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Response to Comment from Consumer Brands Association and FMI – The Food Industry Association on Citizen Petition for the U.S. Food and Drug Administration to adopt a mandatory, nutrient-specific, interpretive front-of-package nutrition labeling system for all packaged foods sold in the United States (FDA-2022-P-1832)

On August 4, 2022, Center for Science in the Public Interest (CSPI) submitted a citizen petition requesting that the Commissioner of Food and Drugs amend 21 C.F.R. § 101 to require on the principal display panel of a food an easy-to-understand, standardized system that is 1) mandatory, 2) nutrient-specific, 3) includes calories, and is 4) interpretive with respect to the levels of added sugar, sodium, and saturated fat per serving.

Since our petition was submitted, the docket has received over 7,700 comments, over 5,500 of which are posted as of today. The overwhelming majority of comments support the petition. These supportive comments include submissions from academics at Harvard T.H. Chan School of Public Health, the University of Pennsylvania and the University of North Carolina-Chapel Hill, prominent NGOs, including the American Public Health Association, American Heart Association, Consumer Federation of America, Consumer Reports, American Cancer Society Cancer Action Network., and the New York City Department of Health and Mental Hygiene.

To our knowledge, only one comment in this petition docket opposes the petition. Consumer Brands Association and FMI - The Food Industry Association, both food industry trade associations (Industry Association Commenters), submitted their joint comment on October 25, 2022.

The Industry Association Commenters raise unconvincing legal arguments and downplay the scientific evidence supporting front-of-package nutrition labeling (FOPNL). These arguments provide no basis for the U.S. Food and Drug Administration (FDA) to hesitate in proceeding with FOPNL. In fact, the deficiencies of the Industry Association Commenters' arguments only affirm that FDA has both authority and a sound scientific basis to move forward expeditiously with a rulemaking to require such labeling. We share quotes from the Industry Association Commentors and respond to their legal and scientific arguments below.

I. Legal arguments

The Industry Association Commenters' language betrays their weak position. Rather than claim that FDA does not have authority to mandate FOPNL, they merely state that FDA "must carefully assess its statutory authority." They write that the FOPNL we requested in our petition poses "potential" constitutional issues, rather than saying that it definitively does.

As the discussion below establishes, there are no legal barriers preventing FDA from developing mandatory FOPNL. The Nutrition Labeling and Education Act of 1990 (NLEA) gives the FDA authority to require that nutrition information be conveyed in the manner that we have requested, and FDA can craft mandatory FOPNL that is constitutional under the First Amendment.

1. The Industry Association Commenters: "We have not identified any instance where Congress has given FDA authority to require a separate statement of nutrient content on the label, outside the Nutrition Facts label."

Response:

The Industry Association Commenters' argument that the NLEA does not give FDA authority to require nutrition information outside of, and duplicative of, the Nutrition Facts label is not grounded in the statutory text and suffers from hindsight bias.

Their comment fails to quote statutory language supporting their argument, because none exists. The NLEA states that:

> The Secretary of Health and Human Services shall...issue final regulations to implement the requirements of [section 403(q) of the Federal Food, Drug, and Cosmetic Act]. Such regulations shall require the required information to be conveyed to the public 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.[1]

Nothing in the NLEA, codified as 21 U.S.C. § 343(q), prevents FDA from requiring that certain nutrition information appear in more than one place on a package. Nor does the NLEA state that the information must be conveyed as a contiguous set, or make any mention of the Nutrition Facts label (NFL).[2] Rather, Congress directed FDA to develop mandatory nutrition labeling and allowed the agency, with assistance from the National Academy of Sciences, to determine the format that such nutrition labeling would take.[3] A House Report for the NLEA states that "in order to present nutrition information in a manner that facilities the public's understanding, the Secretary may choose among a variety of options."[4]

FDA contemplated several different formats while designing the NFL (see Figure 1). David Kessler, the FDA Commissioner when the agency designed and finalized the label, illustrated the design evolution in a 2003 article. The agency designed at least four options that differed from

the 1993 final version, some of which included “high,” “medium,” and “low” claims (see black “L,” “M,” and “H” symbols next to black column in the top left label image in Figure 1).

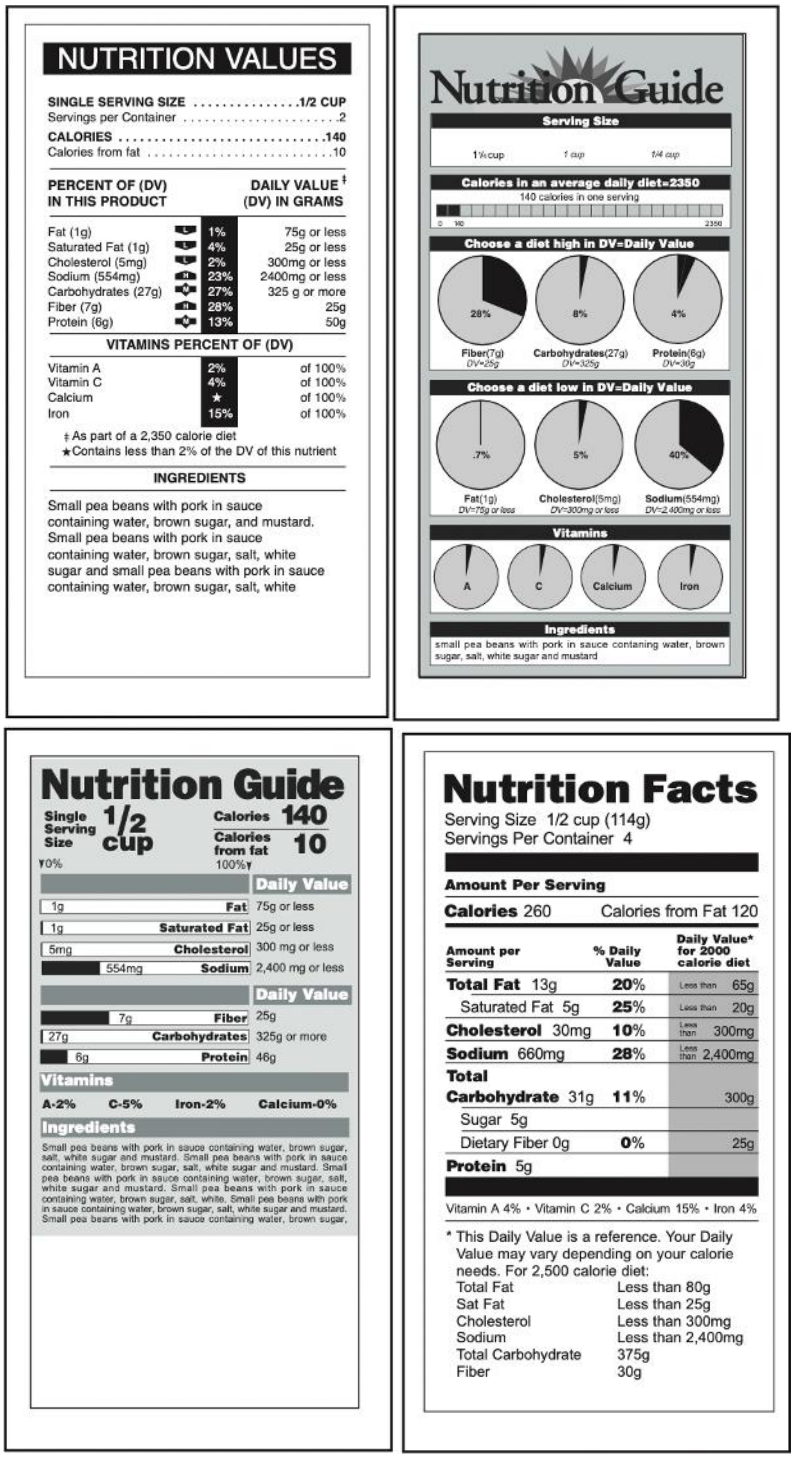

Figure 1. Evolution of the Nutrition Facts Label design during FDA’s rulemaking process.[5]

Although all of the rejected labels and the final NLF format do present nutrition information as a contiguous set, it is not a statutory requirement. The Industry Association Commenters’ repeated

mention of the NFL in the context of the NLEA's statutory language reverses history by suggesting that the statutory language did not provide for mentions beyond the NFL, when, in fact, the NFL did not yet exist.

2. **The Industry Association Commenters: "[A]ll the regulatory authority provided to FDA related to mandatory nutrition information refers to factual information, rather than interpretation of it."**

Response:

Our petition calls for FOPNL that is interpretive with respect to the levels of added sugars, sodium, and saturated fat, meaning that it conveys the relative significance of these nutrients in the context of the total daily diet.

As noted above, the NLEA gives FDA authority to require such information by stating that the agency may "require the required [nutrition] information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of the total daily diet."[6] This language gives FDA broad authority to convey nutrition information in a variety of ways, including through interpretive means, authority that the NLEA House Report cited above supports. This report explicitly suggested that the agency could use "descriptive terms such as 'high,' 'medium' and 'low' or...universal symbols to indicate desirable or undesirable levels of particular nutrients."[7]

Existing authority therefore allows FDA to require interpretive nutrition information on food labels to the extent that it assists consumers in understanding the relative significance of nutrient content in the context of overall diet. FDA's regulations implementing the NLEA already implement this authority by requiring limited interpretive information on the NFL in the form of a percent of the Daily Value (DV) for certain nutrients.[8] The percent DV conveys to the consumer how much a nutrient in a serving of food or beverage contributes to a total daily diet,[9] thus interpreting the amount of a nutrient beyond merely providing the number of grams, milligrams, or micrograms of it present in the food or beverage.

As our citizen petition described in detail, subsequent evidence has demonstrated that the interpretive information presented in the NFP is not sufficient to allow consumers, particularly those with lower educational attainment, to "readily observe and comprehend such information." FDA's own 2019 Food Safety and Nutrition Survey shows that the NFL has low utilization rates.[10] In light of this evidence, it is reasonable for FDA to try a different approach that includes additional interpretive information on the front of package.

3. **The Industry Association Commenters: "In light of [major questions doctrine] 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 interpretive nutrient labeling."**

Response:

The Industry Association Commenters cite the major questions doctrine as a possible barrier to mandatory FOPNL, noting that "Congress must provide clear direction to regulatory agencies . . . if the case implicates the 'major question[s] doctrine.'" However, mandatory FOPNL is a natural outgrowth of the nutrition labeling that FDA already regulates. Therefore, it would not invoke the major questions doctrine.

In *West Virginia v. EPA*, the Supreme Court laid out a two-prong test for identifying "extraordinary cases" where a "clear congressional authorization" is required to grant broad regulatory authority.[11] This inquiry involves asking whether the asserted regulatory authority is 1) "unheralded" and 2) represents a "transformative" change in the agency's authority.[12] If both prongs are met, the major questions doctrine applies and the court then considers if the proposed regulatory action will have "vast economic and political significance" (though this question is not determinative)[13] and if the agency has a "clear congressional authorization" to act.[14]

The Supreme Court held that *West Virginia* was a major questions doctrine case because, in issuing its Clean Power Plan Rule, EPA sought to use an "ancillary provision"[15] to effect a paradigm shift in the way it regulates coal-powered plants.[16] This shift would have remade the national energy industry by significantly reducing the role of coal-powered plants in favor of energy-generation by natural gas-fired plants and renewables sources like solar and wind.[17] Having found that the major questions doctrine applied, the Court then determined that the statute EPA relied on for authority was too vague to be a clear congressional authorization.[18] In 2021, in *Ala. Ass'n of Realtors v. HHS*, the Supreme Court also found that the major questions doctrine barred the Centers for Disease Control and Prevention's (CDC) nationwide moratorium on evictions, one of the agency's responses to COVID-19.[19] CDC implemented the moratorium under the Public Health Services Act, which the Supreme Court characterized as "rarely invoked" and never to justify an eviction moratorium.[20]

While we disagree with the Supreme Court's narrow statutory interpretations and holdings in *West Virginia* and *Ala. Ass'n of Realtors v. HHS,* mandatory FOPNL would not implicate the major questions doctrine regardless because it would not be an unheralded FDA action, nor would it be a transformative change in the agency's regulatory authority. The NLEA is not an ancillary or little-used statute; FDA used it in 1993 to implement the NFL and in 2016 to include added sugars in the NFL. FOPNL would be a natural extension of nutrition disclosures that FDA already requires, by taking information already required to be disclosed on a food label, and modifying its placement and formatting.

Even if a court found that mandatory FOPNL did implicate the major questions doctrine, mandatory FOPNL would not be a matter of "vast economic and political significance" and, as discussed above, FDA has clear statutory authority to require it. Although FOPNL would result in some costs to food and beverage manufacturers, it would not impact the industry on the scale at which the EPA's Clean Power Plan Rule or the CDC's nationwide eviction moratorium would have affected the energy and housing sectors, respectively. In *West Virginia*, the Supreme Court noted that, in addition to compliance costs, the Clean Power Plan Rule would have "require[d] the retirement of dozens of coal-fired plants, and eliminate[d] tens of thousands of jobs."[21] While an FOPNL rulemaking will require companies to phase in new label designs (a process that already occurs regularly within the food industry), it is unlikely to lead any food or beverage manufacturers to shut down or to lay off workers on a large scale. And in *Ala. Ass'n of Realtors*, the Court wrote that the nearly $50 billion that Congress had provided in emergency rental assistance in less than two years was "a reasonable proxy of the moratorium's economic impact.[22] This cost is far higher than the $4.9 billion in costs over 20 years that FDA estimated for the 2016 food and supplement labeling changes that included, but were not limited to, updating the NFL.[23]

4. **The Industry Association Commenters: "It is questionable whether the speech sought to be compelled by the petitioners is 'strictly factual *and* uncontroversial.'"**

Response:

Our petition notes that, under the Supreme Court's decision in *Zauderer v. Office of Disciplinary Council*, compelled commercial speech must be 1) strictly factual and uncontroversial, 2) reasonably related to a legitimate government interest, and 3) not unjustified or unduly burdensome.[24] While the precise nature of FDA's future FOPNL rulemaking has not been determined, the mandatory FOPNL sought in our petition could easily satisfy *Zauderer*'s first prong: it could be strictly factual and uncontroversial by providing objective information about the levels of specific nutrients tied to longstanding, widely-accepted DVs based on a 2,000-calorie diet. Indeed, it would be based upon information FDA itself requires elsewhere on the package.

The Industry Association Commenters acknowledge that front-of-package calorie disclosures meet the constitutional requirements but then errantly characterize labels that are interpretive with respect to the levels of added sugar, sodium, and saturated fat per serving as subjective, and therefore unconstitutional. The Industry Association Commenters do so by claiming that such labels represent "a subjective characterization of the perceived virtuousness ("high/medium/low") of foods based on only three highlighted nutrients."

This understanding of the request in our petition for interpretive FOPNL that includes added sugar, sodium, and saturated fat labels is inaccurate. Our petition specifically does not seek an FOPNL scheme that rates the "perceived virtuousness" of the entire product. Instead, it asks FDA to develop interpretive labeling that allows consumers to identify the relative significance

in the diet of nutrients identified by the Dietary Guidelines for Americans (DGA) as particularly significant.

The Industry Association Commenters also err in confusing "interpretive" with subjective. In this context, "interpretive" means an objective, and therefore factual, statement about the relative significance of the amount of specific nutrients in the context of the total daily diet, based on existing DVs. FDA has already demonstrated how to set objective "high" nutrient thresholds based on DVs in other labeling contexts. The minimum threshold for making beneficial nutrient content claims is 20 percent of DVs.[25] The agency also sets the disclosure levels for nutrient content claims[26] and the disqualifying levels for health claims[27] regarding fat, saturated fat, sodium, and cholesterol at 20 percent of DVs.[28] Although, the nutrient content claims and health claims regulations do not explicitly disclose on the package that such levels are "high," they are objective, factual thresholds that the FDA determined were associated with elevated risk of exceeding recommended daily limits. FDA set the 20 percent level for all three of these categories of claims using the same process "based on...DRVs and available information on food composition and dietary intake patterns. . .[with] the assumption[] that diets generally include approximately 20 food/beverage items per day."[29]

FDA also objectively characterizes nutrient levels as "high" or "low" in consumer education materials (see Figure 2).[30] The agency advises consumers that the percent DV can be used "to determine if a serving of [a] food is high or low in an individual nutrient" and states that "5% DV or less of a nutrient per serving is considered low" and "20% DV or more of a nutrient per serving is considered high."[31] According to former FDA Commissioner David Kessler, this definition of low is based on the same 20 servings of food/beverage items per day intake pattern.[32] That FDA has in the past engaged in a science-based process to set "high" and "low" levels that are tied to widely-accepted DVs shows that the agency will be able to set "high," "medium," and "low" or just "high" levels for FOPNL that are likewise objective interpretations of the levels of specific nutrients in the context of the total daily diet, as opposed to characterizations of the food's overall virtue.

Sample Label for Frozen Lasagna

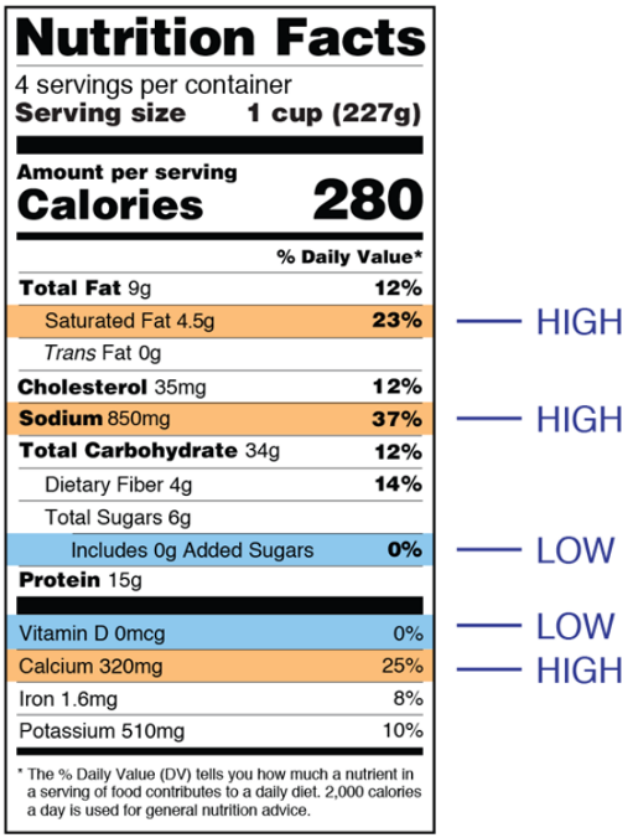

Figure 2. FDA uses objective characterizations of levels of nutrients in a food as "high" or "low" in current consumer education materials[33]

As noted in our petition, courts have already found New York City's sodium warnings and calorie labeling on chain restaurant menus to be factual and uncontroversial.[34] And a FOPNL system with "high," "medium," and "low" or "high in" labels for certain nutrients also would not be required to contain exaggerated graphics that could be open to different interpretations,[35] advice to avoid the product,[36] or other attributes that have led courts to find cigarette warnings not strictly factual and uncontroversial.

Therefore, FDA can craft a FOPNL system that is strictly factual and uncontroversial.

5. **The Industry Association Commenters: "Zauderer itself 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*."**

Response:

The Industry Association Commenters' assertion that compelled commercial speech must be corrective of consumer deception mischaracterizes *Zauderer*. While preventing consumer deception was the government interest in the *Zauderer* case itself, every circuit court that has considered the question of whether *Zauderer* extends beyond preventing consumer deception has

held that it does.[37] For example, in 2019, in *CTIA – The Wireless Ass'n v. City of Berkeley*, the Ninth Circuit held that, if it was substantial, the government's interest in "furthering public health" was sufficient to justify compelled speech under *Zauderer*.[38] In reaching that conclusion, the court noted that "[o]ur sister circuits have...held under *Zauderer* that the prevention of consumer deception is not the only government interest that may permissibly be furthered by compelled commercial speech."[39] Although it has yet to weigh in, as the Ninth Circuit stated in *CTIA*, the Supreme Court also "signaled its agreement with this reading of *Zauderer*"[40] in *Nat'l Inst. of Family & Life Associates v. Becerra* by "not question[ing] the legality of health and safety warnings, long considered permissible, or purely factual and uncontroversial disclosures about commercial products."[41]

As noted in our petition, mandatory FOPNL would help consumers be better informed, a legitimate government interest that courts have recognized in other cases related to labeling, including USDA's mandatory country-of-origin labeling for meat and Vermont's labeling requirement for mercury-containing light bulbs.[42]

6. **The Industry Association Commenters: "[F]orcing manufacturers to comply with the petitioners' proposed new requirements would be unduly burdensome; compliance would likely cost manufacturers millions of dollars."**

Response:

The third prong of the *Zauderer* test asserts that compelled commercial speech must be "not unjustified or unduly burdensome." In assessing the third prong of *Zauderer*, courts focus on whether the disclosure will physically "drown out" the advertiser's message so as to "effectively rule out the possibility" of advertising,[43] rather than on the compelled disclosure's financial cost to the advertiser.[44] In other words, courts assess the free speech burden on advertisers, not the financial one. Therefore, Industry Association Commenters' concern about cost to manufacturers is irrelevant to the First Amendment analysis. In assessing the burden on free speech, courts often look at the size of the compelled disclosure relative to the overall advertisement. Our petition cites disclosure sizes that courts have found to be constitutional, precedents which FDA should consider when designing FOPNL. Although FOPNL outside of the United States is not subject to First Amendment considerations, other countries have found ways to ensure that such labeling does not occupy inordinate package space. For example, Mexico sets the size of the warning based on the package size—the smaller the package, the smaller the warning icon.[45]

Even if courts did consider the financial burden on affected companies, our petition's Economic Impact section cites modeling studies of previous food relabeling and reformulation efforts showing that, although industry would incur some costs, such costs are modest at best, particularly when industry is permitted to phase in changes as part of its existing label design and printing cycle. Furthermore, FOPNL would not necessitate reformulation; rather manufacturers would voluntarily undertake it because consumers are now better informed and want different products as a result.

II. Scientific arguments

The Industry Association Commenters provide an unconvincing critique of the evidence cited in our petition using cherry-picked data and raise concerns regarding the efficacy of interpretive FOPNL that are easily refuted by existing data.

1. The Industry Association Commenters: "[W]hile some of the studies [cited in the petition] show statistically significant changes in nutrient content of purchased products, many of the changes are not meaningful in terms of an overall diet."

Response:

The Industry Association Commenters cite a few studies regarding the real-world effects of traffic light labels to make the case that FOPNL will not have meaningful effects on diet quality. Meanwhile, the Industry Association Commenters did not reference any systematic review of experimental research nor any real-world studies examining changes in consumer habits and nutritional quality in countries that have adopted front-of-package nutrient warnings.

In contrast, our petition cited a systematic review of more than 300 experimental studies which found that FOPNL can be designed to have meaningful effects. For example, the two studies included in the review that compared the effects of front-of-package nutrient warnings versus control on the overall healthfulness of selected and purchased foods found that nutrient warnings led to a 26 percent increase in overall healthfulness.[46] For reference, the average American's diet earns a HEI score of 58 out of 100,[47] and a 5-to-6-point increase in a population's Healthy Eating Index (HEI) score is considered a meaningful change.[48] A 26 percent increase in HEI would equate to an increase of 15 points, raising the average HEI from 58 to 73.

To demonstrate a lack of real-world effect, the Industry Association Commenters cited five studies evaluating policies in the United Kingdom and Ecuador (that were also cited in our petition) but omitted the five additional studies cited in our petition that demonstrate the greater success of front-of-package nutrient warnings in Chile. Neither the United Kingdom nor Ecuador has a FOPNL system that fully aligns with the request in our petition—the United Kingdom has only adopted a *voluntary* front-of-package traffic light system,[49] and Ecuador's mandatory traffic light labels are not required to be placed on the *front* of food packages.[50] As described in our petition, Chile's nutrient warnings—which are mandatory and placed on the front of packages—had much greater effects. An evaluation study comparing purchases from January 2015 through June 2016 (before FOPNL was implemented) versus July 2016 through December 2017 (after FOPNL was implemented) found a 3.5 percent decline in per capita calories, 10.2 percent decline in per capita calories from sugar, 3.9 percent decline in per capita calories from saturated fat, and 4.7 percent decline in per capita milligrams of sodium purchased from packaged foods.[51] These findings are all statistically significant *and* meaningful. A previous modeling study estimated that a much smaller 5.6 percent decrease in added sugars intake from packaged foods in the United States alone would prevent 354,400 cases of cardiovascular disease and 599,300 cases of diabetes over 20 years, resulting in $31 billion in net healthcare cost savings.[52]

2. **The Industry Association Commenters: "We are concerned that interpretive systems, such as a red/green light system, will raise unnecessary fear in consumers based on a single limiter nutrient without providing meaningful information as to how that food item might fit into overall healthy eating patterns."**

Response:

The Industry Association Commenters are incorrect in their assertion that interpretive, nutrient-specific FOPNL would not provide consumers with meaningful information about how foods fit into their overall diets.

Limiting sodium, added sugars, and saturated fat is essential to adhering to a healthy eating pattern. Every day, the average American adult consumes 50% more sodium, 40% more added sugars, and 40% more saturated fat than is recommended by the DGA.[53] Interpretive FOPNL improves consumers' ability to understand the percent DV for these nutrients and assess whether products have higher than recommended levels of these nutrients.[54]

Interpretive FOPNL also helps correct consumers' misperceptions about products (including those produced by members of the Industry Association Commenters) whose labels currently highlight only a single "positive" nutrient. For example, fruit drinks comprised primarily of water and added sugars, and fortified with vitamin C, often bear "100% vitamin C" claims on their front labels without disclosing their high added sugar content. A randomized controlled experiment found that nutrient warnings can correct misperceptions about the added sugar and juice content of these drinks.[55]

With respect to the Industry Association Commenters' concern about interpretive FOPNL raising unnecessary fear, we are confident that FDA can design an interpretive FOPNL label that assists consumers in achieving healthier diets without prompting unnecessary fear about specific foods or nutrients.

In conclusion, FDA has clear authority to require FOPNL under the NLEA and can design a policy that does not unconstitutionally infringe corporate free speech. In asserting that FOPNL will not have a "meaningful" effect, the Industry Association Commenters ignored the expansive body of scientific evidence demonstrating the efficacy of interpretive, nutrient-specific FOPNL at improving food choices and informing consumers. FDA is on solid ground and should proceed with this bold effort to support consumer education and public health.

[1] Pub. L. No. 101-535, 104 Stat. 2353 (1990).
[2] 21 U.S.C. § 343(q).
[3] H.R. Rep. No. 101-538, at 17 (1990).
[4] *Id.* at 18.
[5] Kessler D, et al. Developing the "Nutrition Facts" Food Label. *Harvard Health Public Review*. Fall 2003. Vol. 4. No. 2.

[6] Pub. L. No. 101-535, 104 Stat. 2353 (1990).
[7] H.R. Rep. 101-538, at 18 (1990).
[8] 21 C.F.R. § 101.9(d)(7)(ii).
[9] U.S. Food and Drug Administration. *The Lows and Highs of Percent Daily Value on the New Nutrition Facts Label*. 2022. https://www.fda.gov/food/new-nutrition-facts-label/lows-and-highs-percent-daily-value-new-nutrition-facts-label. Accessed February 2, 2023.
[10] U.S. Food & Drug Administration. *FSANS Explorer*. https://fsans-explorer.fda.gov/. Accessed April 10, 2023. (Select "Frequencies," select "Pick a Survey Question, select "Nutrition Facts Label" from "Choose Survey Topic" drop-down menu, select "When buying a food product for the first time, how often do you use the Nutrition Facts Label?" from "Choose Survey Question" drop-down menu. Only 56.5 percent answered "Always" or "Most of the time.")
[11] *West Virginia v. EPA*, 142 S. Ct. 2587, 2609 (2022) (citing *Util. Air Regulatory Group v. EPA*, 573 U.S. 302, 324 (2014)).
[12] *Id.* at 2610.
[13] *Id.* at 2605.
[14] *Id.* at 2614.
[15] *Id*. at 2610.
[16] *Id.* at 2612.
[17] *Id.* at 2603.
[18] *Id*. at 2614-16.
[19] *Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485 (2021) (per curiam).
[20] *Id*. at 2487.
[21] *West Virginia*, 142 S. Ct. at 2604.
[22] *Ala. Ass'n of Realtors*, 141 S. Ct. at 2489.
[23] United States Food & Drug Administration. Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis. Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Extension of Compliance Dates (Docket No. FDA-2012-N-1210 and FDA-2004-N-0258 (Formerly Docket No.2004N-0456)). April 2018. (Our original petition incorrectly cited the costs as $4.8 billion over 20 years.)
[24] *Zauderer v. Office of Disciplinary Council of Supreme Court*, 471 U.S. 626, 651 (1985).
[25] 21 C.F.R. 101.54(b)(1).
[26] 21 C.F.R. § 101.13(h)(1).
[27] 21 C.F.R. § 101.14(a)(4).
[28] Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2308 (Jan. 6, 1993). FDA set these levels in 1993 and has not adjusted them since its 2016 NFL updates, therefore they are 20 percent of the old levels.
[29] Food Labeling: General Requirements for Health Claims for Food, 58 Fed. Reg. 2478, 2493-2494 (Jan. 6, 1993); Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2308 (Jan. 6, 1993).
[30] U.S. Food & Drug Administration. *The Lows and Highs of Percent Daily Value on the New Nutrition Facts Label*.
[31] *Id*.
[32] Kessler D, et al. Developing the "Nutrition Facts" Food Label. *Harvard Health Public Review*. Fall 2003. Vol. 4. No. 2.
[33] U.S. Food and Drug Administration. *The Lows and Highs of Percent Daily Value on the New Nutrition Facts Label*.
[34] *Nat'l Rest. Ass'n v. New York City Dept. of Health & Mental Hygiene*, 148 A.D.3rd 169 (App. Div. 1st Dept. 2017); *N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 556 F.3d 114 (2009).
[35] *R.J. Reynolds Tobacco Co. Plaintiffs v. United States*, 2022 U.S. Dist. LEXIS 221015, 30-34 (2022); *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1216 (2012).

[36] *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1216-17 (2012).
[37] *CTIA – The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 844 (9th Cir. 2019); *Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 556 (6th Cir. 2012); *N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 556 F.3d 114, 133 (2nd Cir. 2009); *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 310 n. 8 (1st Cir. 2005); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 115 (2nd Cir. 2001).
[38] *CTIA*, 928 F.3d at 844.
[39] *Id*.
[40] *Id*.
[41] *Id*. (quoting *Nat'l Inst. of Family & Life Associates v. Becerra*, 138 S. Ct. 2361, 2376 (2018).
[42] *Am. Meat Inst. v. United States Dep't of Agric*., 760 F.3d 18, 27 (DC Cir. 2014); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 115 (2nd Cir. 2001).
[43] *Nat'l Ins. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2378 (2018).
[44] *Disc.Tobacco*, 674 F.3d 509; *Loan Payment Admin., LLC v. Hubanks*, 821 Fed. Appx. 687 (9th Cir. 2020); *Am. Bev. Ass'n v. City & Cty. of S.F.*, 916 F.3d 749, 757 (9th Cir. 2019).
[45] Norma Oficial Mexicana, NOM-051-SCFI/SSA1-2010, Especificaciones generales de etiquetado para alimentos y bebidas no alcohólicas preenvasados-Información comercial y sanitaria, Diario Oficial de la Federación [DOF]. 27-3-2020 (Mex.).
[46] Song J, Brown MK, Tan M, et al. Impact of color-coded and warning nutrition labelling schemes: A systematic review and network meta-analysis. *PLoS Med*. Oct 2021;18(10):e1003765.
[47] United States Department of Agriculture. *HEI Scores for Americans*. https://www.fns.usda.gov/hei-scores-americans. Accessed April 4, 2023.
[48] Kirkpatrick 2018. Applications of the Healthy Eating Index for surveillance, epidemiology, and intervention research: considerations and caveats. *Journal of the Academy of Nutrition and Dietetics*. 2018;118(9):1603-1621.
[49] United Kingdom. Department of Health and Social Care; Food Standards Agency; Welsh Government; Food Standards Scotland. *Guide to creating a front of pack (FoP) nutrition label for pre-packed products sold through retail outlets*. 5. November 2016. https://www.food.gov.uk/sites/default/files/media/document/fop-guidance_0.pdf. Accessed April 11, 2023.
[50] Ecuador. Ministerio de Industria y Productividad. Resolucion No 14511: Reglamento Tecnico Ecuatoriano RTE INEN 022 (2R) "Rotulado de productos Alimenticos procesados, envasados y empaquetados." 2013.
[51] Taillie LS, Bercholz M, Popkin B, Reyes M, Colchero MA, Corvalán C. Changes in food purchases after the Chilean policies on food labelling, marketing, and sales in schools: a before and after study. *Lancet Planetary Health*. 2021;5(8):e526-e533.
[52] Huang Y, Kypridemos C, Liu Jm et al. Cost-effectiveness of the US Food and Drug Administration added sugar labeling policy for improving diet and health. *Circulation.* 2019;139:2613-2624. DOI: 10.1161/CIRCULATIONAHA.118.036751.
[53] U.S. Department of Agriculture. What We Eat in America, NHANES 2017-March 2020 Prepandemic. Nutrient Intakes from Food and Beverages, by Gender and Age. https://www.ars.usda.gov/ARSUserFiles/80400530/pdf/1720/Table_1_NIN_GEN_1720.pdf. Accessed April 4, 2023; U.S. Department of Agriculture & U.S. Department of Health and Human Services. What We Eat in America, Food Pattern Equivalent Intakes from Food, NHANES 2017-2018. https://www.ars.usda.gov/ARSUserFiles/80400530/pdf/FPED/tables_1-4_FPED_1718.pdf.; U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans 2020-2025.* https://www.dietaryguidelines.gov/sites/default/files/2021-03/Dietary_Guidelines_for_Americans-2020-2025.pdf. Accessed April 11, 2023.
[54] Deliza R, de Alcantara M, Pereira R, Ares G. How do different warning signs compare with the guideline daily amount and traffic-light system? Food Quality and Preference. 2020;80doi:10.1016/j.foodqual.2019.103821.
[55] Musicus AA, Roberto CA, Moran AJ, et al. Effect of front-of-package information, fruit imagery, and high-added sugar warning labels on parent beverage choices for children. *JAMA Network Open.* 2022;5(10):e2236384.