IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR SCIENCE IN THE PUBLIC INTEREST and NATIONAL CONSUMERS LEAGUE, Plaintiffs, v. DR. TOM PRICE, Secretary of the Department of Health and Human Services; DR. SCOTT GOTTLIEB, Commissioner of the United States Food and Drug Administration; and the UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendants.	)	Civil Action No. 1:17-CV-1085 (EGS)

DEFENDANTS' MEMORANDUM
IN SUPPORT OF MOTION TO DISMISS

TABLE OF CONTENTS

INTRODUCTION 1

BACKGROUND 3

I. The Menu Labeling Rule 3

II. Prior Extensions of the Menu Labeling Compliance Date 3

III. The May 4, 2017, Extension of the Menu Labeling Compliance Date 4

IV. Many Restaurants and Similar Establishments Already Provide Nutrition Information 6

V. Plaintiff Organizations and Their Challenge to the May 4, 2017, Extension 7

ARGUMENT 8

I. Plaintiffs' Complaint Should Be Dismissed For Lack Of Standing 8

A. Plaintiffs Lack Organizational Standing 10

1. Plaintiffs Cannot Base Standing On An Alleged Lack Of Access To Nutrition Information Hindering Their Education And Advocacy Efforts 11

2. The Remaining Bases For Standing Are Also Not Cognizable 15

B. Plaintiffs Lack Representational Standing on Behalf of Their Members 16

II. Plaintiffs' Claims Must Also Be Dismissed Because They Are Not Ripe 18

CONCLUSION 20

TABLE OF AUTHORITIES

CASES

Abbott Laboratories v. Gardner,
387 U.S. 136 (1967) 19

Allen v. Wright,
468 U.S. 737 (1984) 9

Am. Chemistry Council v. Dep't of Transp.,
468 F.3d 810 (D.C. Cir. 2006) 16, 17

Am. Freedom Law Ctr. v. Obama,
821 F.3d 44 (D.C. Cir. 2016) 9, 13

Am. Petroleum Inst. v. EPA,
683 F.3d 382 (D.C. Cir. 2012) 19, 20

Californians for Renewable Energy v. U.S. DOE,
860 F. Supp. 2d 44 (D.D.C. 2012) 14

Center for Law and Education v. Dep't of Education,
396 F.3d 1152 (D.C. Cir. 2005) 15

Chamber of Commerce v. EPA,
642 F.3d 192 (D.C. Cir. 2011) 16, 17

** Coalition for Mercury-Free Drugs v. Sebelius*,
671 F.3d 1275 (D.C. Cir. 2012) 18

Conservative Baptist Association, Inc. v. Shinseki,
42 F. Supp. 3d 125 (D.D.C. 2014) 12

Ex Parte Lévitt,
302 U.S. 633 (1937) 15

** Fla. Audubon Soc. v. Bentsen*,
94 F.3d 658 (D.C. Cir. 1996) 13, 15

** Food & Water Watch, Inc. v. Vilsack*,
808 F.3d 905 (D.C. Cir. 2015) 10, 11, 12

Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.,
528 U.S. 167 (2000) 16

Int'l Acad. of Oral Med. & Toxicology v. FDA,
195 F. Supp. 3d 243 (D.D.C. 2016) 18

Int'l Bhd. of Teamsters v. Transp. Sec. Admin.,
429 F.3d 1130 (D.C. Cir. 2005) 9

Lujan v. Defs. of Wildlife,
504 U.S. 555 (1992) 9, 10

Nat'l Park Hospitality Ass'n v. DOI,
538 U.S. 803 (2003) 19

Nat'l Treasury Emps. Union v. United States,
101 F.3d 1423 (D.C. Cir. 1996) 19, 20

Ohio Forestry Ass'n, Inc. v. Sierra Club,
523 U.S. 726 (1998) 20

State Nat'l Bank of Big Spring v. Lew,
795 F.3d 48 (D.C. Cir. 2015) 9

Steel Co. v. Citizens for a Better Env't,
523 U.S. 83 (1998) 8

Summers v. Earth Island Institute,
555 U.S. 488 (2009) 9, 16

United States v. Students Challenging Regulatory Agency Procedures (SCRAP),
412 U.S. 669 (1973) 9

Whitmore v. Arkansas,
495 U.S. 149 (1990) 9

STATUTES

5 U.S.C. § 553 5

5 U.S.C. § 706 8

Pub. L. 111-148 ..... 3, 17

Pub. L. 114-113 ..... 4, 17

RULES

Federal Rule of Civil Procedure 12(b)(1) 1

REGULATIONS

21 C.F.R. § 10.115 4

21 C.F.R. § 101.11(a) 1

21 C.F.R. § 101.13(q)(5) 3

21 C.F.R. § 101.9 ..... 1, 14

21 C.F.R. § 101.10 ..... 1, 14

21 C.F.R. § 101.11 ..... 1, 14

OTHER AUTHORITIES

75 Fed. Reg. 39026 3

76 Fed. Reg. 19192 3

79 Fed. Reg. 71155 ..... 1, 14

79 Fed. Reg. 71156 ..... 3, 12

80 Fed. Reg. 39675 4

81 Fed. Reg. 27067 4

81 Fed. Reg. 96364 4

82 Fed. Reg. 20825 ..... 4, 6

82 Fed. Reg. 30730 ..... 6, 19

* *Authorities upon which we chiefly rely are marked with asterisks*

Defendants move to dismiss the Complaint pursuant to Federal Rule of Civil Procedure 12(b)(1) because Plaintiffs lack standing. Alternatively, Plaintiffs' claims should be dismissed because they are not ripe for review.

INTRODUCTION

Plaintiffs Center for Science in the Public Interest ("CSPI") and the National Consumers League ("NCL") challenge the Food and Drug Administration's ("FDA") recent one-year extension of the compliance date for a rule related to restaurant menu labeling. Pursuant to a federal statute authorizing the promulgation of such a rule, the menu labeling rule imposes new requirements for the provision of nutrition information in restaurants and other similar retail food establishments. *See* 79 Fed. Reg. 71155 (Dec. 1, 2014) (codified at 21 C.F.R. §§ 101.9, 101.10, and 101.11). The rule covers a diverse array of businesses, including bakeries, cafeterias, coffee shops, convenience stores, delicatessens, food service facilities located within entertainment venues (such as amusement parks, bowling alleys, and movie theatres), food service vendors (*e.g.*, ice cream shops and mall cookie counters), food take-out and/or delivery establishments (such as pizza take-out and delivery establishments), grocery stores, retail confectionary stores, superstores, quick service restaurants, and table service restaurants, that are part of a chain of 20 or more such establishments. 79 Fed. Reg. at 71157; 21 C.F.R. § 101.11(a). Its purpose is to provide nutrition information to consumers to help them make informed dietary choices when eating food prepared outside the home. 79 Fed. Reg. at 71157.

As is to be expected with a new regulatory program that has an impact on a variety of establishments of varying organizational structures, means and sophistication, implementing the rule has presented substantial challenges. FDA has sought to address the many and varied complex implementation issues that have been raised by affected industries.

In response to requests from retail and restaurant trade associations and individual restaurant chains, as well as concerns raised by Congress, FDA has extended the compliance date of the menu labeling rule on three occasions to provide industry with additional guidance and time to comply. The most recent extension – the subject of this lawsuit – was prompted by renewed requests from affected industry, seeking, in particular, guidance regarding options for providing the required nutrition information in an effective and economically efficient manner.

Plaintiffs, two public interest groups that are not directly affected by the menu labeling rule, challenged neither prior extension. In this lawsuit, claiming injury to their mission to educate the public about healthful eating, Plaintiffs challenge the most recent one-year extension – raising putative substantive and procedural objections. Plaintiffs do not suggest that they are directly regulated by the challenged rule. And, for various reasons, Plaintiffs do not meet the requisite burden for third parties seeking to establish standing to challenge a rule that does not directly affect them. The injuries alleged in the Complaint are unsupported, self-inflicted by Plaintiffs, or dependent on voluntary actions by third parties who are not parties to this lawsuit. Furthermore, Plaintiffs have failed to identify any individual members of their organizations with standing to sue.

Alternatively, even if Plaintiffs could satisfy their standing burden, their Complaint should be dismissed because their claims are not ripe. The interim final rule extending the compliance date seeks comment on the extension, including whether it should be modified or revoked, as well as on other discrete issues. That comment period just closed on August 2, 2017. FDA is actively considering the voluminous comments that were submitted as part of its deliberations on what compliance date best effectuates, in the agency's view, the goals of this regulatory program. That future agency determination will determine the actual relevant

compliance date, rendering the instant dispute non-ripe. Moreover, because the agency's deliberations are ongoing, any merits determination by this Court may be overtaken by the ultimate decision of the agency. As such, Plaintiffs' claims are premature and should be dismissed.

BACKGROUND

I. The Menu Labeling Rule

In 2010, Congress enacted the Patient Protection and Affordable Care Act ("ACA"), Pub. L. 111-148, 124 Stat. 573-576 (Mar. 23, 2010). Section 4205 of the ACA requires that restaurants and similar retail food establishments with 20 or more locations doing business under the same name and offering for sale substantially the same menu items provide calorie and other nutrition information for standard menu items. *Id.*, § 4205. The ACA required that proposed regulations to implement the menu labeling requirements be promulgated within a year of the ACA's enactment (*id.*), but contains no deadline for the promulgation of final regulations.

On July 7, 2010, FDA published a notice to solicit comments and suggestions on implementing the new law. 75 Fed. Reg. 39026. A proposed rule was published on April 6, 2011, and the final menu labeling rule followed on December 1, 2014. 76 Fed. Reg. 19192 and 79 Fed. Reg. 71156, respectively. The menu labeling rule had an effective date and a compliance date of December 1, 2015. 79 Fed. Reg. 71156.

II. Prior Extensions of the Menu Labeling Compliance Date

The menu labeling statute and rule established entirely new regulatory requirements for restaurants and similar retail food establishments.[1] As the December 1, 2015, compliance date neared, the industry continued to raise serious questions regarding the rule's implementation. In

[1] Restaurants that choose to make certain types of claims about nutrients in the food they serve or about beneficial health effects that can be obtained from the food they serve are required to comply with FDA standards for such claims. 21 C.F.R. § 101.13(q)(5).

response to those concerns, the compliance date for the menu labeling rule was extended to December 1, 2016, through a final rule, published without prior notice and comment, on July 10, 2015. 80 Fed. Reg. 39675.

The second extension of the compliance date for the menu labeling rule was in response to Congressional action in an appropriations bill, as well as to renewed requests from the retail and restaurant industries. On December 18, 2015, then-President Obama signed the Consolidated Appropriations Act, 2016 (Pub. L. 114-113, 129 Stat. 2242), section 747 of which provided that no funds could be used to implement, administer, or enforce the menu labeling rule until one year after FDA published a "Level 1"[2] guidance relating to the rule. A Level 1 guidance was finalized on May 5, 2016, after consideration of comments received on a draft. 81 Fed. Reg. 27067. FDA later changed the compliance date of the menu labeling rule to May 5, 2017, in a final rule, published without prior notice and comment, on December 30, 2016. 81 Fed. Reg. 96364.

FDA was not sued by Plaintiffs or any other party regarding the compliance date extensions announced in 2015 and 2016.

III. The May 4, 2017, Extension of the Menu Labeling Compliance Date

On May 4, 2017, FDA published an interim final rule ("IFR") extending the menu-labeling-rule compliance date for an additional year, to May 7, 2018, in response to renewed requests for more time to comply, as well as to address persistent concerns regarding ways to further reduce the regulatory burden on covered establishments or increase flexibility while continuing to achieve the regulatory objectives. 82 Fed. Reg. 20825. The extension followed

[2] Level 1 guidances set forth initial interpretations of statutory or regulatory requirements, describe significant changes in policy, address complex scientific issues, or cover highly controversial areas. *See* 21 C.F.R. § 10.115. They generally are finalized only after an opportunity for public input. *Id.*

FDA's consideration, *inter alia*, of a letter signed by 49 members of Congress, asking that FDA extend the compliance date to give the agency time to consider revising the rule or providing additional guidance to address lingering questions relating to compliance. FDA also received four letters in 2017 from a number of industry trade associations expressing concerns about the timetable provided for complying with this rule, in part due to the need to generate and display for the first time nutrition information according to the precise requirements of the new rule. FDA also received numerous emails from owners of restaurants, entertainment venues, grocery and convenience stores, as well as law firms and marketing firms, asking specific questions and evincing some uncertainty about how to comply with particular provisions of the menu labeling rule. In addition, FDA received a Citizen Petition filed on behalf of two large trade associations, which requested a stay of the effective date of the menu labeling rule, and reconsideration of the rule. The Citizen Petition is currently under consideration.

Given the numerous, complex issues regarding implementation of the FDA's new menu labeling rule, FDA invoked the "good cause" provision under the Administrative Procedure Act ("APA"), 5 U.S.C. § 553, to issue a final interim rule embodying an additional extension in the compliance date. The good cause provision allowed FDA to forego prior notice and comment and grant the requested extension effective immediately. 82 Fed. Reg. at 20827-28. FDA nevertheless sought comment on the extension in the IFR, and indicated a willingness to modify or revoke the remaining period of the extension in response to comments. *Id*. at 20828.

As described in the requests for extension and as explained in the preamble to the IFR extending the compliance date, "The continued, fundamental questions and concerns with the final rule suggest that critical implementation issues, including some related to scope, may not have been fully understood and the agency does not want to proceed if we do not have all of the

relevant facts on these matters." 82 Fed. Reg. at 20827. The agency cited "the diverse and complex set of stakeholders affected by the rule and continued, numerous, and fundamental questions they raise regarding the final rule and its implementation. *Id*. In particular, FDA noted the need to assess "critical implementation issues" around unresolved matters: these included how to address "calorie disclosure signage for self-service foods, including buffets and grab-and-go foods," and how to distinguish "a menu, which requires the posting of calorie information, from advertisements and other marketing pieces, which do not require calorie information." *Id.*

The comment period for the IFR was originally scheduled to end on July 3, 2017 (*id*. at 20825), but was subsequently extended through August 2, 2017. *See* 82 Fed. Reg. 30730 (July 3, 2017).

IV. Many Restaurants and Similar Establishments Already Provide Nutrition Information

Even though the compliance date for the menu labeling rule has been extended, many restaurants, grocery and convenience stores, and entertainment venues have made nutrition information voluntarily available in their establishments and online, in response to prior local or state regulatory requirements, or in anticipation of their compliance obligations with FDA's menu labeling rule. Large restaurant chains such as McDonald's, Subway, Starbucks, Olive Garden, and Pizza Hut, and other establishments, such as Wegman's grocery stores and AMC movie theaters, currently make nutrition information available to consumers.[3] In fact, CSPI did a

[3] *See* www.mcdonalds.com/us/en-us/about-our-food/nutrion-calculator.html, www.subway.com/en-us/menunutrition/nutrition, www.starbucks.com/menu/catalog/nutrition?food=all#view_control=nutrition, www.starbucks.com/menu/catalog/nutrition?drink=all#view_control=nutrition, www.olivegarden.com/en_us/pdf/olive_garden_nutrition.pdf, www.nutritionix.com/pizza-hut/menu/premium/, https://www.wegmans.com/news-media/press-releases/2017/counting-calories--wegmans-is-making-it-easier-.html, https://www.amctheatres.com/food-and-drink/dine-in/fresh-eats; *see also* Complaint, ¶¶ 38, 39 (listing nutrition information for menu items offered at Panera, Chili's, and TGI Fridays).

"scan of the top 50 restaurant chains in 2016 (by revenue according to National Restaurant News)" and "found that *all 50* had calorie information either on-line (e.g., posted per menu item, provided in PDF or other format, or via an online nutrition calculator) or in the restaurant." Comments Of The Center For Science In The Public Interest, in response to the IFR (Aug. 2, 2017), at p. 3 (emphasis added) (Exhibit 1 hereto) ("CSPI Comments").

Much nutrition information is already available from a range of diverse sources, accessible on smartphones, for consumers who seek such assistance in making healthful dietary selections at restaurants, as well as to organizations like Plaintiffs', that seek to educate consumers about healthy eating.

V. Plaintiff Organizations and Their Challenge to the May 4, 2017, Extension

Plaintiff CSPI is a consumer advocacy organization that describes its mission as conducting innovative research and advocacy programs in health and nutrition, and providing consumers with current, useful information about their health and well-being. www.cspinet.org/about/mission; *see also* Complaint, ¶ 18. CSPI's stated goals are: (1) To provide useful, objective information to the public and policymakers and to conduct research on food, alcohol, health, the environment, and other issues related to science and technology; (2) To represent the citizen's interests before regulatory, judicial and legislative bodies on food, alcohol, health, the environment, and other issues; and (3) To ensure that science and technology are used for the public good and to encourage scientists to engage in public-interest activities. www.cspinet.org/about/mission.

Plaintiff NCL is also a consumer advocacy organization with a broader described sphere of action than CSPI. Complaint, ¶ 19. With respect to food, NCL's mission statement is "We believe that Americans deserve a safe, nutritious, and abundant food supply, with access to healthy food at reasonable prices. From food safety to honest labeling and fighting our growing

food waste epidemic, NCL is working hard to help consumers make smart decisions to nourish their families." www.nclnet.org/food_policy.

CSPI and NCL focus on advocacy, and already have access to extensive nutrition information for food, as a result of the many restaurants and retail food establishments that have provided nutrition information, voluntarily, owing to prior local or state requirements, or in anticipation of their compliance obligations under the federal menu labeling rule. Neither CSPI nor NCL is in the restaurant or retail food industry or has compliance obligations imposed on it by the menu labeling rule.

Plaintiffs claim that the interim final rule extending the compliance date: (1) is arbitrary and capricious under the APA, 5 U.S.C. § 706, because FDA failed to explain "why it was changing its interpretation" of the statutory authority for menu labeling "or its conclusions about the importance of mandating nutrition labeling to protect public health" as articulated in the menu labeling rule; and (2) violates the APA because it was not the subject of notice and comment rulemaking and was made effective less than 30 days after its publication. Complaint, ¶¶ 71-81.

As set forth below, Plaintiffs' claims should be dismissed because Plaintiffs lack standing on their own and on their members' behalf to bring this lawsuit. Alternatively, Plaintiffs' claims are not ripe for review because administrative process that could affect the extension of the compliance date is currently underway at the agency.

ARGUMENT

I. Plaintiffs' Complaint Should Be Dismissed For Lack Of Standing

The Complaint should be dismissed under Rule 12(b)(1) because the Plaintiffs lack standing. Standing must be addressed before the merits, *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 101-02 (1998), because "a showing of standing is an essential and unchanging

predicate to any exercise of our jurisdiction." *Int'l Bhd. of Teamsters v. Transp. Sec. Admin.*, 429 F.3d 1130, 1133 (D.C. Cir. 2005) (internal quotations omitted). In evaluating a motion to dismiss for lack of subject matter jurisdiction, although the Court must "accept as true all of the factual allegations contained in the complaint," it "may consider materials outside the pleadings…." *Am. Freedom Law Ctr. v. Obama*, 821 F.3d 44, 49 (D.C. Cir. 2016), *cert. denied*, 137 S. Ct. 1069 (2017).

To establish standing, Plaintiffs must allege (1) an injury-in-fact that is (2) fairly traceable to the defendants' conduct and (3) redressable by the relief requested. *Int'l Bhd. of Teamsters*, 429 F.3d at 1134. To suffer injury-in-fact, a "plaintiff must allege that he has been or will in fact be perceptibly harmed by the challenged agency action, not that he can imagine circumstances in which he could be affected by the agency's action." *United States v. Students Challenging Regulatory Agency Procedures (SCRAP)*, 412 U.S. 669, 688-89 (1973). The actual injury must be "concrete in both a qualitative and temporal sense," not "conjectural" or "hypothetical." *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990) (citations omitted). Plaintiffs, as the parties invoking federal jurisdiction, "bear[] the burden of establishing these elements." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992).

Because Plaintiffs are not the object of the government action or inaction, it is "'substantially more difficult' to establish" standing. *Lujan*, 504 U.S. at 562 (quoting *Allen v. Wright*, 468 U.S. 737, 758 (1984)). Challenging government regulation of a third party, Plaintiffs shoulder a far heavier burden: "When 'a plaintiff's asserted injury arises from the government's allegedly unlawful regulation (or lack of regulation) of *someone else*, much more is needed.'" *State Nat'l Bank of Big Spring v. Lew*, 795 F.3d 48, 55 (D.C. Cir. 2015) (emphasis in the original) (quoting *Lujan*, 504 U.S. at 562); *see also Summers v. Earth Island Institute*, 555

U.S. 488, 493 (2009) (commenting that when the challenged regulations "neither require nor forbid" action on the part of the plaintiff, standing is not precluded but is substantially more difficult to establish). Third party challengers must overcome the difficulty of establishing injury that is fairly traceable to the challenged actions, particularly where, as in this case, the alleged injury is attributable to the actions of entities that are not party to the action. *See Lujan*, 504 U.S. at 562 (explaining that when "[t]he existence of one or more of the essential elements of standing 'depends on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict,'" the plaintiff must "adduce facts showing that those choices have been or will be made in such manner as to produce causation and permit redressability of injury") (internal citations omitted).

Plaintiffs assert both organizational standing based on injury to themselves and representational standing based on injury to their members (Complaint, ¶ 20), but have not, and cannot, establish either type.[4]

A. Plaintiffs Lack Organizational Standing

Organizational standing requires Plaintiffs, "like an individual plaintiff, to show actual or threatened injury in fact that is fairly traceable to the alleged illegal action and likely to be redressed by a favorable court decision." *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 919 (D.C. Cir. 2015). Thus, Plaintiffs "must have suffered a concrete and demonstrable injury to [their] activities." *Id.* (internal quotation marks omitted). The Complaint raises a litany of alleged injuries, but all fall short of the high bar to challenge government inaction as to third parties. *See Lujan*, 504 U.S. at 562.

[4] The Complaint does not distinguish between injuries alleged to CSPI and injuries alleged to NCL, for either the organizational or member standing arguments. *See* Complaint, ¶¶ 20-23.

1. Plaintiffs Cannot Base Standing On An Alleged Lack Of Access To Nutrition Information Hindering Their Education And Advocacy Efforts

The Complaint's primary basis for standing stems from Plaintiffs' longtime "advoca[cy] for greater transparency about the nutritional content of menu items offered at chain restaurants and similar retail food establishments." Complaint, ¶ 20. The Complaint implies that, if the compliance date had not been extended, Plaintiffs would gain additional nutrition information, and that Plaintiffs are harmed by the absence of the information: "Without access to this information, Plaintiffs are hindered in their ability to educate the public about healthful and nutritious food and beverage choices, advocate for government policies that support access to healthful and nutritious food, and urge restaurants and similar establishments to introduce and promote healthful and nutritious options." *Id.*

The theory does not withstand scrutiny, for multiple reasons.

First, Plaintiffs want the information for education and advocacy purposes, as to the public, the government, and restaurants. Complaint, ¶ 20. But "an organization's use of resources for … advocacy is not sufficient to give rise to an Article III injury." *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 919 (D.C. Cir. 2015). And "an organization does not suffer an injury in fact where it expends resources to educate its members and others unless doing so subjects the organization to operational costs beyond those normally expended." *Id.* (internal quotation marks and brackets omitted). Here, the IFR extends the date by which restaurants and similar retail food establishments are required to comply with the menu labeling rule, so it does not subject Plaintiffs to operational costs beyond those normally expended. Although the Complaint summarily alleges that Plaintiffs "have diverted" staff time and other resources as a result of the extension (Complaint, ¶ 20), the Complaint does not identify any plausible basis for

inferring that the extension of the compliance deadline required Plaintiffs to expend additional resources. To the extent Plaintiffs' diversion of staff resources is to challenge the IFR, such as in this lawsuit, that diversion is not cognizable because the "use of resources for litigation, investigation in anticipation of litigation, or advocacy is not sufficient to give rise to an Article III injury." *Food & Water Watch*, 808 F.3d at 919. Whatever choices Plaintiffs made to challenge the extension, just as they chose not to challenge the 2015 and 2016 extensions, are their own choices and are not Article III injury. *Conservative Baptist Association, Inc. v. Shinseki*, 42 F. Supp. 3d 125, 132 (D.D.C. 2014) (characterizing costs to bring lawsuit as "self-inflicted" costs insufficient to support standing).

Second, the Complaint's theory is unsupported because Plaintiffs already have access to a vast amount of nutrition information, and plaintiffs have not identified any discrete information that they would definitively receive had the FDA's compliance date remained unchanged. *See* CSPI Comments at 3 (Exhibit 1 hereto). Plaintiffs can, at this very moment, access menu information already available at numerous restaurants and retail establishments, voluntarily or because of prior menu-labeling requirements in some jurisdictions, as well as other nutritional information online. *See supra* pp. 6-7. Although the Complaint asserts that "consumers would likely not know" certain nutritional content information, Plaintiffs already have access to all sorts of nutrition information, and Plaintiffs have not identified any incremental information that they would receive through an earlier implementation date. *See* Complaint, ¶¶ 38-39 (providing exemplar nutrition information from a dozen restaurants and retail establishments).

Indeed, the menu-labeling rule is not even designed to provide Plaintiffs with increased information; rather, its goal is for consumers to receive that information directly from restaurants and similar retail establishments. *See* 79 Fed. Reg. at 71157 ("To help make nutrition

information for these foods available *to consumers* in a direct, accessible, and consistent manner *to enable consumers* to make informed and healthful dietary choices, section 4205 of the ACA requires that calorie and other nutrition information be provided *to consumers* in restaurants and similar retail food establishments….") (emphasis added).

Third, Plaintiffs' standing theory relies on speculation about third party restaurants and similar retail establishments providing additional nutrition information that Plaintiffs currently lack. But a claimed injury must be fairly traceable to "the challenged acts of the defendant, not of some absent third party." *Fla. Audubon Soc. v. Bentsen*, 94 F.3d 658, 663 (D.C. Cir. 1996) (en banc). No Court order against FDA can assure that some unidentified third-party will begin providing the nutritional information that Plaintiffs claim to be lacking. The disclosure of that information will only result from further interactions between the agency, non-compliant establishments covered by the rule, and possibly the courts. Also, as with any new regulatory program, once it goes into effect, FDA expects to exercise discretion and work flexibly and collaboratively with companies to achieve compliance, and reserve enforcement action for circumstances in which covered entities have exhibited an intransigent unwillingness or inability to comply.[5] Thus, the injury alleged to Plaintiffs' ability to educate the public about healthful dietary choice is speculative, dependent upon actions of third parties who are not part of this lawsuit, and, not sufficient to support standing. *Am. Freedom Law Ctr.*, 821 F.3d at 50 ("This is a major missing link in the causal chain Appellants must establish to demonstrate that

[5] *See, e.g.*, https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm515020.htm (June 9, 2016 Statement from FDA's Center for Food Safety and Applied Nutrition Director, Susan Mayne, "We will work flexibly and cooperatively with establishments covered by the menu labeling final rule to facilitate compliance and will provide educational and technical assistance for covered establishments and for our state, local, and tribal regulatory partners.").

[defendant's action] is a 'substantial factor motivating' Appellants' alleged harm."); *Californians for Renewable Energy v. U.S. DOE*, 860 F. Supp. 2d 44, 52 (D.D.C. 2012) (Plaintiffs may not rely on "'predictive assumptions' about third-party behavior"; they are not a "substitute for genuine causal connection.")

Finally, the Complaint provides no plausible basis to believe that extending the compliance date hinders, or has any effect on, Plaintiffs' ability to engage in advocacy or lobby restaurants and similar retail food establishments. Plaintiffs are free to continue their advocacy efforts regarding government policies that support providing the American public with access to healthful and nutritious food, including local, state and federal government support for educating the American public about a healthy diet and why it is important to consume healthful and nutritious food; addressing incentives for and cost barriers to obtaining healthful and nutritious food; supporting community-supported agriculture programs and farmers' markets; and bringing affordable healthful and nutritious food to disadvantaged neighborhoods. The extension of the compliance date does not begin to touch on the world of advocacy work the Plaintiffs can do to promote a healthful and nutritious diet for the American public.

Nor does the extension hinder Plaintiffs' ability to urge restaurants and similar retail establishments to introduce and promote healthful and nutritious options. The menu labeling rule does not require covered establishments to alter their standard menu items in anyway. *See* 79 Fed. Reg. 71155; 21 C.F.R. §§ 101.9, 101.10, 101.11. The rule requires no reformulation or revision of offerings to improve their nutritional profile, and no restriction on ingredients or recipes that can be used to craft restaurant meals. Thus, the menu labeling rule, extended or not, has no bearing on Plaintiffs' ability to advocate for healthful and nutritious dining options.

In sum, Plaintiffs' primary standing theory, as alleged in paragraph 20 of their Complaint,

does not give rise to standing.

2. The Remaining Bases For Standing Are Also Not Cognizable

The Complaint's other asserted bases for organizational standing are also not cognizable.

The Complaint asserts that Plaintiffs were deprived of their right to comment on the extension of the compliance date before it was implemented. Complaint, ¶ 22. However, the alleged "injury" suffered by Plaintiffs in this regard is no different than that suffered by any other person who might have cared to comment on the extension before it was effectuated, and does not support standing. *See Ex Parte Lévitt*, 302 U.S. 633, 634 (1937) (finding general interest common to all members of public is not sufficient to support standing). In *Center for Law and Education v. Dep't of Education*, 396 F.3d 1152, 1157 (D.C. Cir. 2005), the D.C. Circuit held that to support standing, the proponent of an alleged "procedural injury" must establish that the procedures in question were designed to protect the specific plaintiffs' concrete interests. The APA, like the No Child Left Behind Act at issue in *Center for Law and Education*, makes no specific mention of protecting the interests of advocacy organizations. Nor can Plaintiffs establish that it is "substantially probable" that lack of opportunity to comment prior to implementation caused essential injury to their own interests, because Plaintiffs have no regulatory responsibilities under the menu labeling rule. *See Fla. Audubon Soc.*, 94 F.3d at 664-65 (Plaintiffs claiming procedural injury must "show not only that the defendant's acts omitted some procedural requirement, but also that it is substantially probable that the procedural breach will cause the essential injury to the plaintiff's own interest."). Plaintiffs' argument also ignores that they have had an opportunity to comment on the IFR, and that the agency may modify or revoke the extension if comments so warrant. *See* 82 Fed. Reg. at 20828. For these reasons, Plaintiffs' claimed procedural injury does not support standing.

The final injury alleged – that extending the compliance date contributes to unspecified

environmental harms that "injure Plaintiffs' members and supporters" – is entirely speculative and insufficiently tied to the menu labeling rule to support standing. Complaint, ¶ 23; *see also id.* ¶ 44 (alleging that implementation of the menu labeling rule can reduce "the environmental degradation associated with food waste and disposal" associated with large portion sizes). There is nothing in the menu labeling rule that requires covered establishments to offer smaller portion sizes, and certainly nothing that requires consumers to order fewer items in restaurants or other retail food establishments. The allegations relating to harm caused by food waste posit that entities who are not defendants in this lawsuit will take a series of voluntary actions, none of which are required by the rule, that affect the environment once the menu labeling rule goes into effect. Plaintiffs offer no basis for their assumptions. These alleged environmental harms are patently speculative, are not fairly traceable to the compliance date extension, and should be rejected as a basis for organizational standing.

B. Plaintiffs Lack Representational Standing on Behalf of Their Members

Plaintiffs also lack representational standing on behalf of their members. An organization can establish representational standing if it can show that: (1) its member would have standing to sue; (2) the interests the organization seeks to protect are germane to its purpose; and (3) neither the claim asserted nor the relief requested requires individual participation by its members. *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 181 (2000).

Plaintiffs have not shown that their members would have standing to sue. When an organization "claims associational standing, it is not enough to aver that unidentified members have been injured." *Chamber of Commerce v. EPA*, 642 F.3d 192, 199-200 (D.C. Cir. 2011). Instead, to establish standing, Plaintiffs must specifically "identify members who have suffered the requisite harm." *Id*. at 199 (quoting *Summers*¸ 555 U.S. at 499); *Am. Chemistry Council v.*

Dep't of Transp., 468 F.3d 810, 820 (D.C. Cir. 2006). Because Plaintiffs fail to identify a single member of their organizations who has allegedly suffered any injury, this allegation is inadequate to support standing. *See Chamber of Commerce*, 642 F.3d at 200 ("Because the Chamber has not identified a single member who was or would be injured by EPA's waiver decision, it lacks standing to raise this challenge."); *Am. Chemistry Council*, 468 F.3d at 820 (requiring organization asserting associational standing to show at least one "specifically-identified member has suffered an injury-in-fact").

It would be futile for Plaintiffs to identify members who have suffered harm in any event because the theory of harm asserted in the Complaint is not cognizable. Specifically, the Complaint alleges harm to Plaintiffs' "members and supporters" because they will lack "nationwide access to calorie contents and other nutrition information for an additional year or possibly longer—more than seven years after Congress passed a law requiring chain restaurants and similar retail food establishments to disclose this information." Complaint, ¶ 21. Similarly, the Complaint asserts that extending the compliance date "depriv[es] [Plaintiffs'] members and supporters of information that federal law gives them the right to know." Complaint, ¶ 21. That is incorrect: the ACA does not contain a statutory deadline by which final rules implementing the law must be made effective. *See* Pub. L. 111-148, § 4205. Subsequent Congressional action, in the form of a restriction on using funds to enforce the menu labeling rule, evinces Congressional sensitivity to the complexity of the new regulatory scheme and the challenges industry faces with implementation. *See* Pub. L. 114-113. Thus, Plaintiffs' allegation of injury is founded on a faulty premise and cannot support the organizations' standing.

The theory is also not cognizable because members' decisions to eat at covered establishments that do not provide nutrition information stem from their own actions, not from

FDA's action in extending the menu labeling compliance date. Plaintiffs' members could choose to dine only at restaurants that provide nutrition information, either at the location or online or both, or by preparing food at home. Because any "injury" averred by Plaintiffs' members from the extension of the menu labeling compliance date would be more proximately caused by the members' choices to dine at restaurants lacking nutrition information than by the extension, such alleged injuries would not be "fairly traceable" to the challenged FDA action and are therefore not cognizable for purposes of supporting standing. *See Coalition for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275, 1277 (D.C. Cir. 2012) (denying standing to challenge the use of thimerosal in vaccines because plaintiffs are free to choose thimerosal-free vaccines); *Int'l Acad. of Oral Med. & Toxicology v. FDA*, 195 F. Supp. 3d 243, 264 (D.D.C. 2016) (organization could not base standing on members who feared exposure to mercury, due to availability of mercury-free options).

Even after the menu labeling rule becomes effective, restaurants and other similar establishments with fewer than 20 locations will not be required to provide nutrition information by the federal rule. While the intent of the menu labeling rule is to make nutrition information more widely available for consumers, there will continue to be an element of choice on the part of consumers, as to whether or not to avail themselves of additional nutrition information – and even whether to make more healthful dietary selections as a result. Any injury Plaintiffs allege to be suffering now as a result of the menu labeling extension are more properly attributed to individual dining choices, rather than to the extension of the compliance date. As such, Plaintiffs also lack standing based on their members, and so the Complaint should be dismissed.

II. Plaintiffs' Claims Must Also Be Dismissed Because They Are Not Ripe

Plaintiffs' claims should also be dismissed as unripe. Ripeness "is a justiciability doctrine designed 'to prevent the courts, through avoidance of premature adjudication, from

entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.'" *Nat'l Park Hospitality Ass'n v. DOI*, 538 U.S. 803, 807-808 (2003) (quoting *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148-149 (1967)).

"Postponing review can also conserve judicial resources, and it 'comports with our theoretical role as the governmental branch of last resort.'" *Am. Petroleum Inst. v. EPA*, 683 F.3d 382, 386-387 (D.C. Cir. 2012) (quoting *Nat'l Treasury Emps. Union v. United States*, 101 F.3d 1423, 1431 (D.C. Cir. 1996)). "For instance, declining jurisdiction over a dispute while there is still time for the challenging party to convince the agency to alter a tentative position provides the agency an opportunity to correct its own mistakes and to apply its expertise, potentially eliminating the need for (and costs of) judicial review." *Id.* at 387 (internal quotation marks omitted). "Even if the challenger fails to persuade the agency, permitting the administrative process to reach its end can at least solidify or simplify the factual context and narrow the legal issues at play, allowing for more intelligent resolution of any remaining claims and avoiding inefficient and unnecessary 'piecemeal review.'" *Id.* "Put simply, the doctrine of prudential ripeness ensures that Article III courts make decisions only when they have to, and then, only once." *Id.*

Plaintiffs challenge an agency "decision" that is in flux. The compliance date extension was interim and tentative in nature; the IFR expressly invited "interested parties [to] provide comment on the compliance date extension" and indicated a willingness to "modif[y] or revoke[]" it. *See* 82 Fed. Reg. at 20828. That comment period ended on August 2, and the agency is actively considering those comments. *See* 82 Fed. Reg. 30730.

Given its familiarity with the intricacies of the menu labeling rule and receipt of the comments and questions regarding implementation challenges, the agency is in the best position to determine, in the first instance, whether the extension of the compliance date for the menu labeling rule should be modified or revoked. "And, of course, depending upon the agency's future actions to revise … or modify [the compliance date], review now may turn out to have been unnecessary." *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 736 (1998); *see Nat'l Treasury Emps. Union*, 101 F.3d at 1431 ("If we do not decide it now, we may never need to."). The Court should, accordingly, avoid "prematurely entangling" itself in this ongoing agency matter, especially since there is or no perceptible harm to Plaintiffs that would result from waiting. *See Nat'l Treasury Emps. Union*, 101 F.3d at 1431. Thus, the Court should dismiss the Complaint on ripeness grounds, or at the very least, stay its hand while FDA decides whether to modify or revoke the compliance date extension. *See Am. Petroleum Inst.*, 683 F.3d at 389 ("To protect against the unlikely and the unpredictable, we can hold the case in abeyance pending resolution of the proposed rulemaking, subject to regular reports from [the agency] on its status.").

CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss should be granted and Plaintiffs' Complaint should be dismissed with prejudice.

August 14, 2017

Respectfully submitted,

CHAD A. READLER
Acting Assistant Attorney General
United States Department of Justice
Civil Division

ETHAN DAVIS
Deputy Assistant Attorney General

JOSHUA I. WILKENFELD
Acting Director
Consumer Protection Branch

ANDREW E. CLARK
Assistant Director
Consumer Protection Branch

/s/ Daniel E. Zytnick

DANIEL E. ZYTNICK
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044
(202) 598-8337
Daniel.E.Zytnick@usdoj.gov

Counsel for Defendants

OF COUNSEL:

JEFFREY S. DAVIS
Acting General Counsel

REBECCA K. WOOD
Chief Counsel
Food and Drug Administration

ANNAMARIE KEMPIC
Deputy Chief Counsel for Litigation

BARBARA J. ALKALAY
Associate Chief Counsel, Litigation
U.S. Dept. of Health & Human Services
Office of the General Counsel
10903 New Hampshire Ave.
White Oak 31, Room 4422
Silver Spring, MD 20993-0002
Telephone: 301-348-3085
Barbara.Alkalay@fda.hhs.gov