is not enough to show merely that the speech is "factual and uncontroversial"; the speech must be corrective of an omission that would otherwise be *deceptive*. Thus, unless FDA were to conclude, based on substantial evidence, that failure to require industry to include the relevant information on all product labels would result in *deception* of consumers, *and* that the compelled language is both "factual and uncontroversial," any attempt to mandate compelled speech may be susceptible to challenge.

Zauderer and its progeny also would require the agency to show, on top of the above, that the proposed compelled speech is reasonably related to a legitimate government interest and is not unduly burdensome. For all the reasons we've explained, it may prove difficult to convince a court that a compelled speech regime is reasonably related to a legitimate government interest when a wealth of *other* statutes and regulations further that interest in a balanced way. And there can be no doubt that forcing manufacturers to comply with a mandatory FOP labeling scheme would be unduly burdensome; compliance would likely cost manufacturers millions of dollars in many cases.

We recognize the FDA has not proposed to mandate any FOP labeling scheme, and FDA certainly has legal authority to conduct consumer research on such labeling options, but we would strongly recommend that the agency critically assess the types of schemes that would risk a statutory authority or First Amendment violation before moving forward with proposing any mandatory FOP scheme.

Design considerations, such as placement and color

Several of the FOP labeling schemes to be tested include an option with color coding, with green for "low", yellow for "medium", and red for "high". FMI believes that color coding is overly simplistic, confusing, and unlikely to achieve the goal of meaningfully educating consumers on nutrition. Additionally, the use of multiple colors adds enormous cost due to the need for additional printing plates. We strongly encourage FDA to avoid schemes with colors because the cost burden imposed by such schemes and potential for consumer confusion far outweigh any benefit.

The general intent of the traffic light type color coding is clear: red means stop, yellow is cautionary, and green means go. These messages, while clear cut in theory, create a confusing application for consumers and foods in the real world. If a product were to have all three colors (or even two), a consumer would be confused about whether they should choose or avoid the product. Additionally, if red means stop, a product with some added sugars but substantial positive nutrition overall would be viewed as wholly negative and not considered to be part of a healthy diet. Examples are too numerous to detail but could include key nutritional staples such as flavored low-fat milk, whole grain/high fiber cereal, or any number of other types of foods and beverages recommended in the DGA and MyPlate. Alternatively, green would mean go or inherently suggest a healthful, nutritious product, and again examples are too numerous to detail, but many foods and beverages with little or no nutritional value would carry three "green lights." Such a simplistic approach does not encourage a deeper dive into the nutritional components of a product or fit with the FDA's stated goal of putting food in the context of consumers' daily diets.

FMI also recommends that the FDA allow for maximum flexibility regarding the placement and size of the FOP icon to limit undue costs to industry. We are concerned that mandating the FOP label to appear on a specific part of a package could cause a costly, complete package redesign. More specifically, it is important to our members that any FOP scheme does not conflict with existing logos and other crucial design pieces, as redesign is costly and existing logos are important to product recognition, etc. In addition, we recommend that the FDA consider modified schemes that could be used to accommodate very small package sizes to ensure proper fit and readability (e.g., soda bottle, candy bar, gum) for all products. A scheme involving iconography that would not fit or would be too small to be readable would not be useful to consumers.

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We greatly appreciate the opportunity to comment on the important topic of front-of-package nutrition labeling and are happy to discuss the above in greater detail should you have any questions.

Sincerely,

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