
COMMENTS

of

WASHINGTON LEGAL FOUNDATION

to the

FOOD AND DRUG ADMINISTRATION

Concerning

**FOOD LABELING: REVISION OF THE NUTRITION
AND SUPPLEMENTAL FACTS LABEL; REOPENING
OF THE COMMENT PERIOD AS TO SPECIFIC DOCUMENTS
(Docket FDA-2012-N-1210; RIN 0910-AF22)**

and

**FOOD LABELING: REVISION OF THE NUTRITION
AND SUPPLEMENTAL FACTS LABEL; SUPPLEMENTAL
PROPOSED RULE TO SOLICIT COMMENTS ON
LIMITED ADDITIONAL PROVISIONS
(Docket FDA-2012-N-1210; RIN 0910-AF22)**

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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—Reopening of the Comment Period as to Specific Documents and Supplemental Proposed Rule to Solicit Comments (Docket FDA-2012-N-1210)

Dear Sir/Madam:

Washington Legal Foundation (WLF) appreciates the opportunity to submit these comments in response to the public notices published at 80 Fed. Reg. 44302 (July 27, 2015) and 80 Fed. Reg. 44303 (July 27, 2015). After detailing the interests of WLF in these proposed regulations, we will explain the serious constitutional concerns we have with the added-sugars labeling mandate and the Percent Daily Value labeling mandate. This comment will also explain why the Food and Drug Administration's failure to comply with certain mandatory procedural requirements, and its flawed reliance on a federal nutrition advisory committee report, are legally suspect.

I. Interests of WLF

Founded in 1977, Washington Legal Foundation is a public-interest law firm and policy center 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. The intense debate over Americans' food and beverage consumption, and what role, if any, government should play in dietary choices, implicates all of those principles.

WLF is especially concerned with the government's role in curtailing the rights of commercial enterprises to communicate truthful messages about their products, as well as mandating that such enterprises communicate government messages (at their own expense) with which they disagree. To that end, WLF provided comments on August 1, 2014 to FDA regarding several aspects of its March 3, 2014 Proposed Revision of the Nutrition and Supplemental Facts Label. Those comments expressed our concern that the agency failed to adequately consider relevant First Amendment standards in proposing those revisions. These comments will reiterate those concerns in relation to the disclosure of the amount of added sugars on the Nutrition Facts label, and provide similar analysis on the new Percent Daily Value requirement for added sugars.

The Reopening of the Comment Period as to Specific Documents and the Supplemental Proposed Rule notices both give rise to serious issues regarding FDA's compliance with federal substantive and procedural laws such as the Administrative Procedure Act (APA), the Information Quality Act (IQA), and the Federal Advisory Committee Act (FACA). Those laws uphold vital due process, open government, and science-based decision-making principles for which WLF has advocated for 38 years. Recent examples of instances where WLF has filed *amicus* briefs in litigation implicating the APA include *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199 (2015); *Prevor v. Food and Drug Administration*, 1:13-cv-01177 (D.D.C. Sept. 9, 2014); and *Christopher v. SmithKline Beecham*, 132 S. Ct. 2156 (2012). On April 27, 2015, WLF filed a brief in the U.S. Court of Appeals for the D.C. Circuit in *Lorillard, Inc. v. FDA*, in which the court will address allegations that FDA violated federal conflict-of-interest law in empaneling an advisory committee. We also advanced FACA concerns in a Citizen Petition filed with FDA regarding an Institute of Medicine advisory panel on medical device review standards, *In re: Citizen Petition Regarding Use of Advice from IOM Committee that Fails to Comply with FACA's Fair Balance Requirement*, June 28, 2011.

Furthermore, WLF's Legal Studies Division frequently produces and distributes articles that address the application of these laws. *See, e.g.*, Jacob and Ramos, *Judicial Review of Informal Agency Pronouncements: Any Clearer After Young v. UPS and Perez v. MBA?*, July 31, 2015; Kogan, *Revitalizing the Information Quality Act as a Procedural Cure for Unsound Regulatory Science: A Greenhouse Gas Rulemaking Case Study*, February 2015; and Ebner, *DC Circuit Shuts Down another Federal Regulatory "Switcheroo,"* May 23, 2014.

Finally, given the Supplemental Proposed Rule's extensive reliance on the Scientific Report of the 2015 Dietary Guidelines Advisory Committee, we also note WLF's public comments to the Department of Health and Human Services and the U.S. Department of Agriculture, filed on May 8, 2015, available at <http://www.wlf.org/upload/litigation/misc/WashingtonLegalFoundationDGACScientificReportComments.pdf>.

II. First Amendment Implications of Mandated Added-Sugars Declaration and Percent Daily Recommended Value

WLF's August 1, 2014 comments on the Proposed Revision of the Nutrition and Supplemental Facts Label expressed our serious concern that FDA failed to consider relevant First Amendment standards in a proposal requiring regulated entities to publish the government's message on their products at their own expense. FDA must implement the federal Food, Drug & Cosmetic Act (FDCA) in a manner that does not offend the First Amendment.

Those comments focused in part on the proposed addition of an "added sugars" declaration to the Nutrition Facts panel and on FDA's inability to demonstrate that the mandate complies with the First Amendment. In its July 27 Supplemental Proposed Rule,

the agency repeats its intention to mandate an “added sugars” declaration and cites two new pieces of evidence that purportedly support adding this information to the Nutrition Facts panel. Once again, however, FDA makes no mention of the First Amendment. Below we will reiterate our constitutional concerns and address the free speech ramifications of the agency’s new evidence.

A. Mandated Listing of Amount of Added Sugars

The First Amendment, subject only to very narrow and well-understood exceptions, protects citizens’ decisions *not* to speak. Such constitutional restrictions on compelled speech extend to corporations as well as to individuals.¹

WLF argued in its August 1 comments that because the governmental interest FDA was purporting to advance with the added-sugars disclosure—assisting “consumers in maintaining healthy dietary practices”—did not relate to correcting misleading speech or reducing consumer confusion, the Supreme Court’s *Zauderer*² decision is inapplicable. Rather than prevent deception, we argued, the added-sugars disclosure threatens to *cause* consumer confusion.³

The proposal, we concluded, must therefore be analyzed under the heightened scrutiny of the Court’s *Central Hudson* ruling.⁴ Because, as FDA itself acknowledged, nutrition science failed to establish a direct connection between added sugars and obesity or heart disease, the proposal was not advancing a “substantial government interest” as required by the first prong of *Central Hudson*’s First Amendment test. Even if the interest were substantial, the proposal does not “directly and materially advance” that interest under *Central Hudson*’s third prong. FDA provided no support beyond its own conjecture for its argument that consumers would benefit from disclosure of added sugars on the Nutrition Facts panel, or even understand the information.⁵

The new information on which FDA seeks comment in the Supplemental Proposed Rule—the results of a survey on consumers’ attitudes toward the added-sugars disclosure and the conclusions of the 2015 Dietary Guidelines Advisory Committee—do not alter the outcome of WLF’s original First Amendment assessment. Neither addition to the record assists FDA in demonstrating that a “reasonable fit” exists between the compelled speech and the asserted government interest.

¹ 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.”).

² *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985).

³ *Zauderer* does not provide the applicable First Amendment standard where statements are “misleading” or “could prove to be [mis]interpreted.” *CTIA-The Wireless Ass’n v. City of S.F.*, 494 F. App’x 752, 753 (9th Cir. 2012). See also *R.J. Reynolds Tobacco v. FDA*, 696 F.3d 1205, 1216 (D.C. Cir. 2012) (compelled statement must be “indisputably accurate and not subject to misinterpretation”).

⁴ *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557 (1980).

⁵ *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995) (quoting *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993)).

In defense against a constitutional challenge, FDA might assert that the conclusion of the Dietary Guidelines Advisory Committee (DGAC) on the connection between added sugars intake and cardiovascular disease (CVD), and the studies underlying that conclusion, fortify its argument that its Nutrition Facts mandate directly advances the goal of assisting consumers under *Central Hudson*'s third prong. The agency presented that supposed evidence in the July 27 Federal Register notice, however, in a significantly misleading fashion.

FDA relies on portions of the DGAC report dealing with *general* dietary patterns and ignores the *specific* portion of the DGAC report pertaining to the relationship of added-sugars consumption and cardiovascular disease. The notice states Part D, Chapter 2 of the DGAC report reflects that "there is evidence of a *strong* association between a dietary pattern of intake characterized, in part, by a reduced intake of sugar-sweetened foods and beverages and a reduced risk of CVD."⁶ That specific part of the DGAC report, though, discusses reduced intake of added sugars as merely *one* factor in decreasing CVD risk; other factors included "higher consumption of vegetables and fruits, whole grains, low-fat dairy."⁷

The section of the report that focuses specifically on scientific studies pertaining to the relationship between added-sugars consumption and CVD found only "moderate" evidence linking primarily sugar-sweetened beverages, but not all foods with added sugars, with an increased risk of hypertension, stroke, and heart disease.⁸ FDA thus mischaracterized a "moderate" finding from the DGAC report as a "strong" finding. That lower level of scientific certainty, and FDA's mischaracterization of the evidence's strength on the record, substantially undermines the agency's claim that there is a reasonable fit between the disclosure mandate and the government interest.

Even if a court did accept FDA's argument on the correlation between added sugars and disease, that is only one part of the "direct and material" advancement case the agency must successfully make. To assist consumers, the added-sugars disclosure mandate must also be understandable. FDA would cite to the results of its "Added Sugars Experiment" as evidence that consumers will understand the information being added to the Nutrition Facts label.

FDA is unlikely to prevail with this argument. According to the July 27 Federal Register notice, the agency performed the research "to help inform consumer education," and the results provide "initial understanding of potential consumer reaction."⁹ The Added Sugars Experiment is at best weak evidence that consumers understand, and thus would benefit from, added-sugars labeling. Other FDA statements both in the Federal

⁶ 80 Fed. Reg. 44,303, 44,308 (July 27, 2015) (emphasis added).

⁷ U.S. Department of Agriculture and U.S. Department of Health and Human Services, Scientific Report of the 2015 Dietary Guidelines Advisory Committee [hereinafter "DGAC report"] (Feb. 2015), at pt. D, ch. 2, p. 8.

⁸ Report, pt. D, ch. 6, p. 20.

⁹ 80 Fed. Reg. at 44,306.

Register notice and a supporting memorandum undermine any “direct and material advancement” argument the agency would make under *Central Hudson*. The notice acknowledges that “the added sugars experiment results show that a number of participants were confused about the distinction between sugars and added sugars.”¹⁰ A memorandum referenced in the Federal Register notice states with regard to the survey:

Results showed that when the more nutritious (*i.e.* lower-calorie, lower-fat, higher-fiber, and higher-vitamin) product has less added sugars, label format had no statistically significant effect on the likelihood of respondent identifying that product as healthier [parenthetical omitted]. *In contrast, when the more nutritious product had more added sugars, the percentage of respondents identifying that product as healthier decreased.*¹¹

FDA assures stakeholders that any initial consumer confusion could be addressed by “future educational efforts.”¹² But the success of any such education is at best speculative and would not support the agency’s First Amendment arguments.

A stakeholder challenging the disclosure rule could question the value of FDA’s experiment, given that it was performed and released *after* the agency had already proposed the added-sugars mandate. Such a plaintiff could also alert the court that due to the Office of Management and Budget’s (OMB) unprecedented “fast track review” of FDA’s proposed study, stakeholders were denied the opportunity to comment on the design of the studies as required by the Paperwork Reduction Act.¹³

Finally, FDA failed to refute, and continues to consciously ignore, a peer-reviewed study on consumers’ reaction to the added-sugars labeling that undermines the proposal.¹⁴ Numerous stakeholders, including WLF, made FDA aware of this study and its findings in comments on the March 3, 2014 Proposed Revision of the Nutrition and Supplemental Facts Label. Despite such notice, the agency stated in the July 27 Federal Register notice that it was “not aware of any previous studies of consumer responses to added sugars information.”¹⁵

¹⁰ *Ibid.*

¹¹ FDA Memorandum to the File, Experimental Study on Consumer Responses to the Nutrition Facts Labels with Declaration of Amount of Added Sugars (OMB, Control No. 0910-0764), at 17 (emphasis added).

¹² 80 Fed. Reg. at 44,306.

¹³ See Grocery Manufacturers Association, Request for Extension of Comment Period, Sept. 3, 2015 at 2.

¹⁴ Laquatra, Sollid, Edge, Petzel & Turner, *Including ‘Added Sugars’ on the Nutrition Facts Panel: How Consumers Perceive the Proposed Change*, J. OF THE ACADEMY OF NUTRITION AND DIETETICS, 2015, available at <http://www.andjrn.org/article/S2212-2672%2815%2900505-5/pdf>.

¹⁵ 80 Fed. Reg. at 44,306.

B. Percent Daily Value Mandate for Added Sugars

The July 27, 2015 Supplemental Proposed Rule, citing a recommendation in the DGAC report, proposes to establish a Daily Reference Value (DRV) for added sugars of 10% of daily calories, and mandates that this Percent Daily Value (%DV) be printed on the Nutrition Facts panel. Reliance solely on the DGAC report—a document FDA acknowledges “does not contain federal government recommendations”¹⁶—to set a DRV is unprecedented. The agency has traditionally followed a standard of “sufficient scientific consensus” to set DRVs,¹⁷ and has in the past relied, at most, only minimally on the Dietary Guidelines for Americans itself.¹⁸ The Supplemental Proposed Rule did not explain why FDA departed from the “sufficient scientific consensus” standard or justify doing so.

Notwithstanding that the %DV mandate fundamentally impacts rights under the U.S. Constitution—by compelling speech—FDA failed to reference the First Amendment in the Supplemental Proposed Rule. As WLF argued in our August 1, 2014 comment, and again above on the added-sugars disclosure, the agency has a duty to implement the FDCA in a manner that is consistent with the Constitution.

The First Amendment analysis WLF provided in its August 1 comment, and in this comment above, with regard to the added-sugars disclosure is germane to the %DV mandate. If required to defend this rule, FDA might argue that because listing the %DV is “reasonably related” to assisting consumers in maintaining healthy dietary practices, the rule is constitutional under the Supreme Court’s *Zauderer* standard for compelled speech.

Zauderer and its lower level of constitutional scrutiny, however, do not apply to FDA’s %DV mandate for at least two reasons. First, the mandate is not designed to advance the substantial government interest in preventing consumer fraud or deception. In fact, the information itself is potentially deceptive.¹⁹ The redesigned Nutrition Facts label would confront consumers not only with newly-listed “Added Sugars,” but also with a specific Percent Daily Value for that nutrient. Above that %DV on the label would be %DVs for Carbohydrates and Dietary Fiber. Immediately preceding it would be an empty space for “Sugars,” because, FDA claims in the July 27 proposal, current science doesn’t support the establishment of a Daily Recommended Value for “Sugars.” A reasonable consumer could easily find that confusing. It is also unclear whether most

¹⁶ *Ibid.*

¹⁷ FDA, Food Labeling; Reference Daily Intakes and Daily Reference Values, 58 Fed. Reg. 2,206 (Jan. 6, 1993).

¹⁸ For example, in setting the DRV for potassium, FDA used major consensus reports, relying primarily on the National Academy of Sciences *Diet and Health* report. FDA specifically rejected the Dietary Guidelines for Americans as a credible source of information on that occasion. FDA stated: “The Dietary Guidelines are intended to provide general good guidance and do not necessarily specify recommended intakes for individual nutrients.” *Id.* at 2,224.

¹⁹ See discussion *supra* at p. 4 and n.3.

consumers even know what %DV represents in the dietary context. FDA cannot provide an answer to that question, or credibly argue that consumers will not find the %DV for added sugars confusing, because its Added Sugars Experiment survey did not seek that information.²⁰

Second, compelled speech aimed at preventing consumer deception passes muster under *Zauderer* only if it mandates “purely factual and uncontroversial information.”²¹ The very concept of “added sugars” is controversial, considering that no physiological difference exists between how intrinsic and non-intrinsic sugars affect the human body. Also, unlike every other nutrient that will appear on the proposed food label, no analytical method exists to confirm the amount of added sugars in a product. FDA’s definition of added sugars for purposes of the Nutrition Facts panel is, as a member of the 2010 Dietary Guidelines Advisory Committee has explained, itself vague and open to many interpretations.²²

Even if %DV is considered a “purely factual” statement, the context in which government is compelling food and beverage manufacturers to make the statement can render it “controversial.” As the Ninth Circuit related in *CTIA-The Wireless Ass’n*, even “factual statements” can convey “more than just facts.”²³ A Nutrition Facts panel with %DV for “Added Sugars” in the absence of a similar disclosure for “Sugars” could lead the average consumer, who is most likely unaware that her digestive system treats all sugars equally, to conclude that added sugars are inherently dangerous. One could argue, given the disproportionate attention the public health community and the government now devote to added sugars, that such a consumer reaction is what FDA intended. Compelled speech built on such a contestable premise, however, does not comport with the First Amendment.

Because *Zauderer* is inapplicable, *Central Hudson* provides the appropriate First Amendment analytical framework. WLF doubts whether FDA can establish that its %DV mandate advances a substantial government interest. Even if it can, WLF believes the regulation fails under the third and fourth prongs of *Central Hudson*.

Under *Central Hudson*’s “reasonable fit” requirement, FDA never demonstrated that an added-sugars %DV disclosure would have a direct and material effect on consumer behavior. First, the agency cannot cite any research that establishes consumers’ understanding of a Percent Daily Value, let alone data that consumers understand a %DV for added sugars and know how to use that information. Second, as discussed above, FDA for the first time relied entirely on a federal advisory committee report to justify the

²⁰ See 80 Fed. Reg. at 44,306 (“The research design did not include a percentage DV for added sugars on the food label.”).

²¹ *Zauderer*, 471 U.S. at 651.

²² Goldfein and Slavinn, *Why Sugar Is Added to Food: Food Science 101*, 14 COMP. REV. IN FOOD SCIENCE & FOOD SAFETY 644, 648-49 (2015), available at <http://onlinelibrary.wiley.com/doi/10.1111/1541-4337.12151/epdf>.

²³ *CTIA-The Wireless Ass’n*, *supra* note 3 at 753.

establishment of a Daily Reference Value and, in turn, a %DV. The dubious nature of that justification is further undermined by the DGAC report's reliance on a single 2013 study as support for its DRV and %DV disclosure recommendations for added sugars.²⁴

Finally, the %DV added-sugars disclosure fails the fourth prong of the *Central Hudson* test because it is "more extensive than necessary to serve [the government] interest."²⁵ FDA's approach to added-sugars labeling, both for the amount of that nutrient and for the %DV, is a blunderbuss that covers every possible food source of added sugars. The DGAC report notes that beverages (other than milk and 100% fruit juices) account for 47% of added sugars consumption.²⁶ Dairies and grains, on the other hand, contributed 4% and 8%, respectively.²⁷ Those latter two food sources, food scientists explain, will have more of a challenge both calculating the amount of added sugars in their products and, if they want to avoid the stigma of specifying that nutrient on the food label, replacing added sugars.²⁸ FDA should have considered a more targeted speech mandate, but it does not appear to have fulfilled this constitutional duty.

III. THE PROPOSED RULES ARE VULNERABLE TO AN ADMINISTRATIVE PROCEDURE ACT CHALLENGE

FDA has put its March 3, 2014 Proposed Revision of the Nutrition and Supplemental Fact Label on a fast track to finalization, as shown in part by its request that OMB invoke a rarely-used emergency exception that forestalled public comment on the agency's proposed Added Sugars Experiment.²⁹ FDA has also rebuffed requests from a significant number of stakeholders to extend the comment period beyond October 13. Yet, the agency took a brief pause in its sprint to finish the rulemaking to invoke the support of the 2015 Dietary Guidelines Advisory Committee and its scientific report. Ironically, *both* FDA's urgency to complete the rulemaking and its attempt to fortify its justification for added-sugars labeling have created procedural and substantive legal flaws that expose the proposal to challenge.

Below we detail legal infirmities under the Information Quality Act, the National Nutrition Monitoring and Related Research Act (NNMRRRA), and the Federal Advisory Committee Act, all of which can be pursued through an Administrative Procedure Act-based lawsuit.

²⁴ Te Morenga, Mallard, & Mann J., *Dietary Sugars and Body Weight : Systematic Review and Meta-analyses of Randomised Controlled Trials and Cohort Studies*, *BMJ*. 2013;346:e7492. PMID: 233214. Notably, 74% of the studies reviewed in the meta-analysis were conducted outside the U.S.

²⁵ *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 566.

²⁶ DGAC scientific report, *supra* note 7; *see also* Goldfein and Slavinn, *supra* note 22 at 655.

²⁷ DGAC scientific report, *supra* note 7

²⁸ Goldfein and Slavinn, *supra* note 22 at 655.

²⁹ *See* discussion, *supra* at p.5 and n.13

A. The Information Quality Act

The IQA requires federal agencies to ensure the quality, objectivity, utility, and integrity of the scientific, technical, and statistical information that they adopt and “disseminate” to the public.³⁰ The law directed OMB to draft implementing guidelines and also required federal agencies to develop information quality guidelines. FDA is subject to its own information quality guidelines which, by specific reference, incorporate the Department of Health and Human Services’ information quality guidelines.³¹

FDA’s release of the Added Sugars Experiment through the July 27 Reopening of the Comment Period as to Specific Documents notice, and the agency’s reliance on the DGAC report in the Supplemental Proposed Rule, raise IQA concerns worthy of separate comment. We will then explain how such IQA noncompliance gives rise to a challenge under the APA.

1. Reopening of the Comment Period as to Specific Documents

This specific Federal Register notice, published separately from the Supplemental Proposed Rule notice, sought comment on two consumer studies, only one of which, the Experimental Study on Proposed Changes to the Nutrition Facts Label Format, is relevant to WLF’s comments.

FDA’s release of the Added Sugars Experiment in support of a federal rulemaking constitutes “dissemination” under the HHS and FDA guidelines. The HHS guidelines dictate, “Research and scientific studies disseminated by HHS are subject to an external, objective peer review process.”³² The Added Sugars Experiment qualifies as “influential scientific information” under the OMB peer-review bulletin³³ and FDA’s information quality guidelines.³⁴ OMB’s peer-review bulletin further requires that when an agency disseminates influential scientific information in support of a regulatory action, the agency must include in the administrative record a certification explaining how it satisfied the relevant information quality guidelines and peer-review standards.³⁵

³⁰ Pub. L. No. 106-554, 114 Stat. 2763, 2763A-153-154 (2000), § 515.

³¹ FDA Guidelines for Ensuring the Quality of Information Disseminated to the Public [hereinafter “FDA guidelines”]; HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public [hereinafter “HHS guidelines”]. WLF notes that upon clicking the link on OMB’s “Agency Information Quality Guidelines” page (https://www.whitehouse.gov/omb/inforeg_agency_info_quality_links) for HHS, one arrives at a page (<http://aspe.hhs.gov/infoquality/requests.shtml>) that displays the following message: “404 Error: The page you requested does not exist.” The HHS guidelines are alternatively available at http://www.thecre.com/pdf/20021026_hhs-hrsa-dqfinal.pdf; the FDA guidelines are available at http://www.thecre.com/pdf/20021026_hhs-fda-dqfinal.pdf.

³² HHS Guidelines, sec. D, pt. 4e.

³³ Office of Management and Budget, *Final Information Quality Bulletin for Peer Review* [Hereinafter “OMB-PRB”] (Dec. 16, 2004) at Preamble, §§ I, p. 11, II, p. 12; § I.6.

³⁴ FDA Guidelines, sec. VII, pt. A.

³⁵ OMB-PRB, *supra* note 33 at Preamble, p. 31 and § VII, p. 43.

The Reopening of the Comment Period as to Specific Documents notice made no reference to any peer review the Added Sugars Experiment underwent and no certification that its dissemination meets relevant information quality guidelines or peer-review standards. Any stakeholder could pursue correction of this noncompliance with the IQA and the agencies' information quality guidelines, and FDA would be required to evaluate and formally respond to that request. FDA's failure to respond, or refusal to make the requested correction, could give rise to an APA-based legal challenge.

Disregard for the IQA and its implementing guidelines is troubling. It is even worse when one considers that OMB allowed FDA to bypass a mandated review procedure prior to the agency's conducting the study. As documented in a request for an extension of the comment period on the FDA consumer studies, the agency sought and received from OMB permission to bypass notice-and-comment requirements for the studies under the Paperwork Reduction Act.³⁶ OMB accepted FDA's explanation that "emergency" clearance was warranted because "a normal clearance is likely to cause a statutory or court-ordered deadline to be missed." In fact, no such emergency situation existed.

2. Supplemental Proposed Rule

The Supplemental Proposed Rule makes specific reference to the 2015 DGAC report as an additional justification for added-sugars amount disclosure on the Nutrition Facts label, and as supporting the establishment of a Daily Reference Value for added sugars and a %DV for the label. While FDA acknowledges that the report "does not contain federal government recommendations," it accepted and embraced its conclusions as a third-party scientific assessment.

FDA is thus "disseminating" the DGAC report, and the report thereby qualifies under the OMB peer-review bulletin as a "highly influential scientific assessment." The report is "novel, controversial, [and] precedent-setting, [and] has significant interagency interest."³⁷ Under the HHS guidelines, such scientific information *must* be peer reviewed, and OMB's peer-review bulletin dictates that such peer review be certified in the administrative record. FDA has done neither with regard to the DGAC report. Any stakeholder could pursue correction of this noncompliance with the IQA and the agencies' information quality guidelines, and FDA would be required to evaluate and formally respond to that request. FDA's failure to respond, or refusal to make the requested correction, could give rise to an APA-based legal challenge.

3. APA Action Challenging IQA Noncompliance

If FDA refuses to respond to or reject those requests for correction, those shareholders who had sought the correction could pursue an APA action for FDA's noncompliance with the IQA.

³⁶ Grocery Manufacturers Association, Request for Extension of Comment Period, Sept. 3, 2015 at 3.

³⁷ OMB-PRB, *supra* note 33 at § III.1, p. 39.

Since the IQA's passage in 2000, federal courts have been generally skeptical of regulated entities' private causes of action to redress agencies' noncompliance with IQA standards. Those complaints have foundered on plaintiffs' standing to sue, as well as their assertion of a "positive" right to properly peer-reviewed government information. In February 2015, WLF published a WORKING PAPER, *Revitalizing the Information Quality Act as a Procedural Cure for Unsound Regulatory Science: A Greenhouse Gas Rulemaking Case Study*,³⁸ which prescribed an alternative approach to redressing IQA violations through litigation.

The contemplated cause of action is based on the fact that Congress intended the IQA, as an implementation of the Paperwork Reduction Act, to protect the *negative* right of a designated class of persons not to be burdened, financially or otherwise, by poor quality science that agencies disseminate in support of major regulations. A challenge to FDA's noncompliance with the IQA could be brought as an action under APA § 706. The plaintiff would argue that such a claim satisfies the requirements of APA § 701(a) because the IQA does not preclude judicial review and FDA's decision not to comply with the IQA and the implementing guidelines is not committed to agency discretion by law. Two federal courts of appeal, though rejecting stakeholders' particular IQA challenges, have found that the OMB information quality guidelines, and analogous federal agency guidelines, impose legally binding obligations on those agencies that merit *Chevron* deference.³⁹

A food or beverage industry stakeholder could establish standing to sue under the APA based on the particularized economic injuries they suffer from FDA's added-sugar labeling mandates. A narrowly-pled, factually-supported challenge such as this would not only be consistent with the longstanding presumption that Congress intends judicial review of administrative action, but it would also suffice to overcome some federal courts' presumption against implied causes of action.

B. The National Nutrition Monitoring and Related Research Act

The National Nutrition Monitoring and Related Research Act of 1990 requires the Secretaries of HHS and USDA to "publish a report entitled 'Dietary Guidelines for Americans.' Each report shall contain nutritional and dietary information for the public and shall be promoted by each Federal Agency in carrying out a Federal food, nutrition, or health program."⁴⁰ To assist in carrying out this statutory mandate, the Secretaries have empaneled a federal advisory committee. Its work, and the scientific report that results from it, must comply with the NNMRRRA.

³⁸ Kogan, *Revitalizing the Information Quality Act as a Procedural Cure for Unsound Regulatory Science: A Greenhouse Gas Rulemaking Case Study*, WLF WORKING PAPER (Feb. 2015), available at <http://www.wlf.org/upload/legalstudies/workingpaper/2015Kogan.pdf>.

³⁹ See *Harkonen v. U.S. Dept. of Justice*, No. 13-15197 (9th Cir., Sept. 8, 2015) available at <http://cdn.ca9.uscourts.gov/datastore/opinions/2015/09/08/13-15197.pdf>; *Prime Time Int'l Co. v. Vilsack*, 599 F.3d 678 (D.C. Cir. 2010), petition for rehearing denied *per curiam* (2010).

⁴⁰ 7 U.S.C. § 5341(a)(1).

The DGAC, in recommending that federal regulatory policies targeting added sugars be a part of the 2015 Dietary Guidelines, violated the NNMARRA. FDA's reliance on those specific sections of the DGAC report to justify its added-sugars labeling proposals thus constitutes a violation of § 706(2) of the APA.

1. The DGAC Cannot Lawfully Recommend Regulation for the Dietary Guidelines

The DGAC's added-sugars labeling recommendation does not constitute "dietary guidance" under the 1990 law. Also, when viewed in the context of FDA's pending rulemaking, the scientific report treads on § 5431(b)(3) of the law by recommending that the Dietary Guidelines advance the mandatory declaration of added sugars on the Nutrition Facts panel, as FDA had already proposed at the time DGAC issued the report.

2. The Report's Added-Sugars Labeling Recommendation is Not Based on a Preponderance of the Evidence

Section 301(a)(2) of the NNMARRA dictates that the "information and guidelines contained in each report . . . shall be based on the preponderance of the scientific and medical knowledge."

The scientific studies on added sugars that the DGAC reviewed did not examine how consumers would comprehend such label disclosures, and hence whether the recommended labeling requirement would "assist consumers in making informed dietary decisions."⁴¹ At the time DGAC issued its study, FDA's Added Sugars Experiment had not been released.

Because the DGAC could not review FDA's unreleased study, and failed to consult any other relevant studies, its added-sugars labeling recommendation is not supported by a preponderance of the evidence as the 1990 law requires.

3. Reliance on the DGAC Recommendation of Added-Sugars Labeling Would Violate the APA

FDA's *post hoc* reliance on the 2015 DGAC report's recommendations for added-sugars labeling in a final Revision of the Nutrition and Supplemental Facts Label rule would violate § 706(2) of the APA.

It is well settled that a court may strike down a regulation if the asserted or necessary "factual basis" of the rule is invalid.⁴² Regulations lacking an adequate "factual basis" are considered to be "arbitrary and capricious" in violation of the APA.⁴³

⁴¹ Report, pt. D, ch. 6, p. 26.

⁴² *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.* 463 U.S. 29 (1983).

⁴³ 5 U.S.C. § 706 (2)(A).

As explained above, the DGAC's added-sugars labeling recommendations violate the NNMRRRA. Given that the DGAC's recommendation is itself thus invalid, and FDA relied on the DGAC report as the factual basis for its added-sugars labeling mandate, therefore the invalid DGAC recommendation undermines FDA's labeling mandate.

C. The Federal Advisory Committee Act

Congress adopted FACA in 1972 to ensure that "standards and uniform procedures" would "govern the establishment, operation, administration, and duration of advisory committees."⁴⁴ Section 5 of FACA requires that all federal advisory committees be "fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee."⁴⁵ In adopting the "fairly balanced" requirement, Congress emphasized the need "to ensure that persons or groups directly affected by the work of a particular advisory committee would have some representation on the committee."⁴⁶

HHS and USDA created the 2015 Dietary Guidelines Advisory Committee in blatant violation of FACA § 5. The committee was homogeneously academic. As Dr. Roger Clemens of the University of Southern California, a 2010 DGAC member, stated in a conference call with reporters, "The flavor [of the committee] was quite evident based on the consultants the DGAC brought on board . . . there was not a balance of presentation. We did not have an adequate amount of agriculture input, nobody on the committee was a food scientist or had been trained in food science, nobody had a background in food law."⁴⁷

Some DGAC members held personal views that should have been well known to the HHS and USDA Secretaries. Those views undoubtedly influenced those members' work on the DGAC and the DGAC's work as a whole. For instance, prior to being named DGAC Committee Vice-Chair, Professor Alice Lichtenstein consistently expressed support for changing dietary habits through government policy. Professor Lichtenstein authored a July 2013 editorial in *The Annals of Internal Medicine* praising the purported success of New York City Mayor Michael Bloomberg's ban on trans fat in city restaurants.⁴⁸ She spoke approvingly to CNN about Mayor Bloomberg's ban on soda and

⁴⁴ 5 U.S.C. Appx. § 2(b)(4).

⁴⁵ 5 U.S.C. § 5(b)(2).

⁴⁶ *Nat'l Anti-Hunger Coalition v. Exec. Comm. of President's Private Sector Survey on Cost Control*, 711 F.2d 1071, 1074 n. 2 (D.C. Cir. 1983).

⁴⁷ *News Bite: 2015 Dietary Guidelines Advisory Committee Report: What Does it Mean for the Actual Guidelines*, International Food Information Council *Food Insight*, available at <http://www.foodinsight.org/newsletters/news-bite-2015-dietary-guidelines-advisory-committee-report-what-means-for-actual-guidelines#sthash.cfjGUIaf.dpuf>.

⁴⁸ Lichtenstein, *New York City Trans Fat Ban: Improving the Default Option When Purchasing Foods Prepared Outside of the Home*, *ANN. INTERN. MED.* July 17, 2012; 157: 144-145.

other “sugary” drinks in portions larger than 16 ounces, saying that “soda restriction could have a similar impact” as the trans fat ban.⁴⁹

Professor Lichtenstein spoke regretfully about the drink portion-size ban being “blocked by the courts” in an illuminating speech at Boston University’s College of Health on December 4, 2013.⁵⁰ During the speech, Professor Lichtenstein praised Mexico for its adoption of an 8% tax on sodas and “junk food” and upbraided the food industry for “giving consumers what they demanded,” such as products with large amounts of “added sugars.” She also stated more generally, “And can we implement changes based on public policy? I think we are now beginning to learn how to do it, and I think we need to put more emphasis now on figuring out how to change behavior.”

During her presentation at a Tufts University academic conference, “Obesity in America: Turning it Around,” DGAC Committee member Miriam Nelson encouraged attendees to intensify their focus on the role government health policy could play, remarking, “We have to be looking at this [obesity epidemic] from a perspective way beyond the realm of personal responsibility.”⁵¹ Professor Nelson—holding up a glass of sugar for dramatic effect and utilizing a PowerPoint slide featuring stacks of sugar cubes—stated, “There’s a huge amount of added sugar that has infiltrated our diet.”

Committee member Mary Story served as Director of the Robert Wood Johnson Foundation national program office of Health Eating Research. Among the program’s research priorities for childhood obesity are “reducing consumption of sugary beverages” and “protecting children from unhealthy food and beverage marketing.”⁵²

Committee member Dr. Frank Hu participated in a February 13, 2013 citizen petition spearheaded by public health activist group Center for Science in the Public Interest (CSPI).⁵³ The petition demanded that FDA review the generally recognized as safe (GRAS) status of added sugars in soda and other beverages. It claimed that added sugars were unsafe at the levels consumed in such beverages. The DGAC report also directly advances the other policy CSPI’s petition urged FDA to adopt: a separate line for “added sugars” on the Nutrition Facts label.

Especially relevant to this comment and FACA’s “fairly balanced” requirement, each of the DGAC members referenced above served on the DGAC’s “Added Sugars

⁴⁹ MacMillan, *NYC Fat Ban Paying Off*, CNN Health.com, July 16, 2012, available at <http://www.cnn.com/2012/07/16/health/nyc-fat-ban-paying-off>.

⁵⁰ Intersection of Nutrition Science and Policy, Current Challenges, available at <https://www.youtube.com/watch?v=7fNTye7ejo&feature=youtu.be>.

⁵¹ Nelson, “Obesity in America: Turning it Around,” Tufts University Back to the Future Academic Conference, Nov. 27, 2012, available at <https://www.youtube.com/watch?v=hHYTpRUPRVM>.

⁵² Robert Wood Johnson Foundation, *Health Eating Research: Building Evidence to Prevent Childhood Obesity* (Jan. 2013) at 5, available at <http://anr.rwjf.org/viewCfp.do?cfpId=1139&cfpOverviewId=>.

⁵³ Petition to Ensure the Safe Use of “Added Sugars,” Submitted by Center for Science in the Public Interest, Feb. 13, 2013, available at http://cspinet.org/new/pdf/sugar_petition_2-12-13_final.pdf.

Working Group.” That group’s work commenced in September 2014, a mere three months before the DGAC process ended on December 15, 2014.

HHS and USDA’s violation of FACA could provide additional and independent impetus for an APA challenge against FDA for its reliance upon the DGAC report. An aggrieved stakeholder could bring a claim under APA § 706(2), arguing that the FACA violations render the DGAC report invalid, and that FDA’s reliance upon the DGAC report is therefore “arbitrary and capricious.”⁵⁴

IV. ACTION SOUGHT

Washington Legal Foundation respectfully requests that FDA withdraw its proposals to mandate disclosure of the amount of added sugars and the Percent Daily Value of added sugars on the redesigned Nutrition Food label in order to comply with the U.S Constitution and the Administrative Procedure Act.

Respectfully submitted,

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⁵⁴ See, e.g., *Public Citizen v. Nat’l Advisory Committee on Microbiological Criteria for Foods*, 886 F.2d 419 (D.C. Cir. 1989); *Colo. Env’tl Coalition v. Wenker*, 535 F.3d 1221 (10th Cir. 2004).