COVINGTON & BURLING LLP

October 27, 2022

Memorandum

From: Covington & Burling LLP

Re: Frequently Asked Questions on FDA's Authority to Impose New Front-of-Pack Nutrition Labeling Requirements

Pursuant to the Nutrition Labeling and Education Act of 1990 (NLEA), the U.S. Food and Drug Administration (FDA) has required that most food labels display a product's serving size and nutrient contents in an easy-to-find, quick-to-read nutrition facts label (NFL). In August 2022, the Center for Science in the Public Interest (CSPI), the Association of SNAP Nutrition Education Administrators (ASNNA), and the Association of State Public Health Nutritionists (ASPHN) filed a citizen petition requesting that FDA issue regulations requiring food manufacturers to highlight certain nutritional information on the principal display panel (PDP) of food products (commonly referred to as "front-of-pack" or "FOP" labeling).

Despite the assertions made in the August 2022 citizen petition, FDA's legal authority to mandate FOP labeling is inherently limited by statute, and FDA has concluded in the past that mandatory FOP labeling is beyond its legal authority, absent a finding that such labeling is necessary to prevent consumer deception. The frequently asked questions below address FDA's authority to impose new FOP nutrition labeling requirements and highlight the shortcomings of the legal rationale presented in the August 2022 citizen petition.

1. What legal showings must FDA make before imposing new food labeling requirements?

To require that information appear on a food label or in food labeling, FDA must demonstrate (1) that there is statutory authority for FDA to impose the requirement under the Federal Food, Drug, and Cosmetic Act (FDCA) or otherwise, and (2) that the requirement does not violate the First Amendment, *i.e.*, that FDA has a sufficient constitutional basis to compel the labeling information under applicable constitutional protections for commercial speech. Labeling requirements are unlawful unless they satisfy both of these criteria.

2. What is the legal basis for FDA's current nutrition labeling requirements?

Most of FDA's existing food labeling requirements are premised on specific and express statutory authority. For example, FDA's current NFL requirements, which are codified in 21 C.F.R. 101.9, are expressly authorized by section 403(q) of the FDCA (as amended by the

NLEA), which provides that food is misbranded unless its label or labeling provides certain nutritional information.

FDA can also impose label requirements after concluding that a label would be misleading under sections 403(a)(1) and 201(n) of the FDCA absent specific information. Section 403(a)(1) provides that a food is misbranded if its labeling is false or misleading in any particular, and section 201(n) provides that labeling can be misleading if it fails to reveal facts that are (1) material in light of representations made or suggested in the labeling, or (2) material with respect to consequences that may result from the use of the food to which the labeling relates. Examples of instances where FDA has imposed labeling requirements under sections 403(a)(1) and 201(n) of the FDCA, even absent specific statutory authority, include:

- FDA's requirement that labels include disclaimers when certain nutrient content claims are made about a product,[1] based on FDA's conclusion that the absence of such information could mislead the consumer in light of other statements made on the label.

- FDA's requirement that reduced fat margarine be labeled as "not suitable for frying,"[2] on the basis that, absent this claim, a consumer could be misled to assume that the food, because of its similarity to another food, has nutritional, organoleptic, or functional characteristics of the food it resembles, when in fact it does not.

- FDA's requirement that a warning statement appear in the labeling of unpasteurized juice[3] to provide information to consumers about the possible consequences of consuming the product (i.e., serious illness from harmful bacteria).

3. Can FDA impose a new labeling requirement based solely on consumer interest?

No. It is well established that FDA cannot require labeling statements based on consumer interest alone. Although FDA may consider consumer opinion in determining whether labeling is required to disclose a material fact under section 201(n) of the FDCA, consumer opinion may not be considered in determining whether a fact is material in the first instance. For example, FDA has concluded that it does not have the authority to require additional labeling of foods derived from bioengineering because bioengineering does not cause foods to be materially different, even if there is significant consumer interest in such information.[4] This is premised on multiple court decisions concluding that FDA's authority

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[1] 21 C.F.R. 101.13.

[2] 58 Fed. Reg. 2431, 2436–37 (Jan. 6, 1993).

[3] 63 Fed. Reg. 37030, 37043-44 (July 8, 1998).

[4] *See* FDA, Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants: Guidance for Industry, https://www.fda.gov/media/120958/download.

does not extend to requirements for disclosing information solely because consumers have an interest in that information.[5]

4. On what basis does the August 2022 citizen petition assert that FDA has statutory authority to impose new FOP nutrition labeling requirements?

The August 2022 citizen petition broadly asserts that FDA has the authority to impose new FOP labeling requirements under sections 403(q) and 403(f) of the FDCA. Specifically, the petition points to sections 403(q)(1)–(2), which establish that labels must contain certain nutrient disclosures (e.g., total calories, total fat, and sodium). The petition then points to section 403(f), which requires that these mandatory nutrition disclosures be sufficiently prominent so as to render them "likely to be read and understood by the ordinary individual under customary conditions of purchase and use." The petition also cites section 2(b) of the NLEA, which required FDA to issue regulations following passage of the NLEA to ensure that mandatory nutrition labeling "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." The petition also references language from a House Report for the NLEA which suggested that FDA could require the disclosure of nutrition information in various ways, including through the use of descriptive terms and universal symbols.

5. Does the August 2022 citizen petition sufficiently establish that FDA has statutory authority to impose new FOP nutrition labeling requirements?

No. The petition's reliance on sections 403(q) and 403(f) of the FDCA and select language from the NLEA is misguided, as it fails to account for the fact that FDA has *already* issued regulations mandating the disclosure of the information required under 403(q) and 403(f). In other words, these sections require the disclosure of certain nutrition information on food labels, and FDA has implemented that requirement through its current nutrition labeling regulations. The petition fails to identify a standalone statutory basis for requiring nutrition labeling *in addition to* the nutrition labeling information already required by FDA, and it also fails to identify how FDA's current requirements do not meet the statutory mandate. Rather, absent additional statutory authority, FDA can only impose new FOP labeling requirements if it can demonstrate that those requirements are warranted under sections 403(a)(1) and/or 201(n) of the FDCA. The petition does not adequately explain why new FOP labeling requirements would be warranted under sections 403(a)(1) and/or 201(n).

6. Could FDA impose new FOP labeling requirements under sections 403(a)(1) and/or 201(n) of the FDCA?

We think it would be highly challenging for FDA to demonstrate that new FOP labeling requirements are warranted under sections 403(a)(1) and/or 201(n) of the FDCA. To justify FOP labeling requirements under section 403(a)(1), FDA would need to show that such labeling

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[5] *See, e.g.*, International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 73 (2d Cir. 1996) (holding that consumer interest alone is not a sufficient government interest on which to compel labeling); Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 179 (D.D.C. 2000) ("[O]nly once materiality has been established may the FDA consider consumer opinion to determine whether a label is required to disclose material fact."); Stauber v. Shalala, 895 F. Supp. 1178, 1193 (W.D. Wisc. 1995).

is necessary to ensure that labels are not "false or misleading." In practice, FDA would likely need to demonstrate, through consumer research or otherwise, that FOP labeling requirements that compel manufacturers to repeat information already required elsewhere on the label is truly needed to prevent consumer deception, even though consumers already have access to that information.

To justify FOP labeling requirements under section 201(n), FDA would need to demonstrate that FOP labeling would provide information that is either (i) material in light of other representations made or suggested in the labeling, or (ii) material with respect to consequences that may result from consuming the food. FDA generally relies on this provision to require labeling in cases where the absence of such information may: (1) pose special health risks; (2) mislead the consumer in light of other statements made on the labeling; or (3) lead a consumer to assume that a food, because of its similarity to another food, has nutritional, organoleptic, of functional characteristic of the food it resembles when in fact it does not. It is highly unlikely that FDA could successfully rely on items (2) or (3) to support universal FOP labeling requirements since, as noted above, such requirements would merely repeat information already available to consumers, rather than clarify specific, potentially misleading label claims. It would be similarly challenging for FDA to reasonably support the argument that the absence of FOP labeling poses similar "special health risks," particularly to the extent such information is already available elsewhere on the label.

Finally, as noted above, FDA will be unable to assert that consumer interest in FOP labeling is, by itself, a "material" fact sufficient to support a labeling requirement under section 201(n). In fact, FDA has explicitly adopted this position both in policy guidance[6] and in the context of litigation,[7] and courts have upheld this proposition on multiple occasions.[8]

7. On what basis does the August 2022 citizen petition assert that new FOP nutrition labeling requirements would be permissible under the First Amendment?

The petition takes the position that courts would review new FOP nutrition labeling requirements under the more lenient "rational basis" review standard outlined in *Zauderer v. Office of Disciplinary Counsel of Supreme Court*, which is the standard courts typically apply when assessing disclosure requirements in the commercial speech context. Under *Zauderer*, such disclosure requirements are permissible if they are "reasonably related to the State's interest in preventing deception of consumers" and they are not "unjustified or unduly burdensome."[9] The petition asserts that new FOP labeling requirements would satisfy this standard, since they would be (1) strictly factual and uncontroversial (i.e., they would concern

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[6] FDA, Background Document for the Food Advisory Committee: Certified Color Additives in Food and Possible Association with Attention Deficit Hyperactivity Disorder in Children at 13 (Mar. 2011), https://foodpoisoningbulletin.com/wp-content/uploads/FAC-Color-Additives-ADHD.pdf.

[7] *See* Alliance for Bio-Integrity, 116 F. Supp. 2d at 179 ("FDA does not read [201(n)] to authorize labeling requirements solely because of consumer demand.").

[8] *See id.* at 178 (upholding FDA's position that section 201(n) does not "authorize labeling requirements solely because of consumer demand" as a "reasonable interpretation of the statute"); *see also* Stauber, 895 F. Supp. at 1193.

[9] Zauderer, 471 U.S. at 651.

factual information regarding a product's nutrient contents), (2) reasonably related to a legitimate government interest (i.e., the government's interest in improving consumer knowledge of potential health risks and reducing consumer confusion), and (3) not unjustified or unduly burdensome (i.e., they would address high rates of diet-related disease in the US and, according to the petition, would take up less than 20 percent of a label's PDP).

8. Does the August 2022 citizen petition sufficiently establish that new FOP nutrition labeling requirements would be permissible under the First Amendment?

This will depend on the specific requirements that FDA seeks to impose. While some FOP labeling requirements may be able to withstand scrutiny under the *Zauderer* standard, FDA does not have unlimited discretion to impose such requirements. For example, courts could find that requirements that take up a large portion of the PDP or that offer insufficient flexibility for manufacturers (e.g., flexibility for small labels) are unduly burdensome, even under *Zauderer*. FDA could also face challenges in demonstrating that FOP labeling requirements reasonably help prevent consumer deception, particularly where such requirements merely duplicate information available elsewhere on the label.

Moreover, there is some possibility that courts could subject FOP labeling requirements to the more rigorous *Central Hudson* standard, under which FDA would be required to demonstrate that the requirements (1) serve a substantial government interest, (2) directly advance the asserted governmental interest, and (3) are not more extensive than is necessary to serve the governmental interest.[10] Here, FDA could face particularly steep challenges in demonstrating that FOP labeling requirements directly advance a substantial government interest, since doing so would likely require that FDA provide data demonstrating that FOP labeling serves a public health interest that existing NFL requirements do not. FDA may also struggle to show that such requirements are not "more extensive than necessary" to advance the asserted government interest, since stakeholders could challenge FDA's regulation by pointing to various less intrusive alternatives, including existing NFL requirements and the possibility of requiring targeted FOP disclosures tied to specific claims that pose a risk of misleading consumers, rather than imposing universal FOP nutrition labeling requirements.

9. What other considerations are relevant to FDA's authority to impose new FOP labeling requirements?

Recent legal developments suggest that courts may be increasingly resistant to far-reaching regulatory action that lacks a clear statutory basis. Most notably, in *West Virginia v. EPA*, the Supreme Court recently held that the Clean Air Act did not authorize the EPA to impose certain regulations regarding greenhouse gas emissions.[11] In doing so, the majority opinion embraced the "major questions doctrine," which stands for the proposition that if Congress wishes to authorize an executive agency to make "decisions of vast economic and

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[10] Central Hudson Gas & Electric Corp. v. Public Service Commission, 447 U.S. 557, 566-571 (1980).

[11] 597 U.S. __ (2022).

political significance," it must explicitly grant such authority.[12] The Court's embrace of the major questions doctrine in *West Virginia v. EPA* indicates that, moving forward, the Court may be particularly hesitant to embrace significant agency actions that lack a clear statutory basis. This could include an attempt by FDA to impose expansive FOP nutrition labeling requirements absent additional statutory authority clearly requiring that it do so.

[12] *Id.* at 28