



COMMENTS

of

THE WASHINGTON LEGAL FOUNDATION

to the

**FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH & HUMAN SERVICES**

Concerning

**FOOD LABELLING: REVISION OF THE NUTRITION AND
SUPPLEMENTAL FACTS LABEL
(Docket FDA-2012-N-1210; RIN 0910-AF22)**

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
(Docket FDA-2004-N-0258; RIN 0910-AF23)**

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Comments Concerning the Proposed Revision of the Nutrition and Supplemental Facts Label (Docket FDA-2012-N-1210) and Dual Column Labeling Requirement (Docket FDA-2004-N-0258)

Dear Sir/Madam:

In response to the public notices published at 79 Fed. Reg. 41 (March 3, 2014) and 79 Fed. Reg. 11989 (March 3, 2014), the Washington Legal Foundation (WLF) hereby submits these comments questioning the constitutionality of the compelled speech provisions contained in FDA's proposed revisions to the Nutrition and Supplemental Facts Label and the new Dual Column Labeling Requirement.

WLF has serious concerns that the agency failed to adequately consider relevant First Amendment standards in proposing revisions to existing nutrition labeling regulations. Notwithstanding that the agency's regulations governing nutrition labeling fundamentally impact rights under the First Amendment—by compelling speech—FDA fails to acknowledge the First Amendment a single time in either proposed rulemaking. Particularly in light of the number of cases where courts have reprimanded FDA for its failure to give appropriate weight to First Amendment concerns, we hope that the agency will seriously consider the issues that arise from its highly prescriptive nutrition labeling requirements.

I. Interests of WLF

Founded in 1977, the Washington Legal Foundation is a public-interest law firm and policy center based in Washington, D.C. with supporters throughout the United States. WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, a limited and accountable government, and the rule of law. As an ardent supporter of the First Amendment, WLF objects to government efforts

to restrict speech—either by banning or compelling speech—without adequate justification. WLF has successfully challenged the constitutionality of FDA restrictions on truthful speech by pharmaceutical manufacturers. *See Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dismissed*, 202 F.3d 331 (D.C. Cir. 2000). As a result of that litigation, FDA is subject to a permanent injunction limiting FDA authority to suppress manufacturer dissemination of certain journal articles and medical texts discussing off-label uses of their FDA-approved products. More recently, WLF attorneys played a key role in overturning—on First Amendment grounds—the criminal conviction of a pharmaceutical representative for conspiring to violate the FDCA; the representative’s “crime” consisted of speaking truthfully about off-label uses of a drug manufactured by his company. *See United States v. Caronia*, 703 F.3d 149 (2d. Cir. 2012).

While WLF believes that the government should play a role in ensuring that commercial speakers do not provide false or misleading information to consumers, WLF has consistently opposed government efforts to censor speech or otherwise prevent consumers from hearing truthful commercial speech. Likewise, WLF has opposed regulatory efforts to compel commercial speakers to convey controversial messages with which they disagree. To that end, WLF has opposed unconstitutional regulations both via amicus litigation in federal and state courts, *see, e.g., Sorrell v. IMS Health*, 131 S. Ct. 2653 (2011); *Educational Media Co. at Va. Tech., Inc. v. Insley*, 731 F.3d 291 (4th Cir. 2013); *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012), and by participating in the regulatory process, *see, e.g.,* FDA Docket No. 2008-D-0053 (April 21, 2008)(response to FDA Draft Guidance on good reprint practices); FDA Citizen Petition No. 2006P-0319/CPI (August 11, 2006) (documenting repeated First Amendment violations by FDA’s Division of Drug Marketing, Advertising, and Communications (DDMAC) and calling on DDMAC to conform to constitutional constraints on its activities); FDA Docket No. 2011-D-0868 (March 29, 2012) (response to FDA Draft Guidance on unsolicited requests for off-label information); FDA Docket No. 02N-0209 (October 28, 2002) (response to FDA’s request for public comments on First Amendment issues).

Furthermore, WLF’s Legal Studies Division frequently produces and distributes articles on a wide array of legal issues related to the commercial free-speech implications of federal regulation. *See, e.g.,* Robert Hahn and John Dillard, *Mandated Labeling for Genetically Engineered Foods: Vermont’s Legislation Implicates the First Amendment*, WLF LEGAL BACKGROUNDER, MAY 23, 2014; Richard Frank and David Weinrieb, *Updated Medical Privacy Rules Under Federal HITECH Act Constitutionally Suspect*, WLF LEGAL BACKGROUNDER, July 19, 2013; Patrick Basham and John C. Luik,

Nutrition Labeling on Menu Boards and Menus: A Recipe for Failure, WLF WORKING PAPER SERIES, Dec. 2007.

II. First Amendment Precedent

The Supreme Court has long recognized that the First Amendment, subject only to very narrow and well-understood exceptions, does not countenance government control over the content of messages conveyed by private individuals. Beginning with its decision in *W. Virginia Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943), which struck down a law requiring school children to recite the Pledge of Allegiance over their objections to doing so, the Supreme Court has recognized that the First Amendment protects not only the freedom of speech, but also the freedom *not* to speak. The Court reiterated this view over thirty years later in *Wooley v. Maynard*, holding that New Hampshire may not require objecting motorists to display the state motto “Live Free or Die” on automobile license plates. 430 U.S. 705, 713-15 (1977). This right not to speak extends to statements of fact as well as statements of opinion. See *Riley v. Nat’l Fed. Of the Blind*, 487 U.S. 781, 797-98 (1988). Such constitutional restrictions on compelled speech extend to corporations as well as to individuals. See, e.g., *Pacific Gas & Elec. Co. v. Public Utils. Comm’n of Cal.*, 475 U.S. 1, 12 (1986) (“For corporations as for individuals, the choice to speak includes the choice of what not to say.”). These well-established restrictions on the government’s ability to compel speech apply with equal force to the FDA. See, e.g., *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012).

Although the government has somewhat greater leeway to regulate commercial speech, the burden rests on FDA at all times to demonstrate an interest sufficient to justify such regulation of speech. At a minimum, the Supreme Court requires that the restriction “directly advances” a “substantial government interest” and is “narrowly tailored” to achieve a reasonable “fit” between FDA’s stated goals and the agency’s means of achieving them. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557 (1980). Under the four-part *Central Hudson* test, courts consider as a threshold matter whether the commercial speech concerns unlawful activity or is inherently misleading. If so, then the speech is not protected by the First Amendment. If the speech concerns lawful activity and is not misleading, then the challenged regulation violated the First Amendment unless the government regulators can establish that (1) they have identified a substantial government interest, (2) the regulation “directly advances” the asserted interest, and (3) the regulation “is no more extensive than is necessary to serve that interest.” *Cent. Hudson*, 447 U.S. at 566.

For the *Central Hudson* test to be satisfied, the court must be persuaded that the cost of the regulation has been “carefully calculated.” *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 416 n.12 (1993). As with fully protected speech, the burden of justifying restrictions rests squarely with the government. *Bolger v. Young Drug Prods. Corp.*, 463 U.S. 60, 71 n.20 (1985)(reiterating that the “party seeking to uphold restrictions on commercial speech carries the burden of justifying it”); *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 373 (2002).¹ The evidentiary burden is not light. For example, the government’s burden of showing that a commercial speech regulation advances a substantial government interest “in a direct and material way . . .’is not satisfied by mere speculation or conjecture; rather a government body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restrictions will alleviate them to a material degree.” *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995)(quoting *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993)).

Because the government has an interest in regulating advertisements to reduce the possibility that consumers will be misled by such voluntary commercial speech, the Supreme Court has recognized that tweaking that speech is sometimes necessary “to dissipate the possibility of consumer confusion or deception.” *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985). In *Zauderer*,² the Court upheld the state’s imposition of a disclaimer after finding that the possibility of deception was “self-evident” from an attorney’s advertisement and that “substantial numbers of potential clients would be so misled” without the state’s clarifying disclosure rule. *Id.* at 652. The Court has repeatedly cautioned, however, that such mandatory disclosures are not permitted unless the state demonstrates an actual likelihood that consumers will be misled by absent the disclosure. *See e.g. Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 249-50 (2010) (upholding a disclosure requirement

¹ Tellingly, in *none* of the cases in which the U.S. Supreme Court has addressed First Amendment challenges to regulations on commercial speech has the Court so much as suggested that it was willing to defer to a federal agency’s determinations regarding the need for such restrictions or their likely effectiveness. Such willingness would be inconsistent with the language quoted above; the burden of demonstrating that speech restrictions alleviate real harms to “a material degree” would amount to nothing if the government could meet that burden by simply pointing to legislative or administrative fact-finding devoid of any empirical evidence.

² In *Zauderer*, the Supreme Court overturned a state court’s reprimand of an attorney for an advertisement that was neither false nor deceptive, but sustained the reprimand to the extent that the advertisement omitted a disclosure that a client would be liable for costs in the event a contingent-fee lawsuit was unsuccessful. Upholding the disclosure requirement for the sole purpose of correcting misleading commercial speech, *Zauderer* cautioned: “We recognize that unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech.” 471 U.S. at 651 (emphasis added).

directed at “misleading commercial speech” but emphasizing that *Zauderer* is limited “to combat[ing] the problem of inherently misleading commercial advertisements”); *Glickman v. Wileman Bros. & Elliott*, 521 U.S. 457, 490 (1997) (Souter, J., dissenting) (“[H]owever long the pedigree of such mandates may be, and however broad the government’s authority to impose them, *Zauderer* carries no authority for a mandate unrelated to the interest in avoiding misleading or incomplete commercial messages.”); *Pacific Gas & Elec.*, 475 U.S. at 15 n.12 (“Nothing in *Zauderer* suggests . . . that the State is equally free to require [entities] to carry the message of third parties, where the messages themselves are biased against or are expressly contrary to the [entity’s] views.”).

Although *Zauderer* endorsed compelled disclaimer requirements solely for the purpose of counteracting potentially misleading messages in an advertisement, the Supreme Court has never suggested that “companies can be made into involuntary solicitors for their ideological opponents.” *Cent. Ill. Light Co. v. Citizens Utility Bd.*, 827 F.2d 1169 (7th Cir. 1987). Rather, *Zauderer* allowed the state to require that advertisers “include in [their] advertising *purely factual and uncontroversial information* about the terms under which [their] services will be available.” 471 U.S. at 651 (emphasis added). In all events, even under *Zauderer*, such disclosure requirements are constitutionally impermissible if they are “unduly burdensome” and thereby “chill protected commercial speech.” 471 U.S. at 651.

III. Overview of Proposed Regulations and Legal Issues to be Addressed

FDA is required to implement the Federal Food, Drug & Cosmetic Act (FDCA) in a manner that does not offend the First Amendment. Under applicable First Amendment precedent, FDA must show through substantial evidence that the particular speech restrictions at issue will directly advance the governmental interest sought to be advanced. In proposing revisions to nutrition labeling requirements, however, FDA failed even to consider relevant First Amendment standards—despite the fact that the proposed regulations fundamentally restrict speech by compelling speech. Inexplicably, FDA’s published rulemaking omits any reference the First Amendment. WLF respectfully suggests that FDA is doing a major disservice to the cause of improved nutrition by its continued refusal to explain its understanding of First Amendment constraints and the extent to which the Constitution permits it to restrict truthful commercial speech.

Many aspects of FDA’s proposed amendments to nutrition labeling requirements present First Amendment concerns. In these comments, WLF highlights two revisions to

FDA regulations governing nutrition labeling that are particularly problematic under well-established First Amendment principles. First, FDA's proposal to require mandatory declaration of "added sugars" raises serious First Amendment concerns in light of FDA's longstanding acknowledgement that added sugars are not physiologically distinguishable from naturally occurring sugars. Second, FDA's proposal to compel dual-column labeling to require nutrition facts information on a per serving and per package basis presents issues under the First Amendment because it is not clear what interests FDA seeks to advance and whether and how the dual-column labeling requirement will do so.

Furthermore, both proposals are fundamentally suspect under the First Amendment because they assume that FDA may use speech-based regulations for reasons other than to alleviate consumer deception or confusion. By FDA's own admission, these policies lack sufficient scientific nexus to consumer health. As such, we are left to hypothesize as to why FDA believes it is acceptable to restrict free speech rights. As recent court decisions make clear, FDA can no longer get by with its "the-First-Amendment-does-not-apply-to-us" approach to federal rulemaking.

Because many provisions and additional labeling requirements in the proposed rules are aimed at correcting neither illegal activity nor false or misleading advertising, they are extremely vulnerable to constitutional challenge under the First Amendment. FDA has acknowledged that its goal is to shape consumer behavior rather than to provide noncontroversial, purely factual information necessary to prevent the kind of consumer deception addressed by *Zauderer*. Absent the compelling need to combat inherently misleading or deceptive commercial speech, FDA lacks the necessary substantial government interest required under *Central Hudson*.

FDA's proposed revisions to existing nutrition labeling regulations also present fundamental problems under the FDCA. Neither FDCA section 403(q) nor any other provision of the FDCA requires FDA to compel "added sugars" or dual column nutrient/serving and nutrient/package Nutrition Facts, and even if FDA sought to allow the voluntary declaration of such information, the agency's insistence that "nutrition information" under FDCA 403(q) equals "Nutrition Facts" on the "label" is too cramped a reading of the FDCA.³ Recognizing that First Amendment standards applied, Congress

³ While the Nutrition Facts format has been in existence since the FDA's implementation of the Nutrition Labeling Education Act of 1990 (NLEA), it is worth noting that Congress declined to prescribe any particular format for how nutrition information would be conveyed. Indeed, section 403(q) of the Federal Food, Drug & Cosmetic Act (FDCA) provides that a food will be misbranded "unless its label *or labeling* bears nutrition information" and thus permits the

gave FDA discretion to provide for nutrition labeling in many ways, not simply through highly prescriptive regulations. The statute authorizes FDA to promulgate regulations governing nutrition labeling, but does so in a manner that gives the agency broad discretion to terminate requirements that are unjustified, and to refrain from adopting unjustified new requirements. From the beginning, FDA has failed to take advantage of the flexibility the statute provides to tailor its nutrition labeling regulations in a manner that accounts for First Amendment standards and maximizes the opportunities companies have to communicate nutrition information about their products that is of interest to consumers.

IV. FDA’s Proposed Regulation to Compel Mandatory Declaration of “Added Sugars” Raises Serious First Amendment Concerns that the Agency Failed to Consider

FDA proposes to require mandatory declaration of “added sugars” on top of the preexisting mandatory declarations of total “sugars” (which already includes intrinsic and added sugars), “Calories,” and “Essential Nutrients” on a per serving basis. FDA relies in part on FDCA section 403(q)(2)(A), which permits FDA to require information “if the Secretary determines that a nutrient other than a nutrient required . . . will assist consumers in maintaining healthy dietary practices.”⁴ It is worth emphasizing that this statutory standard, of course, cannot trump the agency’s obligations to comply with constitutional requirements imposed by the First Amendment. As such, FDA must demonstrate both that the declaration of added sugars will assist consumers in maintaining healthy dietary practices and that this interest is directly advanced by the mandatory declaration at issue.

FDA argues that mandatory declaration of added sugars will assist consumers in adhering to dietary guidance from the 2010 Dietary Guidelines, which encourage Americans to consume more nutrient-dense diets (i.e., more essential nutrients per calorie) and to limit consumption of added sugars and certain fats. This rationale is

information to be conveyed through any “written, printed or graphic matter . . . accompanying such article.” In addition, “labeling” has been construed broadly to include a broad range of product related information that is conveyed through non-label forms of communication that do not physically accompany the product. *Kordel v. United States*, 335 U.S. 345 (1948). FDA’s failure to consider the provision of nutrition information through other less prescriptive means than the Nutrition Facts approach raises First Amendment concerns in of itself given the multitude of ways that a food manufacturer could convey the same information through accompanying materials beyond the actual label (*e.g.*, at point of purchase, on the internet, through a smart phone application, etc.).

⁴ 21 U.S.C. § 343(q)(2)(A).

apparently premised on the notion that adding calories without nutrients to the diet through “added sugars” can reduce the nutrient density of the diet overall, and that many Americans need to limit calories to manage their weight, and also need to consume enough nutrients.⁵ And yet, FDA’s proposed definition would require “added sugars” to be declared for foods without regard to the nutritional density or caloric content of the labeled food.⁶

FDA traditionally has regulated “sugars” in connection with “calories,” and because the body does not know the difference between a sugar that is “added” and one that is naturally occurring or intrinsic, FDA has never before even suggested that “added sugars” qualifies as a “nutrient” for nutrition labeling purposes under Section 403(q) of the FDCA. Nor has FDA given any indication, until now, that the declaration of “added sugars” would somehow constitute the declaration of a material fact under Sections 403(a) and 201(n). FDA’s proposal is also inconsistent with its regulation of “sugars” in related nutrient content claims; “no added sugar,” for example, is a claim that can be made for foods that substitute for other foods that normally contain added sugar, so that a sugar-free version of a food could claim to be both “sugar-free” with “no added sugar.” These claims, of course, are regulated, but are made on a voluntary, not compelled, basis.

Given the arbitrariness of FDA’s definition of “added sugars,” it is no wonder that FDA acknowledges such a profound lack of understanding among consumers for the term “added sugars.”⁷ Indeed, it is curious that FDA is only now conducting the necessary

⁵ See 79 Fed. Reg. 11,880, 11905 (Mar. 3, 2014) (“In light of current dietary recommendations that advise Americans to reduce their intake of calories from added sugars, we consider that an added sugars declaration will help individuals identify foods that are nutrient-dense within calorie limits and aid in reducing excess discretionary calorie intake from added sugars. We tentatively conclude that the declaration of added sugars on the Nutrition Facts label is necessary to assist consumers to formulate diets consistent with current dietary recommendations and, thus, maintain healthy dietary practices.”).

⁶ For example, under the FDA’s proposal, 100 percent orange juice that is made from concentrate would be required to declare sugars that are intrinsic to oranges as “added sugars” whereas 100 percent orange juice that is expressed from fruit would list intrinsic sugars as simply “sugars,” with no “added sugars” listed. This is so even though the nutritional density and caloric content of the two types of juice products are equivalent.

⁷ See 79 Fed. Reg. 11,880, 11905 (Mar. 3, 2014) (“We acknowledge that, if finalized, a requirement for declaration of added sugars on the Nutrition Facts label will need to be accompanied by consumer education on the role of added sugars, along with solid fats, and the use of the new information on the label in overall dietary planning. We will be conducting consumer studies that include questions regarding including added sugars on the Nutrition Facts label.”).

consumer research—while the notices of proposed rulemaking are already pending. Rather than prevent consumer confusion, it is far more likely that FDA’s proposed new format, which would list “added sugars” underneath total “sugars,” will only further confuse consumers. For example, honey sold in retail packages would list the same number of grams of total “sugars” and “added sugars.” Surely some consumers will mistakenly believe that they are consuming twice the amount of sugars than they actually are.

The arbitrary nature of FDA’s definition of “added sugars” only highlights the agency’s inability to demonstrate how declaring “added sugars” will advance a substantial government interest. FDA’s goal in compelling the mandatory declaration of added sugars is, by the agency’s admission, to reduce consumer intake of products containing added sugars. Indeed, the assumption underlying the entirety of FDA’s proposal requiring declaration of added sugars is that “a declaration of added sugars on the Nutrition Facts label would assist consumers in maintaining healthy dietary practices by providing them with information necessary to meet the key recommendations to construct diets containing nutrient-dense foods and reduce calorie intake from added sugars by reducing consumption of added sugars.”⁸

While FDA has attempted, at times, to characterize the mandatory declaration as necessary to provide information to consumers, the underlying premise of its reasoning is that the provision of such information is necessary for its goal of limiting consumption of added sugars (e.g., manipulating consumer behavior). But FDA has acknowledged the lack of physiological difference between added sugars and intrinsic sugars, conceding the fact that “there are currently no analytical methods that are able to distinguish between naturally occurring sugars and those sugars added to a food.”⁹ FDA has also conceded the dearth of “scientifically supported quantitative intake recommendation for added sugars on which a DRV for added sugars can be derived.”¹⁰ Even more damning, FDA acknowledges that “U.S. consensus reports have determined that inadequate evidence exists to support the direct contribution of added sugars to obesity or heart disease.”¹¹

The substantial lack of scientific evidence establishing a material difference between added and intrinsic sugars only reinforces FDA’s lack of an adequate

⁸ 79 Fed. Reg. at 11,904.

⁹ 79 Fed. Reg. at 11,905.

¹⁰ *Id.* at 11,906.

¹¹ *Id.* at 11,904.

justification for infringing commercial free speech rights. In the absence of a sufficient scientific nexus to consumer health, “added sugars” (which are already accounted for by “total sugars”) is not the sort of purely factual and uncontroversial information authorized by *Zauderer* to correct voluntary commercial speech, nor has FDA offered any evidence that would indicate that the proposed amendments are necessary to prevent consumer fraud or deception. Not only does the proposed mandatory disclosure for added sugars not seek to prevent consumer deception, it may even be deceptive itself, given the lack of physiological distinction between added and intrinsic sugars. *Zauderer* has never applied in such cases.

Even if *Zauderer* did supply the appropriate test, FDA may not mandate even a purely factual and noncontroversial disclosure if it is “unjustified or unduly burdensome.” *Zauderer*, 471 U.S. at 651. Here, in light of FDA’s own concession that no scientific evidence exists to support FDA’s assumption that added sugars contribute to obesity or heart disease, as well as FDA’s admitted inability to promulgate a recommended daily allowance for added sugars, it only follows that imposing mandatory declarations for “added sugars” on the food and beverage industry is an “unjustified” and “unduly burdensome” restriction on First Amendment rights.

Because *Zauderer* is inapplicable, *Central Hudson* provides the appropriate First Amendment test. But for many of the same reasons that FDA’s proposed added sugar rule is unjustified and unduly burdensome under *Zauderer*, it cannot satisfy the first prong of *Central Hudson*. Simply put, scientific studies have not sufficiently shown that the government has a substantial interest in preventing consumer intake of added sugars, as defined by the proposed regulations. Absent that most basic of requirements—a substantial interest—no burden on truthful commercial free speech is permitted. *See Cent. Hudson*, 447 U.S. at 566.

Even if FDA had a substantial interest in preventing consumer intake of added sugars, under the third prong of *Central Hudson*, FDA bears the burden of proving that a restriction on commercial speech “directly advances the governmental interest asserted,” *Cent. Hudson*, 447 U.S. at 566, and that it does so “to a material degree.” *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 626 (1995). This prong is “critical” because, without it, the Government “could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression.” *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1985) (quoting *Edenfield*, 507 U.S. at 771). Indeed, it is insufficient that a restriction “provides only ineffective or remote support for the government’s purposes,” or if the restriction has “little chance” of advancing the state’s goal. *Edenfield*, 507 U.S. at 770-71.

Because it has not shown that mandatory declaration of added sugars content would have any discernable effect on consumer behavior, FDA's proposed rule cannot possibly satisfy the third prong of *Central Hudson*. FDA's rulemaking attempts to establish a link between reduced added sugars and improved health by reference to the Dietary Guidelines. But that reference is fundamentally flawed because FDA acknowledges that the Dietary guidelines "state that added sugars do not contribute to weight gain more than any other source of calories."¹² The peculiar result is that FDA seeks to require the mandatory declaration to "provid[e] consumers with the information necessary to follow the 2010 DGA recommendations to reduce the intake of calories from added sugars," while also acknowledging that the "2010 DGA states that added sugars do not contribute to weight gain more than any other source of calories."¹³

Even if FDA could provide the necessary evidence to show that a decreased intake of added sugars will result in improved health or lower obesity levels, it has provided absolutely no evidence that the mandatory declaration of "added sugars" on a nutrition label will somehow further that goal. Indeed, FDA has not even shown that mandating "added sugars" is rationally related to its desired change in consumer behavior or an improvement in consumer health.

So long as the purchase and sale of sugary foods and beverages continue to be lawful, there can be no basis for asserting that the alleged health hazards posed by sugars justify a relaxation of normal First Amendment constraints on government action. See *United Foods, Inc.*, 533 U.S. at 410-11 ("[T]hose whose business and livelihood depend in some way upon the product involved no doubt deem First Amendment protection to be just as important for them as it is for other discrete, little noticed groups.").

V. FDA's Proposed Regulation to Compel Dual-Column Labeling that Includes Nutrition Facts Information on Both a Serving and Package Basis Raises Serious First Amendment Concerns that the Agency Failed to Consider

FDA proposes to require dual-column labeling for certain food products "[t]o address containers that may be consumed in one or more sittings, or shared."¹⁴

¹² 79 Fed. Reg. 11,904.

¹³ 79 Fed. Reg. 11,880, 11,904 (Mar. 3, 2014).

¹⁴ "To address containers that may be consumed in one or more sittings, or shared, FDA is proposing that containers that contain at least 200 percent and up to and including 400 percent

Specifically, FDA proposes that containers containing at least 200 percent and up to and including 400 percent of the RACC (Reference Amount Commonly Consumed) be labeled with dual-column labels. FDA chose the 400% cut-off because “the data show that products that contain more than 400 percent of the RACC are less likely to be consumed in one-eating occasion.”¹⁵ Somewhat arbitrarily, however, FDA proposes exceptions from the dual labeling requirement for “bulk products that are used primarily as ingredients (e.g., flour, sweeteners, shortenings, oils)” and “bulk products traditionally used for multi-purposes (e.g., eggs, butter, margarine), and multipurpose baking mixes because labeling these products with nutrition information based on the entire container would not be consistent with how these products are typically consumed.”¹⁶

In attempting to justify its proposal to require dual-column labeling, FDA points to a study concluding that “dual-column label reduces snack food consumption when compared to a single-column labeling for people who are not currently dieting.”¹⁷ FDA acknowledges, however, that “[t]he authors of this study speculated that a dual column label works as a contextual cue that raises awareness of the amount of food consumed in a package among certain consumers.”¹⁸ Impliedly conceding the insufficiency of the very study it cites, FDA admits that it will be conducting consumer research throughout the rulemaking process to “help enhance our understanding of whether and how much modifications to the label format may help consumers use the label.”¹⁹

FDA cites as the source of its statutory authority section 2(b)(1)(A) of the NLEA, which provides that nutrition information should 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.” As previously

of the RACC be labeled with dual-column labels that include a column of nutrition information within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values (percent DVs) for the entire container, as well as the preexisting required column listing the quantitative amounts and percent DVs for a serving that is less than the entire container (i.e., the serving size derived from the RACC).” 79 Fed. Reg. 11,990, 11,991 (Mar. 3, 2014).

¹⁵ 79. Fed. Reg. at 12,003.

¹⁶ 79. Fed. Reg. at 12,001.

¹⁷ 79 Fed. Reg. 11,990, 11,999 (Mar. 3, 2014).

¹⁸ *Id.*

¹⁹ *Id.*

discussed, FDA's statutory mandate must be implemented in accordance with the First Amendment.

Because it is unnecessarily duplicative, FDA's proposed dual-column labeling requirement is the sort of compelled speech that should be subject to *Central Hudson*, rather than *Zauderer*. Admittedly, FDA is attempting to influence consumer behavior through the dual-column labeling format by discouraging consumers from consuming food that is packaged between 200% and 400% RACC. Yet, based on its own studies, FDA does not have a substantial governmental interest in discouraging consumption of food that is packaged between 200% and 400% RACC.

Because it has not shown that mandatory imposition of dual column labeling would have any discernable effect on consumer behavior, FDA's proposed rule cannot satisfy the third prong of *Central Hudson*. Indeed, FDA has failed altogether to show that dual-column labeling would directly advance its interest in promoting consumer health and preventing over-eating of certain foods. FDA relies in part on study results suggesting that dual column labeling reduces snack food consumption but fails to consider the effect of dual column labeling on consumption of other categories of food besides snacks. FDA inexplicably concludes that consumption of all foods packaged as RACCs between 200% and 400% should be discouraged by citing only studies of junk foods.

FDA's vastly overbroad regulation shows that the regulation does not meet *Central Hudson's* reasonable fit test. Indeed, FDA even acknowledges that "modifying the Nutrition Facts label would require some re-education on how to read the Nutrition Facts label."²⁰ In failing to adequately consider comments that suggested that dual-column format may be confusing, FDA erroneously suggests that the burden is on opponents to provide evidence that dual column labeling may be confusing: "None of these comments, however, provided data or information to support the possible consumer reactions identified. We are not convinced that dual column labeling may be confusing to consumers and that dual-column labeling would imply that consumers should eat more of an item."²¹ But under binding Supreme Court precedent, the evidentiary burden is entirely on FDA, not those opposed to FDA's speech regulations.

²⁰ *Id.*

²¹ 79 Fed. Reg. at 12,002.

VI. Conclusion

The Washington Legal Foundation respectfully requests that FDA withdraw its proposed revisions to the Nutrition and Supplemental Facts Label and the new Dual Column Labeling Requirement in order to bring them into compliance with First Amendment limitations.

Respectfully submitted,

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