Docket No. FDA-2016-D-2335

COMMENT

of

WASHINGTON LEGAL FOUNDATION

to the

FOOD AND DRUG ADMINISTRATION

Concerning

FOOD LABELING: NUTRIENT CONTENT CLAIMS; DEFINITION OF TERM "HEALTHY"

IN RESPONSE TO THE PUBLIC NOTICE PUBLISHED AT 87 FED. REG. 59,168 (Sept. 29, 2022)

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Submitted Electronically (http://www.regulations.gov)
Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane
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Rockville, Maryland 20852

Re: Food Labeling: Nutrient Content Claims; Definition of Term "Healthy" Docket No. FDA-2016-D-2335

Sir or Madam:

On behalf of Washington Legal Foundation, please consider this comment responding to the invitation for comments at 87 Fed. Reg. 59,168 (Sept. 29, 2022). WLF appreciates the opportunity to weigh in on whether the Food and Drug Administration should adopt its proposed amendments to the healthy-labeling rule. As explained below, while the FDA may update the healthy-labeling rule, the Proposed Rule goes too far and violates both the First Amendment and the Administrative Procedure Act.

Over thirty years ago, Congress passed the Nutrition Labeling and Education Act of 1990. *See* Pub. L. No. 101-535, 104 Stat. 2553. That statute requires the Secretary of Health and Human Services to issue regulations about implied labeling claims. *See id.* § 3(b). The Secretary tasked FDA with issuing the regulations. Four years later, FDA interpreted 21 U.S.C. § 403(r) to permit regulation of the term "healthy" on food labels. *See Food Labeling: Nutrient Content Claims, Definition of Term: Healthy*, 59 Fed. Reg. 24,232 (May 10, 1994) (codified at 21 C.F.R. § 101.65(d)). This comment, however, does not focus on whether FDA had the authority to promulgate the Proposed Rule. Rather, this comment focuses on other constitutional and statutory problems.

In 2016, FDA began a long process of updating its nutrition labeling requirements. Late last year, it proposed curtailing what foods could be labeled as "healthy." The Proposed Rule imposes new limits on non-nutrients—outside the agency's statutory authority—and changes what nutrients must be

included in food to qualify as healthy. The Proposed Rule would upend billions of dollars per year in commerce. Although an exact calculation is impractical, estimates suggest that about 90% of foods currently labeled as healthy would not qualify under the Proposed Rule.

The Proposed Rule violates the First Amendment by broadly restricting truthful commercial speech. It also violates the APA because it is arbitrary and capricious. FDA is correct that nutrition science has evolved over the past three decades. But the Proposed Rule ignores many advances in nutrition science and regulates labels in a way that will lead consumers to eat less healthy food. FDA should withdraw the Proposed Rule, go back to the drawing board, and issue regulations that comply with both the Constitution and the APA.

I. Interests of WLF

WLF is a nonprofit, public-interest law firm and policy center based in Washington, DC, with supporters nationwide. WLF devotes much of its resources to defending free enterprise, individual rights, limited government, and the rule of law. To that end, WLF often submits comments to FDA about nutrition labels. *See, e.g.*, WLF Comment, *In re Revision of the Nutrition and Supplemental Facts Label; Supplemental Proposed Rule* (Oct. 13, 2015); WLF Comment, *In re Revision of the Nutrition and Supplemental Facts Label* (Aug. 1, 2014); WLF Comment, *In re FDA Petition to Require Warning Labels on Sodas* (Dec. 16, 2005).

WLF's Legal Studies Division, its publishing arm, often produces and distributes articles on a wide array of legal issues related to nutrition labels. *See, e.g.*, Bert W. Rein & Megan L. Brown, *Precautions for Commercial-Speech Regulation*, WLF Legal Opinion Letter (June 16, 2017); Richard L. Frank, *Federal Dietary Guidelines Lack a Consistent and Scientific Approach to Caffeine*, WLF Legal Opinion Letter (May 8, 2015); Richard L. Frank, *FDA's "Added Sugars" Labeling Mandate Raises First and Fourth Amendment Concerns*, WLF Legal Backgrounder (Sept. 26, 2014). WLF believes that nutrition-labeling requirements must comply with both the First Amendment and the APA.

II. The Proposed Rule Violates Regulated Parties' Free-Speech Rights Because It Does Not Satisfy The Test For Restricting Commercial Speech.

Government may restrict lawful, non-misleading commercial speech only if the restrictions satisfy the Supreme Court's test in *Cent. Hudson Gas &*

Elec. Corp. v. Public Serv. Comm'n of N.Y., 446 U.S. 557 (1980). (The laxer test in *Zauderer v. Office of Disciplinary Counsel of Supreme Ct. of Ohio* does not apply because the Proposed Rule's restrictions on the use of "healthy" is not a disclosure requirement. *See* 471 U.S. 626, 651 (1985)). To satisfy the First Amendment's requirements, commercial speech restrictions must (1) "directly and materially advanc[e]" a "substantial" governmental interest and (2) be no "more extensive than necessary to serve the interests that support it." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 554-56 (2001) (cleaned up). The government bears the burden to make both showings. *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993). "This burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173, 188 (1999) (quotation omitted).

Everyone agrees that labeling food as "healthy" is lawful. And FDA does not argue that the current regulations allow for misleading commercial speech. Nor could it. The government bears the burden of providing real evidence that a claim is misleading. *See Peel v. Att'y Registration and Disciplinary Comm'n of Ill.*, 496 U.S. 91, 106 (1990). The Proposed Rule lacks any such evidence that using the word "healthy" for foods that comply with current regulations are misleading. As the D.C. Circuit has said, "health claims lacking 'significant scientific agreement'" are not inherently misleading. *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999). In other words, the First Amendment protects labeling a product as healthy, even if some nutritionists may disagree with that claim.

Government cannot narrowly define a term and then argue that any other use of that term is misleading. For example, Arkansas tried to restrict the labeling of food as a "burger." A company that used that term for products that did not contain meat from a red-blooded animal sued. The court held that the statute was unconstitutional. In reaching this conclusion, it rejected the idea that a food label is misleading just because the government defined a term and a company used that term for a different product. *Turtle Island Foods SPC v. Soman*, 2022 WL 4627711, *15-16 (E.D. Ark. Sept. 30, 2022).

If the use of the term healthy is misleading, then a company like Amazon could be barred from using the term e-book just because the product includes no paper. *See Ang v. Whitewave Foods Co.*, 2013 WL 6492353, *4 (N.D. Cal. Dec. 10, 2013); *see also Miyoko's Kitchen v. Ross*, 2021 WL 4497867 (N.D. Cal. 2021) (barring the government from limiting the use of term "butter" in vegan

foods). The absurdity of such an argument is self-evident. Because the Proposed Rule regulates truthful, non-misleading speech, the inquiry turns to whether the Proposed Rule directly and materially advances a substantial governmental interest.

A. The Proposed Rule Does Not Directly And Materially Advance A Substantial Governmental Interest.

1. FDA asserts that the Proposed Rule "will better inform consumers who are selecting [products labeled as healthy] to choose a more healthful diet, which may lower incidence of diet-related chronic diseases." 87 Fed. Reg. 59,169. This is not a substantial governmental interest as required by *Central Hudson*.

Government lacks "an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 374 (2002). In *Thompson*, the Court rejected government regulation based on a "fear that advertising compounded drugs would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway." *Id.* This makes sense. Rather than adopt a "highly paternalistic approach" governments should "assume that [] information is not in itself harmful, that people will perceive their own best interests . . . and that the best means to that end is to open the channels of communication rather than to close them." *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976).

Here, FDA is trying to babysit Americans' food choices. All food packaging includes the nutrition facts that help consumers determine whether the food is healthy. FDA is worried, however, that Americans will not make the right food choices given the nutrient information. This is exactly what the Supreme Court said is not a substantial interest. Thus, the *Central Hudson* inquiry can end at this early stage. But even if the FDA's asserted interest is substantial, the Proposed Rule does not directly and materially advance that goal.

2.i. FDA believes that "[s]ome consumers use nutrient content claims such as 'healthy' to inform their food purchases." 87 Fed. Reg. at 59,195. Continued reading of the Proposed Rule shows that the word "some" is doing too much work in that sentence. FDA "estimate[s] that a small number (0 to 0.4 percent of people that try to follow current dietary guidelines) of these consumers would use the 'healthy' implied nutrient content claim to make

meaningful, long-lasting food purchasing decisions." *Id.* In other words, FDA admits that the Proposed Rule may not benefit a single consumer nationwide. Even the top of the FDA's estimated range—which is almost certainly higher than it should be—shows that only 0.4 percent of the tiny sliver of the population that tries to follow governmental dietary guidance would see long-lasting changes to their diets. In fact, very few Americans follow the dietary guidelines. *See* Susan M. Krebs-Smith et al., *Americans Do Not Meet Federal Dietary Recommendations*, 10 J. of Nutrition 1832, 1835-36 (2010). This 0.4 percent of a tiny number is far from material.

As used in *Central Hudson*, the word "material" means "significant." *See* Black's Law Dictionary (11th ed. 2019). At most, giving FDA the benefit of the doubt, 0.4% of a fraction of Americans will change their diets after the healthy-label requirements change. This is not significant. Rather, it is the opposite of significant. It is *de minimis*. And a speech regulation that has only a *de minimis* effect does not materially advance a governmental interest for purposes of *Central Hudson*. *BellSouth Telecomms., Inc. v. Farris*, 542 F.3d 499, 512 (6th Cir. 2008) (Daughtrey, J., concurring and dissenting).

ii. Nor does the Proposed Rule materially advance FDA's alternative interest, increasing the availability of "nutrient dense foods." 87 Fed. Reg. at 59,184. As described more fully in § III, *infra*, the Proposed Rule may make such foods harder to find because the Proposed Rule excludes foods like hummus and bagged salads, which do not contain the exact mix of food groups required by the Proposed Rule. If FDA's assumption is correct, that companies will change their food offerings so they can label food as healthy, these nutrient-rich foods will become harder to find. So even if some other nutrient-rich foods are introduced, the effect will be negligible at best. This does not satisfy *Central Hudson*'s materiality requirement.

3.i. Even if the Proposed Rule materially advanced the interest of lowering diet-related chronic diseases, it does so indirectly—not directly. FDA hopes that consumers buy different foods, which would improve their health outcomes. The FDA, however, cannot explain how the Proposed Rule would lead to consumers making healthier food decisions. But even if there were a link, it is not direct enough to satisfy *Central Hudson*. The D.C. Circuit's decision in *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012), *overruled on other grounds*, *Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014) (*en banc*) is illustrative on this matter. There, FDA wanted to require a warning label on cigarettes. The court found that the warning-label requirement violated the First Amendment because it was "mere speculation" that consumers "who report increased thoughts about [not smoking] will

actually follow through on their intentions." *Id.* at 1219 (emphasis removed). FDA uses the same type of speculation here. It believes that using the term healthy on food labels will change consumers' purchasing decisions and allow them to avoid chronic disease. This falls far short of *Central Hudson*'s strict requirements.

ii. Similarly, the Proposed Rule does not directly lead to more nutrient-rich foods being on store shelves. Again, the actual outcome will be negligible at best because many nutrient-rich foods marketed after the Proposed Rule will just replace nutrient-rich foods that do not meet the Proposed Rule's requirements. But even if the number of nutrient-rich foods increases, that will be an indirect result of the Proposed Rule. Consumers will have to stop buying certain foods. Companies would have to realize that consumers have stopped buying those foods because they are not labeled healthy. Next, companies would have to determine whether consumers are willing to bear the increased cost and accept diminished taste and palatability associated with making food that complies with the Proposed Rule's requirements. If so, then they will produce more foods that satisfy the Proposed Rule's requirements. And then, depending on consumer demand compared to the demand for nutrient-rich foods that no longer can be labeled as healthy, the supply of nutrient-rich foods may increase.

FDA's asserted governmental interest stands on an unlikely series of speculations stacked on speculations. It is anything but "direct" as required by *Central Hudson*. So the Proposed Rule does not materially and directly advance the two governmental interests outlined in the Federal Register. Because the Proposed Rule fails this prong of the *Central Hudson* test, the FDA should withdraw the Proposed Rule and start anew.

B. The Proposed Rule Is Much Too Broad For The Interests That Support It.

Even if the Proposed Rule directly and materially advances one or two substantial governmental interests, it is "more extensive than necessary to serve the interests that support it." *Greater Phila. Chamber of Com. v. City of Philadelphia*, 949 F.3d 116, 154 (3d Cir. 2020) (quotation omitted). The "fit between the [government's] ends and the means chosen to accomplish those ends," need not be "perfect" or "necessarily the single best disposition but" the scope must be proportional "to the interest served." *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 632 (1995) (cleaned up).

To comport with the First Amendment, FDA had to consider whether it could achieve its two goals with its own speech rather than by limiting others' speech. *See Nat'l Inst. of Fam. and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2376 (2018). FDA does not explain why its own speech could not achieve its goals. It could, for example, run a public education campaign discouraging consumers from eating food with added sugars or encouraging them to eat foods that contain large servings from multiple food groups. That way, consumers would eat food that FDA prefers. This, in turn, would lead companies to make those foods more available on store shelves. But again, FDA did not consider these options that the Supreme Court has said it must before limiting regulated parties' protected speech. That, however, was not the only alternative that FDA ignored.

Under the Proposed Rule, any added sugar in some foods eliminates the ability to label them as healthy. Yet companies must already disclose any added sugar on the label. FDA cannot explain why consumers cannot make their own healthy decisions based on this data. Rather, it seeks to limit the food companies' speech. This shows that the Proposed Rule is far too broad. FDA could also require foods with added sugar and bearing the "healthy" label include the added sugar in larger type or in a separate box. The failure to explain why the many alternatives to the overbroad Proposed Rule cannot advance the governmental interests confirms that it is unconstitutional. *See Thompson*, 535 U.S. at 357.

In short, labeling foods as healthy is speech protected by the First Amendment. Because FDA seeks to restrict constitutionally protected commercial speech, it must satisfy the *Central Hudson* test. But the Proposed Rule fails that test for four reasons. Thus, FDA should scrap the unconstitutional Proposed Rule and go back to the drawing board.

III. The Proposed Rule Violates The APA Because It Is Arbitrary And Capricious.

Courts must set aside regulations if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706. To pass arbitrary-and-capricious review, agencies must "articulate a satisfactory explanation for the action including a rational connection between the facts found and the choice made." *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2383 (2020) (cleaned up). The Proposed Rule falls well short of this requirement.

The Proposed Rule is built on the assumption that following the dietary guidelines for 2020-2025 is the only way to eat healthy. *See* 87 Fed. Reg. 59,181. Yet the Proposed Rule itself does not follow the dietary guidelines. Broadly, the dietary guidelines focus on ensuring that diets contain necessary nutrients. But the Proposed Rule does not focus on how these nutrient requirements can be satisfied. Rather, it focuses only on food groups. In other words, the Proposed Rule ignores nutritional requirements.

The dietary guidelines have several examples of healthy diets. But the Proposed Rule is based on just one of those healthy diets. This makes no sense and comes without any explanation from FDA. If the other diets in the dietary guidelines are healthy, why can't foods that fit in those diets also be labeled as healthy? It's a mystery because the Proposed Rule does not explain this decision—probably because there is no reasonable explanation.

At least that deviation does not directly contradict the dietary guidelines. But other parts of the Proposed Rule vary from the dietary guidelines. For example, the protein subgroups are "different from the subgroups in the Dietary Guidelines, 2020–2025 because they are based on what [FDA] determined as the specific needs for variation." 87 Fed. Reg. at 59,188. It should be obvious that basing the entire Proposed Rule on the dietary guidelines but then just deviating from the dietary guidelines without a convincing explanation is arbitrary and capricious.

This is just one example of conflict between the Proposed Rule and the dietary guidelines. The dietary guidelines recommend that at least one-half of grains come from whole grains and recommend dairy consumption. The Proposed Rule, however, limits labeling these products as healthy. Similarly, the dietary guidelines say that up to half of grain consumption can come from refined grains. Yet the Proposed Rule ensures that such foods are not labeled as healthy.

Even the Department of Health and Human Services—whose authority FDA is using in this rulemaking process—has a website that contradicts the Proposed Rule. MyPlate.gov is a site that contains many meals that HHS and the United States Department of Agriculture believe are healthy. Whether a meal is considered healthy is based on the dietary guidelines—the same guidelines that the Proposed Rule claims to be built on.

MyPlate includes a recipe for teriyaki lettuce wraps. *Teriyaki Lettuce Wraps*, https://tinyurl.com/3nmvc8sf (last visited Feb. 12, 2023). But this would not be healthy under the Proposed Rule because it contains three grams

of added sugar. *See* 87 Fed. Reg. at 59,185-86. MyPlate also has fifty-two recipes that are comprised mainly of whole grains. But of those, only twelve would be considered healthy under the Proposed Rule. Why? The other forty have too much added sugar to be healthy under the Proposed Rule. Again, the MyPlate website is meant to provide meal options that comply with the dietary guidelines. But the authors of the Proposed Rule evidently believe that over three-fourths of the breakfast recipes containing whole grains on the MyPlate website are not healthy.

In short, FDA says that the entire Proposed Rule is based on the dietary guidelines. But the Proposed Rule violates the dietary guidelines more than it follows them. There is scant explanation in the Proposed Rule for these many deviations from the dietary guidelines despite their being the key to the substantial governmental interests advanced by FDA. Thus, the Proposed Rule also violates the APA because it is arbitrary and capricious. For this reason alone, FDA should withdraw the rule and try again.

* * *

Nutrition science has changed since FDA first issued its healthy-label requirements. So updating those requirements is not the worst idea that FDA has had. But the updated regulations cannot flout the First Amendment and must comply with the APA. Because the Proposed Rule both violates the First Amendment and is arbitrary and capricious, FDA should withdraw the Proposed Rule and start the rulemaking process anew.

Respectfully submitted,

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