Legal Backgrounder

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FDA's "Added Sugars" Labeling Mandate Raises First and Fourth Amendment Concerns

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The Food and Drug Administration ("FDA" or "the Agency") is mulling over comments on proposed regulations that modify the Nutrition Facts label found on practically all food packages. One addition to the label FDA has proposed is the disclosure of the amount of sugar processors add to packaged foods. That mandate implicates other requirements, such as the preparation of extensive records and the need to provide those records to FDA inspectors. If finalized, violations of the added sugars mandate could result in seizures and criminal penalties. As this LEGAL BACKGROUNDER discusses below, these requirements expose FDA's proposed rule to First and Fourth Amendment challenges.

First Amendment Concerns—the First and Second Prongs of the Supreme Court's *Central Hudson* Test

As the Washington Legal Foundation (WLF) pointed out in comments filed with FDA, the U.S. Supreme Court has recognized that the First Amendment protects not only the freedom of speech, but also the freedom not to speak.[1] FDA's proposed requirements raise serious First Amendment concerns. Under the Supreme Court's test set forth in *Central Hudson Gas & Electric Corp. v. Public Service Comm'n,*[2] courts, as a threshold matter, consider whether the commercial speech concerns an unlawful activity or is inherently misleading. If not, *Central Hudson* then requires the government to prove that it has a substantial interest in requiring the disclosure of the amount of sugars added by food processors.

Every nutrient currently required to be listed on the Nutrition Facts label has a Daily Reference Intake (DRI) set by the National Academy of Sciences, Institute of Medicine (IOM), based on a diet-disease relationship. Here, however, FDA concedes that "U.S. consensus reports have determined that inadequate evidence exists to support the direct contribution of added sugars to obesity or heart disease."[3] FDA further admits that there is no chemical difference between naturally occurring sugars in foods and sugars added to foods,[4] (total "Sugars" content is already required to be disclosed on the label).[5] In addition, the U.S. *Dietary Guidelines for Americans* (2010) "state that added sugars do not contribute to weight gain more than any other source of calories."[6] Thus, the Agency's tentative decision to differentiate between the total amount of sugars in a food and the amount which are added during processing is highly questionable.

FDA attempts to justify its proposed regulations by stating that the labeling requirement is part of an effort to inform consumers about the nutrient density of foods, *e.g.* certain foods contain more essential nutrients per calorie than others. But FDA admits that there is insufficient science to support the development of a Daily Value

[1] Comments of the Washington Legal Foundation, Docket FDA-2012-N-1210; RIN 0910-AF22, (Aug. 1, 2014) citing, *Virginia Bd. of Educ. V. Barnette*, 319 U.S. 624, 642 (1943); *Wooley v, Maynard*, 430 U.S. 705, 713-15 (1977).
[2] 447 U.S. 557, at 566 (1980).
[3] 79 Fed. Reg. 11880 at 11904 (Mar. 3, 2014).
[4] *Id*, at 11903.
[5] 21 CFR § 101.9.
[6] 79 Fed. Reg. at 11904.

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for added sugars, stating "we have no scientifically quantitative intake recommendation for added sugars on which a DRV [Daily Reference Value] can be derived.[7]

Instead, FDA merely relies on statements in the *Dietary Guidelines* encouraging consumers to eat more nutrient dense foods and argues that the proposed label disclosure and recordkeeping requirements will help consumers "construct diets containing nutrient-dense foods."[8] At best, FDA is proposing a massive new labeling and costly recordkeeping requirement in a misguided effort to help consumers with general dietary planning—an objective that could best be accomplished through a consumer education program. At worst, the Agency is also confusing the public. FDA asserts that under § 403(q)(2)(A) of the Food, Drug, and Cosmetic Act (FDCA) the Agency can add to the list of nutrients required to be disclosed on the Nutrition Facts label to help consumers maintain "healthy dietary practices."[9] But FDA's own definition of the term "Healthy" does not even consider the amount of sugars in a food.[10] In brief, the Agency's contorted basis for the proposed rule not only falls short of its statutory authority and the Administrative Procedure Act's requirements for reasoned decision making,[11] but also fails to demonstrate that the government has a *substantial* interest in compelling speech about added sugars content.

Further, WLF argues in its comment that FDA's proposed regulation fails to meet the second prong of the Supreme Court's test in *Central Hudson* because the requirement does not "directly advanc[e] the governmental interest asserted."[12] FDA admits that it does not know whether the mandatory disclosure of added sugars, as opposed to simply the total amount of sugars in a product, would have any impact on consumer behavior. FDA states:

> [T]he Agency is not aware of any existing consumer research that has examined this topic and is therefore interested in pursuing this study to enhance its understanding of how consumers might currently perceive and use the new information if it is presented on the Nutrition Facts label.[13]

The Agency has put the cart before the horse. FDA published the proposed rule in the Federal Register before commencing a planned Agency consumer behavior study to examine the impact of an "added sugars" disclosure. Such research is plainly necessary. First, FDA's triple-indented format for the proposed disclosure can make even lawyers wince. Second, other information submitted to the Agency, including a study conducted by the International Food Information Council,[14] concludes that FDA's proposed labeling requirement would in fact mislead consumers.

The Third Prong of the *Central Hudson* Test

In light of these deficiencies, further inquiry into the constitutionality of FDA's proposed regulation is warranted. The third prong of the Supreme Court's test in *Central Hudson* dictates that the regulation "is no more extensive than is necessary to serve [the government's] interest."[15] FDA must demonstrate that the harms it recites are real and that the Agency's proposed disclosure requirement will in fact alleviate them to a material degree. A government regulation will not be upheld if it provides only ineffective or remote support for the government's stated purpose.[16]

In establishing that a proposed regulation is no more extensive than necessary, a regulatory agency, while not necessarily required to employ the least restrictive means conceivable, must still demonstrate that the regulation is narrowly tailored to serve the interest asserted by the government.[17] Thus, even assuming FDA

[7] 79 Fed. Reg. 11906.
[8] 79 Fed. Reg. at 11904.
[9] 21 U.S.C. § 343(q)(2)(A).
[10] 21 CFR § 101.65(d)(2).
[11] *Motor Vehicle Mfrs. Ass'n of U.S. Inc. v State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 103 S. Ct. 2856 (1983).
[12] 447 U.S. 557 at 566.
[13] 78 Fed. Reg. at 32395.
[14] http://www.regulations.gov/#!docketDetail;D=FDA-2012-N-1210.
[15] *Id.*
[16] 164 A.L.R. Fed 1, *citing, Greater New Orleans Broadcasting Ass'n, Inc. v. U.S.*, 527 U.S. 173 (1999).
[17] *Greater New Orleans Broadcasting Ass'n, Inc. v. U.S.*, 527 U.S. 173 (1999); *See Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011).

could demonstrate it had a substantial interest in requiring food processors to distinguish on the Nutrition Facts label between total, naturally occurring, and added sugars, the Agency would have to demonstrate that the scope of its proposed disclosure requirement is narrowly tailored to address that purported interest, and while not necessarily representing the single best disposition, is nonetheless in proportion to the interest served.[18]

Whether FDA could meet the third prong of *Central Hudson,* given the remoteness of the Agency's interest and the demonstrated lack of efficacy of the proposed disclosure requirement, needs to be carefully examined. FDA already requires the disclosure of the content of total sugars per serving. In addition, FDA requires the calorie content of the food to be disclosed. Moreover, all ingredients, including sugars, are required to be disclosed in order of predominance on the ingredient list of every food label.[19] The *Dietary Guidelines,* upon which FDA relies so heavily, specifically advises consumers that "The ingredient list can be used to find out whether a food or beverage contains . . . added sugars . . ."[20]

Moreover, such a requirement would not be "narrowly tailored." FDA states that the greatest sources of added sugars in the diet are cakes and similar desserts, soft drinks and other sweetened beverages, ice cream and related frozen dairy products—facts that should not surprise many consumers. Is a requirement compelling *all* manufacturers to disclose content of added sugars "narrowly tailored" when the issue (even accepting FDA's purported justification) is limited to a handful of food categories? Would a targeted consumer education campaign be more appropriate than requirements applying to all food processors? In light of these considerations, it is questionable whether still another disclosure could be justified under the third prong in *Central Hudson.*

Fourth Amendment Concerns

FDA's proposed method for enforcing its added sugars labeling proposal also raises Fourth Amendment issues regarding constitutional protections against unreasonable searches and seizures. FDA normally enforces compliance with its nutrition labeling regulations by conducting nutrient analyses to determine the accuracy of the amounts stated on the Nutrition Facts label. However, FDA admits that such nutrient analysis is not possible because there is no analytical method that is capable of distinguishing between added and intrinsically occurring sugars in a food product[21] because "added sugars are not chemically different than naturally occurring sugars."[22]

The Agency concludes that enforcement of the proposed added sugars labeling mandate would require an alternative means to verify compliance. The Agency's solution to its dilemma is to propose a massive new recordkeeping requirement for food companies. FDA's proposal would require all companies, even those that add minimal amounts of sugars to their products, to develop and maintain new sets of records detailing the amount of sugars added to all foods they process. Such information would be subject to searches by FDA inspectors.[23] Non-complying products could be seized and firms could be subjected to criminal penalties.[24]

A FDA inspection is clearly a "search" under the Fourth Amendment and has long been a source of constitutional challenges to the Agency's authority.[25] A legislative scheme such as the FDCA falls under the "closely regulated industry" exception where Congress "has broad authority to fashion standards of reasonableness for searches and seizures."[26]

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[18] *Id.*

[19] 21 CFR § 101.4.

[20] *Dietary Guidelines for Americans* (2010), Chapter 3, p. 29. The *Dietary Guidelines* do not recommend disclosure of added sugars on the Nutrition Facts label.

[21] 79 *Fed. Reg*. at 11906.

[22] FDA quotes the National Academy of Sciences, Institute of Medicine as stating ". . . added sugars are not chemically different than naturally occurring sugars," 79 Fed. Reg. at 11903.

[23] *Id*., See 79 Fed. Reg. at 11956-957.

[24] 21 U.S.C. § 333(a)(2).

[25] O'Reilly, James T., *Food and Drug Administration,* § 20:15 Administrative search warrants: Legal aspects – Constitutional parameters (2014).

[26] *Colonnade Catering Corp. V. United States*, 397 U.S. 72, 78 (1970).

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However, there are limits. In a closely regulated industry, administrative warrantless searches are permitted so long as the following conditions are met: (1) there is a substantial government interest that informs the regulatory scheme pursuant to which inspection is made; (2) warrantless inspection is necessary to further the regulatory scheme; and (3) the inspection program, in terms of certainty and regularity of its application, must provide a constitutionally adequate substitute for a warrant. The inspection program must advise a company that a search is being made pursuant to the law, has a properly defined scope, and that the discretion of inspection officials is limited.[27]

The courts have upheld FDA's right to conduct inspections pursuant to the FDCA as consistent with the Fourth Amendment in areas involving adulterated foods.[28] While there is strong precedent for the proposition that FDA has authority to require and inspect records in situations involving safety, the case of added sugars labeling deserves a close review. Here, the basic question is whether the government's interest in purportedly helping consumers eat more nutrient dense foods—an objective not related to the prevention of any disease or health-related condition—is substantial enough to justify the warrantless governmental intrusion. The Supreme Court, in the landmark case *Marshall v. Barlow's Inc.*[29] held that inspections by administrative agencies without judicial warrants are generally unreasonable. The case specifically held that warrantless inspections are prohibited under the Occupational Safety and Health Act.

While the Court avoided discussion of the FDCA, its holding is still relevant.[30] It might be reasonable for the food industry to expect that FDA could conduct a warrantless inspection to ensure compliance with labeling requirements intended to help consumers reduce their risk of diet-related illnesses (ranging from allergic reactions to cancer) and to prevent consumer fraud or deception. Food companies, however, may not reasonably have an expectation that their records will be searched and seized by FDA as part of the Agency's effort to help consumers with dietary planning. Indeed, as FDA has learned, the exception to the Fourth Amendment for closely regulated industries has boundaries and the courts can rebuff an attempt to search and seize when the Agency overreaches.[31]

The question is as simple as this: Does the government have the constitutional right to arrive at a food processing facility and demand that the owner produce records showing how much sugar is being added to a sugar cookie? Given the paucity of the purported justification for FDA's proposed labeling requirement, it may be time to revisit the question of when FDA's interest is substantial enough to justify an intrusion that would otherwise be prohibited by the Fourth Amendment.

Food for Thought

The March 3, 2014 Nutrition Facts proposed rule makes no mention of the First or Fourth Amendments to the U.S. Constitution despite the proposal's requirements that businesses engage in expressive activity, collect records, and make those records available upon Agency demand. The compelled printing of "added sugars" on the label is vulnerable to a First Amendment challenge. When the Agency moves to enforce a finalized recordkeeping requirement with unannounced warrantless inspections, food processors will have Fourth Amendment arguments for unconstitutional search and seizure too. FDA should acknowledge and address these constitutional concerns, and amend its proposed regulations accordingly, before taking final Agency action.

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[27] *New York v. Burger,* 482 U.S. 691, 703 (1987).

[28] *United States v. New England Grocers Supply Co*. 488 F. Supp 230, 238 (D.Mass. 1980); *U.S. v. Thriftimart, Inc.* United States Court of Appeals, 429 F.2d 1006 (9th Cir. 1970).

[29] *Marshall v. Barlow's Inc.* 436 U.S. 307 (1978).

[30] O'Reilly, *Food and Drug Administration,* § 20:15.

[31] *U.S. v. Articles of Drug Consisting of Imported from New Zealand Neptone Lyophilizied-Homogenized Mussels (Aquaculture Corp.)*, 568 F. Supp. 1182 (1983) (Commercial enterprise regulated by FDA had a legitimate expectation of privacy. Absent the showing of exigent circumstances, there was no excuse for the government's failure to obtain a valid warrant). *See also*, *U.S. v. An Article Consisting of One DEVICE, More or Less, LABELED in Part: "THERAMATIC" and Dr. Ralph B. Cloward*, 641 F.2d 1289 (9th Cir. 1981).

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