Legal Backgrounder
Vol. 39 No. 6 April 5, 2024

Washington Legal Foundation
Advocate for Freedom and Justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302 wlf.org

FDA Lacks Statutory Authority to Mandate Front-of-Pack Nutrition Labeling

by Martin J. Hahn, Veronica Colas, Andrea Bruce, and Trenton H. Norris

The White House Strategy on Hunger, Nutrition & Health, released by the Biden Administration in September 2022, calls on the Food and Drug Administration (FDA) to develop a standardized front-of-pack (FOP) nutrition labeling system for foods to "help consumers . . . quickly and easily identify foods that are part of a healthy eating pattern."[1] The White House directive came shortly after three NGOs petitioned FDA to mandate FOP nutrition labeling. The NGOs urged FDA to adopt a FOP scheme that provides information about calories, saturated fat, sodium, and added sugars and that for the latter three would convey an evaluative judgment about the amount present (e.g., high/medium/low).[2]

FDA acted quickly in response to the White House direction. It completed an evaluation of the scientific literature concerning FOP systems and has fielded a quantitative assessment of possible designs for FOP nutrition labeling with consumers.[3] Indeed, FDA's most recent agenda of planned regulatory activity indicates it intends to publish a proposed rule requiring FOP labeling in June 2024. Yet despite all the agency activity and its aggressive timeline for rulemaking, a critical threshold legal question remains unresolved—does FDA have the legal authority under the Federal Food, Drug and Cosmetic Act (FFDCA) to mandate FOP nutrition labeling of this type? We conclude the answer is no.

The NGOs contend the Nutrition Labeling and Education Act of 1990 (NLEA) confers the necessary authority on FDA. We agree NLEA is the right place to look. Prior to its passage, FDA characterized its authority to mandate nutrition labeling on all foods as "unclear," a fact cited by NLEA's sponsors as a reason for the law's passage, so FDA cannot credibly look to other provisions in the FFDCA for authority for this type of action.[4]

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[1] *See* The White House, Biden-Harris Administration National Strategy on Hunger, Nutrition, and Health 22 (2022).

[2] *See generally* Ctr. for Sci. in the Pub. Interest, 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 (2022).

[3] Notably, the designs tested with consumers include saturated fat, sodium, and added sugars but do not include calories despite the proven relationship between calorie intake and overweight and obesity.

[4] H.R. Rep. No. 101-538, at 7 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337 ("The purpose of this legislation is to clarify and to strengthen the Food and Drug Administration's legal authority to require nutrition labeling on foods . . . ."). Although FDA attempted in 1990 to move forward with mandatory nutrition labeling despite the lack of clarity surrounding its authority to do so, publishing a proposed rule that would have required it, the agency relied entirely on *Chevron* for its legal basis to do so. Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, 55 Fed. Reg. 29487, 29491-92 (proposed July 19, 1990).

Martin J. Hahn is a Partner, **Veronica Colas** is Counsel, **Andrea Bruce** is Senior Counsel, and **Trenton H. Norris** is a Partner, with Hogan Lovells.

And a careful reading of the authority provided by NLEA exposes critical gaps in FDA's authority to move forward as planned. The plain language of NLEA mandated the use of nutrition information and also allowed for the use of voluntary nutrient content and health claims. For the mandatory information, NLEA's drafters were very detailed and precise about the nutrition information the legislation authorized FDA to require. The drafters did not simply direct FDA to require nutrition labeling and defer to the agency's best judgment on how to accomplish it. Instead, they authorized FDA to mandate a highly specific, *complete set* of information consisting of serving size, 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.[5]

NLEA authorized nothing else by way of *mandatory* nutrition information. There is no indication in the statute, its legislative history, or elsewhere in the food-related provisions of the FFDCA that FDA has authority to cherry pick select portions of this complete set of information and mandate their disclosure outside of the nutrition facts panel. In short, Congress provided very specific and limited authority when it comes to mandatory nutrition information.

Mandating FOP schemes like those FDA is testing with consumers would exceed the statutory authority and create a conflict within the plain language of NLEA. NLEA and implementing regulations define a nutrient content claim as a statement that characterizes the level of a nutrient of the type required in nutrition labeling.[6] The plain language of the statute and regulations make it clear nutrient content claims are voluntary. The FOP labeling contemplated by FDA would fall within the definition of nutrient content claims because each statement or symbol would characterize the level of the nutrient in the product. The FFDCA does not confer upon FDA the legal authority to ignore the express intent of Congress and impose a mandatory requirement on the use of a nutrient content claim.

Perhaps anticipating the constraints posed by the plain language of NLEA, the NGOs look to other provisions of the FFDCA, uncodified notes in NLEA, and statements in its legislative history as a basis for arguing FDA possesses the necessary authority to move forward. First, they point to a subsection in the FFDCA's general misbranding provision, which requires that all mandatory label information be "prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."[7] Second, they look to an uncodified note in NLEA that calls on FDA to promulgate regulations implementing mandatory nutrition labeling that "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."[8] Finally, they note statements in the legislative history referring to the potential for FDA to require use of descriptive terms such as "high," "medium," and "low" or universal symbols to indicate desirable or undesirable levels of particular nutrients.

In each instance, however, the cited language relates to FDA's authority to mandate comprehensive nutrition information that includes *all* mandatory nutrients. It does not speak to or

[5] 21 U.S.C. § 343(q)(1). This authority is supplemented by provisions that permit FDA to add a required nutrient or remove a nutrient from the aforementioned list if it determines that doing so will assist consumers in maintaining healthy dietary practices. 21 U.S.C. § 343(q)(2). FDA looked to this authority, for example, when it updated its regulations to require trans-fat and added sugars in the nutrition label.

[6] 21 U.S.C. § 343(r); 21 C.F.R. § 101.13(b)(1).

[7] 21 U.S.C. § 343(f).

[8] 21 U.S.C. § 343 note.

otherwise confer authority to require some subset of this information elsewhere on the label apart from the Nutrition Facts Panel (NFP).

The language in NLEA surrounding the grant of mandatory nutrition labeling authority reinforces this point. Immediately following the enumeration of required nutrients, NLEA states: "the Secretary may by regulation require any information required to be placed on the label by this subparagraph . . . to be highlighted on the label . . . by larger type, bold type, or contrasting color if the Secretary determines that such highlighting will assist consumers in maintaining healthy dietary practices."[9] Thus, the statute explicitly delimits the agency's authority to emphasize some elements of the required set of nutrition information over others. FDA can use type size, bolding, and color in the full NFP. Had Congress intended to give FDA flexibility to take steps beyond these, for example by mandating repetition of selected elements of the full NFP elsewhere on the label in the name of rendering them likely to be read and understood by ordinary individuals, as the NGOs claim, it would have listed them. Indeed, if FDA's authority is as unfettered as claimed, a provision enumerating the ways in which FDA may highlight certain elements of the nutrition information (e.g., bolding, type size) would not have been necessary at all. Yet Congress included it.

Further, the NGOs' insistence that the above-cited uncodified note supports their position makes little sense given the language of the note itself, which directs FDA to require that the authorized mandatory nutrition information be conveyed in a manner that enables consumers to understand "its relative significance in the context of a total daily diet." Excerpting portions of the required nutrition information, particularly portions that do not include calories, and presenting them separately does not square with the goal of enhancing consumers' ability to evaluate relative significance. Without information about the level of the other required nutrients and calories, the context of how the food fits into the full daily diet is lost.

That NLEA does not confer authority on FDA to require nutrition information outside the NFP makes sense because in that same legislation Congress gave the agency clear authority to take other steps that are highly effective in improving diets, promoting reformulation, and advancing public health. First, experience teaches that FDA's power to add nutrients to the NFP has a big impact on both consumer and industry behavior. For example, when FDA mandated the declaration of trans fat as part of the Nutrition Fact Panel in 2006,[10] industry swiftly reformulated away from added trans fats and a meaningful reduction in trans fat intake followed.[11] Similar reductions are taking place following FDA's addition of added sugars to the NFP.[12] Second, Congress gave FDA authority to define voluntary nutrient content claims. Leveraging that authority, FDA proposed an updated definition of "healthy" and is in the process of developing a voluntary healthy nutrient content claim symbol, which FDA explains will assist consumers in quickly identifying products that can help maintain healthy dietary practices and encourage reformulation.[13]

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[9] 21 U.S.C. § 343(q)(1).

[10] 21 C.F.R. § 101.9(c)(2)(ii).

[11] *See* FDA Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information, 78 Fed. Reg. 67169, 67171 (Nov. 8, 2013) (commenting that following the agency's 2003 final rule mandating trans-fat declaration, "many food products have been reformulated to eliminate or to substantially reduce the amount of industrially-produced *trans* fatty acids . . . . Based on [the agency's estimates], the mean dietary intake of industrially-produced *trans* fat has decreased significantly since our estimate in the July 2003 final rule. . . . The data that we collected show that many foods (e.g., frozen potato products, most frozen breaded products) have been reformulated to remove PHOs.").

[12] 21 C.F.R. § 101.9(c)(6)(iii).

[13] Other nutrient content claim regulations, such as those for no added sugars, reduced sugar, good source of fiber/protein, low saturated fat, and many others, can and do encourage reformulation or initial formulation of products

Finally, an agency attempt to mandate FOP labeling would present potentially significant constitutional issues. Commercial speech is entitled to First Amendment protection.[14] Fundamentally, it must be "not more extensive than necessary" to achieve the government's purpose.[15] There are many other means for the government to promote its view on the nutritional value of products "'without burdening [businesses] with unwanted speech' . . . most obviously through a public-information campaign."[16]

Courts apply a more deferential level of scrutiny to compelled speech that is "purely factual and uncontroversial."[17] But many of the FOP schemes that FDA is considering are not both "strictly factual *and* uncontroversial." Most go beyond a factual disclosure of the number of calories or other nutrients. Several involve a subjective characterization of the relative virtue ("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.

For all these reasons, efforts to mandate FOP nutrition labeling of any type should be approached with caution. Congress has not provided FDA with the statutory authority to mandate the use of nutrient content claims on the front panel or to treat FOP as a form of "mandatory nutrition labeling," and FDA of course must ensure that any mandated disclosures meet the exacting standards of the First Amendment and not force businesses to promote the government's controversial views of nutritional virtue.

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to qualify for these claims, thus improving the availability of healthful foods. All of these, of course, are claims that manufacturers may make voluntarily, and that FDA has the explicit statutory authority to regulate.

[14] *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557 (1980).

[15] *Id.* at 566.

[16] *Nat'l Inst. of Family Life Advocates v. Becerra*, 585 U.S. 755, 757 (2018) (quoting *Riley v. Nat'l Fed'n of the Blind of North Carolina*, 487 U.S. 781, 800 (1988); *see also Nat'l Ass'n of Wheat Growers v. Bonta*, 85 F.4th 1263, 1283 (9th Cir. 2023).

[17] *Zauderer v. Off. of Disciplinary Couns.*, 471 U.S. 626, 651 (1985).

