UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR SCIENCE IN THE PUBLIC INTEREST and PUBLIC CITIZEN HEALTH RESEARCH GROUP,	)	
Plaintiffs,	)	Case No. 03-1962 (RBW)
v.	)	
FOOD AND DRUG ADMINISTRATION,	)	
Defendant.	)	

PLAINTIFFS' CROSS-MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Local Rule 108(h), plaintiffs Center for Science in the Public Interest and Public Citizen Health Research Group hereby move for summary judgment on the ground that there is no genuine issue of disputed material fact and that Plaintiffs are entitled to judgment as a matter of law.

In support of this motion, Plaintiffs submit the accompanying (1) memorandum in support of Plaintiffs' motion for summary judgment and in opposition to Defendant-Intervenors' motion for summary judgment, (2) statement of material facts as to which there is no genuine dispute, (3) response to Defendant-Intervenors' statement of material facts, and (4) a proposed order. This cross-motion is also based on the declarations and exhibits filed by Plaintiffs and by defendant Food and Drug Administration in connection with Defendant's November, 2003, motion to dismiss.

Dated: March 8, 2004

Respectfully submitted,

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PLAINTIFFS' MEMORANDUM IN SUPPORT OF PLAINTIFFS' CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO INTERVENORS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

As set forth in Plaintiffs' complaint and in their opposition to the pending motion to dismiss filed by the Food and Drug Administration ("FDA"), the Nutrition Labeling and Education Act ("NLEA") establishes a statutory scheme for the regulation of health claims for foods. Plaintiffs challenge the FDA's decision to substitute its views for those of Congress by setting up a new regulatory scheme that violates both the substantive and procedural requirements of the NLEA.

Defendant-Intervenors Whitaker, *et al*. have moved for summary judgment based largely on the same justiciability grounds (enforcement discretion, ripeness, and standing) raised in the FDA's motion to dismiss. In addition, Intervenors argue that the First Amendment justifies the FDA's violation of the NLEA and existing regulations. The combined effect of Intervenors' constitutional and justiciability arguments would be that an agency could unilaterally decide that a statutory regime was unconstitutional, set up a new regime inconsistent with that established by Congress, and forever insulate its action from judicial review. Intervenors' theories, however, lack merit. The NLEA's procedural and substantive standards are constitutional, and the case is justiciable at this time. Intervenors' motion for summary judgment should be denied, and Plaintiffs' cross-motion for summary judgment should be granted.

BACKGROUND

The background of the litigation is set forth in Plaintiffs' opposition to the FDA's motion to dismiss, filed by Plaintiffs on January 15, 2004. For the Court's convenience, Plaintiffs offer here an abbreviated statement of the factual background.

A. Statutory and Regulatory Background

Prior to 1984, food companies made few, if any, health claims—that is, claims characterizing the relationship of a nutrient in a food to a disease or health-related condition. Until that time, the FDA's view was that making a health claim for a food brought that food within the Food, Drug, and Cosmetic Act ("FDCA") definition of a drug: an "article[] intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals" 21 U.S.C. § 201(g)(1)(B). Thus, the FDA required that a food company submit and receive FDA approval of a new drug application prior to making such a claim.

In the mid-1980s, companies began making health claims for foods, without requesting FDA approval. In 1990, Congress responded by passing the NLEA, which allows health claims for foods, but only after authorization by the FDA and subject to certain substantive and procedural criteria set forth in the statute. Unless made in accordance with these criteria, a health claim for a food renders the food misbranded. 21 U.S.C. § 343(r)(1), (3). As the House Committee Report on the NLEA observed, without the authority established in the NLEA, "there is a serious question as to whether the Agency has the legal authority to . . . permit health claims regarding the usefulness of a food in treating a disease, without also requiring that the claim meet the premarket approval requirements applicable to drugs." H.R. Rep. No. 101-538, at 9 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3339.

The NLEA permits FDA approval of food health claims only when the agency "determines, based on the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified

by scientific training and experience to evaluate such claims, that the claim is supported by such evidence." 21 U.S.C. § 343(r)(3)(B)(i). As the House Report stated: "The standard is intended to be a strong one. The bill requires that the Secretary have a high level of confidence that the claim is valid." 1990 U.S.C.C.A.N. at 3351.

The statutory standard—significant scientific agreement—is repeated verbatim in a regulation the FDA issued to implement the NLEA. 21 C.F.R. § 101.14(c). In promulgating the regulation, the FDA expressly rejected suggestions that it adopt a lower substantive standard so as to allow claims with disclaimers or other language to express a lesser degree of scientific certainty that the claim was accurate. The FDA stated: "FDA does not have authority to modify the scientific standard for health claims . . . . [T]he requirement objected to by several of the comments, that there be significant scientific agreement that the claim is supported by the publicly available evidence, derives directly from the act." 58 Fed. Reg. 2478, 2504 (1993).

After receipt of a petition asking the FDA to authorize a health claim, the FDA must either deny the petition or "file" it "for further action." 21 U.S.C. § 343(r)(4)(A)(i). The NLEA instructs the FDA that, if it preliminarily determines that the proposed health claim in a filed petition meets the statutory requirement ("significant scientific agreement"), the FDA must "issue a proposed regulation" to authorize the claim. *Id.* The agency must then accept public comment on the proposal. If, taking into consideration the comments, the agency makes a final determination that the statutory standard has been met, it must then issue a final rule allowing the claim. 21 C.F.R. §§ 101.14(d)(1), 101.14(e), 101.70.

When issuing its regulations to implement the NLEA, the FDA recognized that, as a general matter, "the comment period following publication of proposed rules is a critical step in determining

whether a proposed regulation is appropriate for adoption." 58 Fed. Reg. 2523. With regard to health claims for foods, the FDA stated that "significant information concerning the validity of the substance-disease relationship underlying the proposed health claim may be submitted by interested parties during the comment period," and that "the comment period may bring to light a previously unforeseen potential for the health claim to be misleading to consumers" if adopted as proposed. *Id.*

B. <u>FDA's July 2003 Guidance</u>

On July 11, 2003, the FDA issued a notice announcing the availability of two guidance documents, entitled Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data, and Guidance for Industry, and FDA: Interim Procedures for Health Claims in the Labeling of Human Food and Human Dietary Supplements (collectively "July Guidance"). *See* 68 Fed. Reg. 41387 (2003).

The July Guidance states that the agency will continue to follow the NLEA and the regulations implementing the NLEA only for "unqualified" health claims—that is, for health claims that meet the statutory standard set forth in the NLEA. Interv. SJ Motion, Exh. A at 3.

The July Guidance identifies three categories of "qualified" health claims—that is, health claims that do not meet the statutory standard. The three categories, called Categories B, C, and D, are distinguished by the level of evidence supporting the claim: Category B claims are those based on a "*moderate/good level of comfort* among qualified scientists that the claimed relationship is scientifically valid. Qualified experts would rank the relationship as 'promising,' but not definitive." Interv. SJ Motion, Exh. B at 7 (emphasis in original). Such claims will be qualified by language stating that "although there is scientific evidence supporting the claim, the evidence is not

conclusive." *Id.*, Exh. A at 4. Category C "represents a *low level of comfort* among qualified scientists that the claimed relationship is scientifically valid. It would have low consistency with statements from authoritative bodies or be ranked as 'low' in terms of scientific support by qualified scientists." *Id.*, Exh. B at 8 (emphasis in original). Such claims will be qualified by language stating that "Some scientific evidence suggests . . . however, FDA has determined that this evidence is limited and not conclusive." *Id.*, Exh. A at 4. Category D "represents an *extremely low level of comfort* among qualified scientists that the claimed relationship is scientifically valid." *Id.*, Exh. B at 8 (emphasis in original). Category D claims will be qualified by language stating that "Very limited and preliminary scientific research suggests . . . FDA concludes that there is little scientific evidence supporting this claim." *Id.*, Exh. A at 4. The exact language may vary from case to case. *Id.*

Although the NLEA and the FDA regulations promulgated to implement the NLEA do not permit B, C, or D health claims, the Guidance states that the FDA will use "enforcement discretion" to allow qualified claims in categories B, C, and D, subject to certain procedures. 68 Fed. Reg. 41389. Specifically, if the FDA determines that a petition for a qualified health claim is complete, the FDA will "file" it, post it on its website, and request public comment for 60 days. The FDA will then conduct its own scientific review, either internally through an advisory committee or using a third-party reviewer. After completion of the review, the FDA will decide whether to "exercise enforcement discretion" to allow the proposed claim. The FDA will notify the petitioner by letter of its decision whether to allow the claim, and will post its letter and any third-party review report on its website. Interv. SJ Motion, Exh. A at 5-6.

The FDA will not issue a proposed rule before allowing a qualified health claim. The Guidance does not contemplate that the FDA will respond to public comments on a qualified health claim petition. The Guidance does not contemplate that the FDA will provide an opportunity for public comment on its internal or third-party review of the petition or on its decision to allow a particular qualified claim. *Id*., Exh. A at 4-7.

The July Guidance stated that the FDA would begin accepting petitions for qualified health claims in September 2003. *Id*., Exh. A at 4. The FDA has accepted and begun processing three petitions for approval of qualified claims, *see* www.cfsan.fda.gov/~dms/lab-qhc.html#petition, and it expects to complete processing at least one of the petitions prior to the issuance of any proposed rule addressing qualified health claims. *Id*., Exh C (FDA expects to make final decision by April 15, 2004); *see also* www.fda.gov/ohrms/dockets/dockets/03q0559/03q0559.htm (doc. 6) (final decision by July 31, 2004); www.fda.gov/ohrms/dockets/dockets/04q0072/04q0072.htm (final decision by Oct. 4, 2004).[1]

[1]On November 21, 2003, three days before the deadline for the FDA to respond to the complaint in this case, the FDA issued an advance notice of proposed rulemaking ("ANPR"), which sought comment on alternatives for regulating qualified health claims in the labeling of foods, among other things. 68 Fed. Reg. 66040 (2003) (attached as Exh. G to Interv. SJ Motion). The ANPR states that the regulatory regime established by the July Guidance and effective as of September 1, 2003, has been implemented on an "interim" basis and that the agency intends to adopt long-term procedures through notice-and-comment rulemaking. *Id.* at 66041. The ANPR also reiterates the agency's plan, as set forth in a timeline accompanying the July Guidance, to conduct consumer research, which it hopes to complete "[w]ithin the next year," prior to developing a proposed rule. *Id.* at 66041 & n.8. Thus, the ANPR makes clear that any final rule addressing regulation of qualified health claims for foods is years away and that, until then, the FDA intends to regulate in accordance with the July Guidance.

DISCUSSION

I. THE JULY GUIDANCE VIOLATES THE PROCEDURAL AND SUBSTANTIVE REQUIREMENTS OF THE NLEA AND FDA REGULATIONS.

Under the July Guidance, the FDA will consider petitions for approval of health claims for foods without following the procedural requirements of the NLEA and of FDA regulations. Likewise, the FDA will approve health claims that do not meet the substantive standard of the NLEA and of FDA regulations. Neither the FDA (in the July Guidance) nor Intervenors (in their motion) suggest otherwise.

Intervenors' justification of the FDA's decision to violate the NLEA and the agency's own regulations is premised on the theory that the First Amendment requires the agency to disregard the substantive standard established by Congress for health claims used to promote foods. This theory, in turn, is premised on the view that *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), applies to health claims for foods. As explained below, both premises are wrong. Accordingly, Intervenors have offered no valid justification for the FDA's implementation of a regime that disregards Congress's express instruction about the appropriate standard to be applied to health claims for foods.

Moreover, even if *Pearson* applied to food claims, it would not justify the FDA's decision to violate Congress's mandate in ways not *required* by *Pearson*'s interpretation of the First Amendment. Yet the FDA's new regulatory regime for preliminary health claims for foods does just that: It violates the NLEA's notice-and-comment requirement, which *Pearson* does not address, much less invalidate. And with respect to so-called Category C and D claims and some Category B claims, the new regime adopts a substantive standard not only far below the standard mandated by Congress, but also below the standard accepted in *Pearson*. Accordingly, Plaintiffs are entitled

to summary judgment on their challenge to the procedural aspect of the July Guidance and on their substantive challenge to Category C and D and some B claims, whether or not *Pearson* controls here.

In contrast to Intervenors, the FDA has not argued that the NLEA is unconstitutional. According to the agency, the Guidance is not based on a determination of unconstitutionality, but only on a concern that a court considering an as-applied challenge to an FDA decision not to permit a qualified health claim for a food "*might* well find the same tension between the NLEA provisions and the first amendment" that the court found in *Pearson*. 68 Fed. Reg. 41389 (emphasis added). Thus, the agency has instituted a new regulatory scheme in violation of a statute and its own regulations, not because it believes it is compelled by the Constitution to do so, but because it has decided that it is "good sense" to do so. *Id.* The FDA states: "The reason for the decision to apply *Pearson* to conventional foods is to provide consumers with better health/nutrition information so they can make better dietary choices," as well as "to avoid further litigation over the constitutionality of the health claims provisions of the NLEA applicable to conventional food labeling." *Id.* And it describes its new regime as "a reasonable effort to combine the spirit of the NLEA with the current public health and legal circumstances, and one that reflects practical common sense." *Id.* In other words, the FDA decided that it has a better idea than did Congress about how to regulate health claims for foods.[2] The agency's authority to regulate foods, however, derives solely from Congress,

[2]The November 2003 ANPR justified the FDA's decision in similar terms: "FDA decided to apply the enforcement discretion factors to conventional foods to promote consistency in health messages, to enable consumers to learn about important health information even if it may not meet the current SSA standard, and to avoid further litigation over the constitutionality of the health claims provisions of the NLEA applicable to conventional food labeling to the extent that these provisions do not permit qualified claims." 68 Fed. Reg. 66041.

via the provisions of the NLEA and the FDCA. The FDA simply has no authority to disregard its statutory mandate or to substitute its views for those of Congress. *See FDA v. Brown & Williamson*, 529 U.S. 120, 125-26 (2000) (agency "may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'. . . And although agencies are generally entitled to deference in the interpretation of statutes that they administer, a reviewing 'court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.'") (citations omitted); *cf*. *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 215 (1994) ("adjudication of the constitutionality of congressional enactments has generally been thought beyond the jurisdiction of administrative agencies").

A. The FDA's July Guidance Violates The NLEA's Procedural Requirements.

Under the July Guidance, the FDA will authorize health claims for foods without issuing a proposed rule for public comment and without issuing a final rule responding to comments and explaining the basis for its decision. Plaintiffs' third and fourth causes of action are based on the FDA's decision blatantly to violate the requirements of the NLEA and the agency's own regulations that permit the FDA to authorize health claims for foods only through notice-and-comment rulemaking.

Intervenors' summary judgment motion offers little defense of this violation. On the merits of the case, Intervenors defend only the FDA's substantive violation of the NLEA, which they justify by pointing to the D.C. Circuit's decision in *Pearson*. That decision, however, in no way calls the NLEA's procedural requirements into question. Indeed, the FDA's October 6, 2000, Federal Register notice regarding implementation of *Pearson* indicated that the agency believed the D.C. Circuit's decision required reconsideration of the *substantive* health claim regulations as to

dietary supplements, but did not suggest that the agency believed that the decision called into question the validity of any *procedural* requirements applicable to health claims for any product. 65 Fed. Reg. 59855 (2000); *see also Nutritional Health Alliance v. Shalala*, 144 F. 3d 220 (2d Cir. 1998) (upholding NLEA's procedural requirements with respect to dietary supplements). Put simply, neither the NLEA, current FDA regulations, nor *Pearson* give the FDA authority to disregard the requirement of notice-and-comment rulemaking before a health claim, whether qualified or unqualified, is permitted. *See also Lopez v. FAA*, 318 F.3d 242, 247 (D.C. Cir. 2003) (court's duty to enforce administrative regulations is "most evident when compliance with the regulation is mandated by . . . federal law") (quoting *United States v. Caceres*, 440 U.S. 741, 749 (1979)).

The circumstances here are similar to those at issue in *Cutler v. Kennedy*, 475 F. Supp. 838 (D.D.C. 1979), in which this Court overturned the FDA's decision to allow marketing of certain new drugs without prior approval of a new drug application. The decision in that case could easily have been written with this case in mind:

> This [procedure] flies in the face of the statutory scheme. Under the Act, with very limited exceptions not here relevant, drugs can be lawfully marketed in only two ways. They are either new drugs which must be licensed, or they are generally recognized by experts as safe and effective, and are therefore not subject to active regulation. The goal of the Act is to insure that every marketed drug is both safe and effective. [footnote omitted] There are no other possibilities, no interim provisions under which safe, but only potentially effective drugs can be marketed pending testing. Even assuming that defendants are correct that Category III drugs are not necessarily unlawful new drugs, there is no question that they are potentially unlawful new drugs. To say that the Commissioner has the authority under the Act to affirmatively sanction the marketing of such drugs, effectively exempting them from the enforcement provisions of the Act for periods ranging from two to at least five years, is nothing less than a frontal assault on the premarket licensing scheme of the Food, Drug, and Cosmetic Act.

Id. at 854.

As in *Cutler,* the statute at issue here sets forth specific procedures. Just as the FDA lacked authority to exempt drugs from statutory requirements even if the agency believed the drugs to be safe but of questionable efficacy, the FDA lacks authority to exempt health claims from statutory procedures even if the agency believes the statute's substantive standard to be constitutionally questionable. The FDA has exceeded its authority by inviting companies to make health claims prior to receiving authorization for a given claim via notice-and-comment rulemaking. Accordingly, Plaintiffs are entitled to summary judgment on their third and fourth causes of action.

B. The FDA's July Guidance Violates The NLEA's Substantive Standard.

Comparison of the NLEA and the FDA's implementing regulations, on the one hand, and the July Guidance, on the other, makes plain that the regulatory scheme announced in the July Guidance—and in effect today—violates the "significant scientific agreement" standard set forth in the NLEA and FDA regulations. Neither the FDA nor Intervenors suggest otherwise. Instead, the FDA defends the Guidance as "good sense" and an effort "to avoid further litigation," 68 Fed. Reg. 41389—neither of which justifies an Executive Branch decision to override a statutory mandate. Intervenors, on the other hand, defend the substantive standard of the Guidance on the theory that the NLEA standard violates the First Amendment. Because the NLEA is consistent with the First Amendment, and because there is no other possible justification for the agency's violation of the terms of the statute, Plaintiffs are entitled to summary judgment on their first and second causes of action.

1. The NLEA's "Significant Scientific Agreement" Standard Passes First Amendment Scrutiny.

Under *Central Hudson Gas & Electric Corp. v. Public Service Comm'n*, 447 U.S. 557 (1980), the government may ban or restrict commercial speech that is false or misleading.

Commercial speech that is not false or misleading may be restricted to the extent that the restrictions are narrowly tailored to directly advance a substantial government interest. *Id.* at 566. In considering the fit between the governmental interest and the means chosen to accomplish it, the Supreme Court has emphasized that the restriction should be "no more extensive than is necessary," *id.*, but that it need not be "perfect," only "reasonable." *Pearson*, 164 F.3d at 656 (citing *Board of Trustees v. Fox*, 492 U.S. 469, 480 (1989)).

a. Health Claims Unsupported By "Significant Scientific Agreement" Are Inherently Misleading.

The problem with health claims, and particularly claims based on preliminary evidence, is that no one knows whether they are accurate or inaccurate. The nature of nutritional science is such that rarely can one say with certainty that a health claim is "true." Congress reasonably determined, however, that, with respect to foods, health claims supported by "significant scientific agreement" carry a sufficient degree of scientific certainty to warrant allowing them. Conversely, Congress determined that claims based on preliminary evidence are too uncertain, too likely to be inaccurate, to warrant allowing them on food labels. (Congress did not restrict claims made in academic literature or public discourse, only promotional claims on labeling.) The NLEA thus reflects Congress's reasonable view that health claims that have not been validated by science are false or misleading, and that claims are not scientifically valid until supported by "significant scientific agreement." *Accord* 58 Fed. Reg. 2478, 2504 (1993) (FDA final rule implementing NLEA's "significant scientific agreement" standard). Congress's decision represents a reasonable means of protecting the public health. Significantly, just prior to passage of the NLEA, the FDA itself proposed a rule to permit health claims for foods only when supported by "significant agreement" among "qualified experts," and to prohibit claims based on "preliminary data or significantly

contradictory findings." 55 Fed. Reg. 5176, 5180 (1990). The FDA proposed this standard (soon thereafter adopted by Congress in the NLEA) in recognition of the "numerous ways in which [health claims for foods] can be misleading." *Id.* at 5179.

Congress's determination passes First Amendment scrutiny because food health claims that are not supported by "significant scientific agreement" are unreliable and misleading. The NLEA was passed in response to a barrage of false and misleading health claims directed at consumers by food companies. Some claims exaggerated the potential benefits of a particular food. For example, advertisements for Quaker Oats implied that eating oatmeal could reduce cholesterol by ten percent, when the companies' studies showed that most of the benefit came from switching to a low-fat, low-cholesterol diet. *See Hearing on H.R. 3028, Before Subcomm. On Health & Environ*., 101st Cong., 1st Sess. 45-46 (1989) (CSPI submission). Some companies made claims that are largely irrelevant for Americans. For example, labels on Land O' Lakes butter claimed that the Vitamin A in the butter helps keep skin soft and smooth. In fact, skin problems related to Vitamin A result only from severe deficiencies that rarely if ever occur in the United States. *Id.* And other claims touted benefits from one product component, without mentioning another component that could promote either the same or another disease. For example, Campbell's Soup claimed that its low-fat, low-cholesterol soups could help reduce the risk of certain forms of heart disease, but did not mention that the soups' high sodium content could raise blood pressure and thus increase the risk of heart disease. Similarly, based on a study by the National Cancer Institute that found that high-fiber, low-fat diets could reduce the risk of certain cancers, Kellogg's Cracklin' Oat Bran boasted that it could help reduce the cancer risk. That cereal, however, had a particularly high fat content, which could increase the risks of heart disease, cancer, and obesity. Whole milk labels touted the benefits of

calcium for preventing osteoporosis, without mentioning the high fat content of whole milk. *Id.* Moreover, claims boasting of the health benefits of high fiber, low fat, or high calcium generally failed to note the different nutritional needs, physiology, and metabolism of adults and children. For example, a high-fiber diet can be dangerous for children, potentially causing poor absorption of essential nutrients. *FDA Proposals To Permit the Use of Disease-Specific Health Claims on Food Labels: Hearing Before Subcomm. of Comm. on Gov't Operations*, 100th Cong., 1st Sess. 140 (1987) (submission of American Academy of Pediatrics).

As an FDA consumer safety officer testified in the hearings that led up to the NLEA, "once health claims are made, they almost enter the folklore. They tend to acquire a life of their own, and they are very hard to extinguish if they are deceptive." *Id.* at 48. The illusory relationship between drinking orange juice and preventing colds offers one well-known example. Yet whereas the folklore about orange juice has no adverse health consequence, given that medical science has found no cure for colds and orange juice is not harmful, not all examples are so benign because preliminary claims—too premature or controversial to be supported by significant scientific agreement—may be not only inaccurate, but dangerous. For instance, in 1989, the hypothesis that beta-carotene in foods could help prevent lung cancer was considered "promising." Since that time, three significant clinical trials (using supplements) were undertaken to investigate that hypothesis. The trials not only "failed to substantiate a possible preventive role" for beta-carotene with regard to lung cancer, but in two of the trials, "lung cancer incidence was significantly increased rather than reduced" for individuals who smoked or had prior exposure to asbestos—the very populations most at risk for the disease. *See* Institute of Medicine, *Evolution of Evidence for Selected Nutrient and Disease Relationships* 28-29 (Nat'l Acad. of Sciences 2002) (report undertaken for FDA) ("IOM Report").

Because Congress found that health claims for foods have historically been ill-founded and have such a high potential to mislead, the claims can lawfully be proscribed under *Central Hudson*. *See Edenfield v. Fane*, 507 U.S. 761, 768 (1993) ("[O]ur cases make clear that the State may ban commercial expression that is fraudulent or deceptive without further justification."). As the Supreme Court has stated:

> Obviously, much commercial speech is not provably false, or even wholly false, but only deceptive or misleading. We foresee no obstacle to a State's dealing effectively with this problem. The First Amendment, as we construe it today, does not prohibit the State from ensuring that the stream of commercial information flows cleanly as well as freely.

Friedman v. Rogers, 440 U.S. 1, 9-10, (1979) (citations omitted); *see also United States v. Edge Broadcasting Co.*, 509 U.S. 418, 434 (1993) ("Within the bounds of the general protection provided by the Constitution to commercial speech, we allow room for legislative judgments."); *Mainstream Marketing Serv. v. FTC*, __ F.3d __, 2004 WL 296980 at *6 (10th Cir. Feb. 17, 2004) (same).

The Court need not worry that the NLEA prohibits some preliminary health claims that may eventually be supported by significant scientific agreement. First, of course, there is no way of knowing in advance which preliminary claims will in fact turn out to meet this standard. *See* IOM Report 51-58. Second, the Supreme Court's lawyer solicitation cases show that bans that encompass some truthful commercial speech may be justified by a record of abuse (such as the legislative record of the food industry's conduct in the 1980s) and the government's interest in protecting the public (such as its substantial interest in protecting the public health). *See also Florida Bar v. Went for It, Inc*., 515 U.S. 618 (1995) (historical evidence of abuse may justify broad prophylactic restraints on speech); *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447 (1978) (same); *Mainstream Marketing Serv.*, 2004 WL 296980 at *1, *5 (restriction on commercial telemarketing justified by

government's interest "in combating the danger of abusive telemarketing"). Third, as soon as a claim does meet the statutory standard—as soon as its validity is sufficiently demonstrated in FDA proceedings—companies may make it.

In *Pearson*, discussed in more detail in part b. below, the D.C. Circuit addressed the issue whether the false and misleading nature of preliminary health claims for dietary supplements can be cured by the addition of a qualifier or disclaimer. The court held that even if a supplement claim is not supported by "significant scientific agreement," the FDA could not prohibit the claim unless a disclaimer or qualifier would not cure the potential to mislead. If a disclaimer—such as "The evidence in support of this claim is inconclusive"—would cure any such potential, then the government could not prohibit companies from making the claim. In arriving at this conclusion, the court considered the asserted governmental interest and held that prohibiting the four preliminary supplement claims at issue was too broad a restriction. In other words, the court held that the restriction failed under the final prong of *Central Hudson* because the "fit" between the government's goal and the means chosen to advance it was not "reasonable." 164 F.3d at 657.

However, the Supreme Court cases that address commercial speech about unverified or unverifiable product characteristics suggest that this speech is properly regulated under the first prong of *Central Hudson*. For example, in *Bates v. State Bar of Arizona*, the Court explained that the First Amendment protects a lawyer's right to advertise services and fees, but noted that "the peculiar problems associated with advertising claims relating to the quality of legal services" would present a different question because "[s]uch claims probably are not susceptible of precise measurement or verification and, under some circumstances, might well be deceptive or misleading to the public, or even false." 433 U.S. 350, 366 (1976). Again in *Zauderer v. Office of Disciplinary*

Counsel, the Court reiterated that its "decisions have left open the possibility that States may prevent attorneys from making non-verifiable claims regarding the quality of their services." 471 U.S. 626, 641 n.9 (1985).

Consistent with these cases, the D.C. Circuit in *Pearson* did not question the government's right to ban unverified, preliminary claims about drugs or medical devices, until such time as the scientific evidence provides a reasonable certainty of both safety and efficacy. *See Pearson*, 164 F.3d at 656 n.6. The same reasoning applies here: The First Amendment does not preclude Congress from requiring that, before a food may carry a disease prevention claim—a claim that until enactment of the NLEA was deemed a disease claim that brought the food within the purview of drug regulation—that claim must be supported by significant scientific agreement.

Citing *Pearson* and *Ibanez v. Florida Department of Business & Professional Regulation*, 512 U.S. 136, 146 (1994), Intervenors argue (at 14) that Congress was wrong to "presume that health claims will mislead" and that the government "must prove misleadingness with empirical evidence (i.e., must prove that, in fact, consumers will be misled)." Under their theory, the government must "await the Godot of scientific certainty," *United Steelworkers of Am. v. Marshall*, 647 F.2d 1189, 1266 (D.C. Cir. 1980), before it can prohibit a food company from making a promotional health claim. In so arguing, Intervenors make no attempt to distinguish among inconclusive, preliminary, non-replicable, discredited, and even crackpot evidence.

Neither *Pearson* nor *Ibanez* supports Intervenors' theory. In fact, the Supreme Court has long recognized that half-truths and deceptive commercial statements can be regulated because of their capacity to deceive. *See*, *e.g.*, *Virginia State Pharmacy Bd. v. Virginia Citizens Consumer Council*, 425 U.S. 748, 769-70 & n.24 (1976). Congress determined that food health claims that do

not satisfy the "significant scientific agreement" standard are misleading because claims based on preliminary studies are unreliable and suggest a level of scientific authority that is non-existent, and because consumers may rely on such claims to their detriment. *See also infra* at I.B.1.b. (discussing substantial government interest served by NLEA). Furthermore, Congress's determination that health claims too speculative to be supported by significant scientific agreement are inherently misleading because they are too likely to be invalid is entitled to considerable deference. *See Edge Broadcasting Co.*, 509 U.S. at 434; *Fox*, 492 U.S. at 478-80.

As for *Pearson*, the portion of the opinion cited by Intervenors does not stand for the proposition that the government can prohibit qualified health claims only if it can "prove that, in fact, customers will be misled." *See* Interv. SJ Motion 14 (citing *Pearson*, 164 F.3d at 655). Intervenors' theory comes closer to the court's later suggestion that the government would bear the burden of proving that a disclaimer could not cure deceptiveness with respect to the specific dietary supplement claims at issue in the case. Yet in that same discussion, the court recognized that the government may ban a health claim "where evidence in support of a claim is outweighed by evidence against" it, without suggesting any requirement that the government make an empirical showing that no possible disclaimer could cure the "misleadingness." 164 F.3d at 660. Thus, *Pearson* did not take the extreme position advocated by Intervenors.

b. There Is A Reasonable Fit Between Substantial Governmental Interests And The NLEA Standard.

Even if preliminary health claims for foods were not false or misleading, the NLEA's substantive standard would pass First Amendment scrutiny because it is narrowly tailored to serve substantial governmental interests.

1. Although Intervenors frame the NLEA's standard as *establishing* a ban, Congress properly viewed the standard as *lifting* one. Prior to 1990, the FDCA prohibited all health claims for foods. A food company that wanted to make a health claim first had to obtain approval through the FDCA's new drug approval process. *See supra* at 2. Thus, the NLEA standard was crafted to *permit* certain claims—claims that until then were prohibited except for drugs—by relaxing a statutory framework that effectively prohibited health claims for foods. No one seriously disputes that the First Amendment allows Congress to impose some limits to protect consumers from unreliable promotional claims touting dubious relationships between particular foods and serious diseases. The question is thus not whether Congress can take regulatory action, but whether the line it drew in the NLEA went too far. In assessing Congress's judgment, the Court should keep in mind that courts owe significant deference to governmental judgments in cases of line-drawing. *See Went for It,* 515 U.S. at 633; *Edge Broadcasting,* 509 U.S. at 432-34; *Fox*, 492 U.S. at 479-80.

Congress's judgment was based on the voluminous record amassed in hearings leading up to the passage of the NLEA.[3] Congress was well aware that food health claims—both valid and specious—had become increasingly common. *See*, *e.g.,* 136 Cong. Rec. H5843 (daily ed. July 30, 1990) (statement of Rep. Madigan) ("Consumers today are confronted with a variety of labels that

[3]*See FDA Proposals to Permit the Use of Disease-Specific Health Claims on Food Labels: Hearing Before a Subcomm. of the House Comm. on Gov't Operations*, 100th Cong., 1st Sess. (1987); *House Comm. on Gov't Operations*, *Disease-Specific Health Claims on Food Labels: An Unhealthy Idea*, H.R. Rep. No.561, 100th Cong., 2d Sess. (1988); *FDA's Continuing Failure to Regulate Health Claims for Foods: Hearings Before the Subcomm. on Human Resources and Intergovernmental Relations of the House Comm. on Government Operations*, 101st Cong. 1st Sess. (1989); *House Comm. on Gov't Operations, FDA's Continuing Failure to Prevent Deceptive Health Claims for Food,* H.R. Rep. No. 980, 101st Cong., 2d Sess. (1990); *Health and Nutrition Claims in Food Advertising and Labeling: Hearings Before the Senate Comm. on Gov't Affairs*, 101st Cong., 2d Sess. (1990).

provide them with disjointed and confusing information."). "[W]hen the FDA relaxed enforcement of regulation during the [1980s], it lost control of the marketplace, and many unfounded claims began being used for foods." 136 Cong. Rec. H12953 (daily ed. Oct. 26, 1990) (statement of Rep. Waxman). In 1987, the FDA issued a proposed rule to "clarify" its "enforcement policy." *See* 52 Fed. Reg. 28842, 28845 (1987). Under that policy:

> The information should be based on and be consistent with valid, reliable, scientific evidence that is publically available (prior to any health related claim being made), including data derived from clinical and other studies performed and evaluated by persons qualified by experience and training to evaluate such studies, and should conform to generally recognized medical and nutritional principles. Preliminary findings should be confirmed. Conclusions supported by a less-than-clear data base may prove in time to be correct, but are not appropriate for use on food labeling if they do not reflect the weight of scientific evidence. This approach will ensure that the substance of the message has achieved sufficient recognition to be appropriate and nonmisleading.

Id. 28845. In 1990, the FDA rescinded that proposal as too lax, in the wake of a marketplace free-for-all of unreliable disease claims based on preliminary, unreliable, or speculative research. *See* 55 Fed. Reg. 5176, 5178 (1990). Then-HHS Secretary Louis Sullivan lamented the confusion that prevailed in grocery store aisles, noting that "all of us have encountered the mayhem," and that "some unfounded health claims are being made in the marketplace. It is a real mess." Louis Sullivan, Secretary of HHS, Remarks at National Food Policy Conference at 2 (Mar. 7, 1990). Congress's decision, through the NLEA, to relax the otherwise applicable new drug application process, but to establish a pre-clearance system under which only reliable claims would be authorized, was a reasonable means of conveying solid health information to consumers while also protecting against the failures of the FDA's 1980s regulatory policy.

2. In *Pearson*, the D.C. Circuit held that, based on the rulemaking record with respect to four dietary supplements, the First Amendment did not permit the FDA to reject outright each of the four

claims at issue if the claim was supported by the qualitative and quantitative weight of the evidence and a disclaimer could cure the potential to mislead. 164 F.3d at 659 & n.10. Under the NLEA, health claims for dietary supplements, like those for foods, are forbidden unless approved by the FDA. However, rather than specifying the substantive standard applicable to such claims (as it does for food claims), the NLEA directs the FDA to choose a standard and procedures for approval of health claims for dietary supplements. 21 U.S.C. § 343(r)(5)(D). The broad discretion delegated to the FDA reflects the fact that, in contrast to the congressional hearing record with respect to food claims, the record before Congress contained little information about dietary supplements. In fact, no hearings were held on the subject of supplements. *Compare infra* n.3. Ultimately, the FDA chose to apply to supplement claims the "significant scientific agreement" standard, implemented through the same notice-and-comment rulemaking process that the NLEA mandates for food claims. 21 C.F.R. § 101.14(c).

The differences between the NLEA's treatment of supplements and foods require a different outcome in this case than in *Pearson*. Indeed, after *Pearson*, some food industry groups and supporters urged the FDA to apply the holding of the case to conventional foods. The FDA rejected those suggestions. In a May 2000 letter to Congressman David McIntosh, the FDA explained that "absent a court ruling finding the statute unconstitutional, FDA does not have authority to authorize health claims for conventional foods when such a claim would require a disclaimer to render it truthful and nonmisleading." Plaintiffs' Opposition to FDA Motion to Dismiss ("Pltf. Opp."), Exh. 1 at 7; *cf*. *Mainstream Marketing Serv.*, 2004 WL 296980 at *1, *8 (legislative history supports FTC decision to restrict calls from commercial telemarketers, but not non-commercial telemarketers).

Moreover, *Pearson* stated that health claims could be prohibited outright based on health or safety concerns, or where the quality or quantity of the evidence against the claim outweighed the quality or quantity of the evidence in support of it. 164 F.3d at 656 & n.6, 659 & n.10; *see also* 65 Fed. Reg. 59837 (FDA discussion of *Pearson*). At the same time, the court expressly noted that it read the government's argument to assert an economic injury to consumers, not a concern about health. 164 F.3d at 656 ("It is important to recognize that the government does not assert that appellants' dietary supplements in any fashion *threaten* consumer's [sic] health and safety.") (emphasis in original). Thus, *Pearson* did not consider Congress's judgment that claims on food labels touting prevention of serious diseases, such as cancer and heart disease, pose too high a risk that consumers will "self-medicate," for instance with nuts and eggs, in lieu of using reliable therapies, and that the government's duty to protect the public health therefore required restricting such claims. *See also* 55 Fed. Reg. 5176, 5178-79 (1990) (FDA expressing concern that people "will forgo needed medical treatment based on the information that they obtain from the label and labeling of the food products they consume" and that "consumers who are under a doctor's care for treatment of chronic disease conditions and who may be taking drugs for those conditions, not substitute commonly available foods for the prescribed treatment."). Likewise, *Pearson* did not consider that some claims, such as those associating food rich in beta-carotene with a reduced risk of cancer, might be not only invalid, but dangerous. *See* IOM Report 28-29.

Here, the principal injury identified by Congress and alleged in the complaint is injury to health. *See* Complt. ¶¶ 3, 4, 37; Pltf. Opp., Exhs. B-E. This distinction from *Pearson* is crucial because the First Amendment does not prohibit the government from restricting even truthful commercial speech where the restriction is narrowly tailored to advance a substantial governmental

interest. *See Central Hudson*, 447 U.S. at 566. Notably, during notice-and-comment rulemaking to implement the NLEA, the FDA emphatically agreed with Congress. The agency stated that "allowing preliminary claims would open the floodgates to a large number of partially supported claims, thereby undercutting the credibility of valid health claims on food labels and of the food label itself." 58 Fed. Reg. 2505. It explained that the "impact [of permitting preliminary claims] could easily involve a perception among many consumers that health claims and food labels are not reliable." If that occurred, the agency predicted that consumers would "not change their dietary practices to reduce their risk of disease" and therefore "they will be less healthy, and there will be needless deaths from disease as well as costs to the national economy." *Id.*

2. Even If *Pearson* Applied To Foods, That Decision Would Not Justify The FDA's July Guidance With Respect To Category C And D Claims And Some Category B Claims.

Even assuming that the First Amendment required the FDA to violate the NLEA by authorizing some claims that do not satisfy the NLEA's significant scientific agreement standard, the agency could only authorize those additional claims that the First Amendment required it to authorize—and no others. And even assuming that *Pearson*'s reasoning applied to foods, the First Amendment would not require the FDA to allow any and all health claims, however dubious, as long as the claims were qualified to reflect the weakness of the supporting evidence. At most, *Pearson* would require violation of the NLEA only to allow claims that were supported by the "weight of the evidence," but not by "significant scientific agreement." 164 F.3d at 659 & n.10. Such claims would fall under the July Guidance's Category B. Other Category B claims and all Category C and D claims are wholly unjustified by *Pearson*, even assuming that *Pearson*'s understanding of the

regulatory regime for dietary supplement claims is properly transported wholesale to the regime for food claims.[4]

The July Guidance suggests that the FDA's decision to allow claims that do not meet even the *Pearson* standard was based on *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002). *See* 68 Fed. Reg. 41388-89. That case concerned the FDA's denial of a petition seeking authorization to claim that antioxidant vitamins help prevent cancer. In *Whitaker*, the court held that where a health claim for a dietary supplement was supported by some "credible" evidence, but not by the weight of the evidence, the FDA had to allow it, subject to an appropriate disclaimer. *Id*. at 10-11. *Whitaker*, however, did not involve foods, was not appealed to the court of appeals, and went beyond *Pearson* by ordering the FDA to authorize a claim *contrary* to the weight of credible evidence. Its holding that commercial speakers have a constitutional right to make promotional health claims that are more likely than not to be *untrue* is unsupported either by the Supreme Court's commercial speech jurisprudence or by the limited holding in *Pearson*. *Whitaker* thus fails to justify the scheme implemented through the July Guidance.

This Court should not follow *Whitaker* by holding that the First Amendment requires the government to permit misleading or untruthful speech as long as the speech is accompanied by a disclaimer. The Supreme Court has explained that "there is no First Amendment rule . . . requiring

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[4]Again, Category B claims are those based on a "*moderate/good level of comfort* among qualified scientists that the claimed relationship is scientifically valid. Qualified experts would rank the relationship as 'promising,' but not definitive." Category C "represents a *low level of comfort* among qualified scientists that the claimed relationship is scientifically valid. It would have low consistency with statements from authoritative bodies or be ranked as "low" in terms of scientific support by qualified scientists." Category D "represents an *extremely low level of comfort* among qualified scientists that the claimed relationship is scientifically valid." Interv. SJ Motion, Exh. B at 7-8 (FDA Guidance) (emphasis in original).

a State to allow deceptive or misleading commercial speech whenever the publication of additional information can clarify or offset the effects of the spurious communication." *Friedman*, 440 U.S. at 12 n.11. Thus, the First Amendment does not give a commercial speaker the right to make a false statement in its advertising as long as the ad includes a disclaimer disclosing that the statement is false. With respect to qualified health claims, such as Category C and D claims, for which the weight of the evidence refutes the claim or where the only evidence is too preliminary or otherwise inadequate to support the claim, no Supreme Court or D.C. Circuit case requires the government to allow the claim to be made, even with qualifying language. Such claims lack First Amendment protection because, by a preponderance of the evidence, *they are not true*. *Central Hudson*, 447 U.S. at 563 ("[T]here can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity.") (citation omitted). To clutter the marketplace with such claims is to invite the confusion and consumer distrust that Congress sought to eliminate by enacting the NLEA and to disregard entirely Congress's assessment of the government's interest in doing so.

Allowing Category C and D claims, and those Category B Claims supported only by a "moderate . . . level of comfort among qualified scientists," also creates a disincentive for companies to do the research necessary to validate a claim. If companies can boost sales by making preliminary and even specious health claims, they may choose not to devote resources to studying whether such claims are actually valid. Moreover, the research necessary to satisfy the statutory standard, or even the *Pearson* standard for dietary supplements, may demonstrate not just whether a claim is valid, but whether it is dangerous. For example, the FDA's regulation authorizing a health claim associating consumption of psyllium husk with reduced risk of heart disease requires that the claim

warn of the risk of esophageal and gastrointestinal obstructions. 21 C.F.R. § 101.17. The rulemaking associated with this regulation identified other potential risks, which the FDA addressed in the notice-and-comment process. 63 Fed. Reg. 8103, 8112-14 (1998). The FDA was able knowledgeably to address both the benefits and risks of psyllium husks only because substantial research had been done. Accordingly, a drastic departure from the statutory standard defined by Congress in the NLEA is both unwise and unlawful.

II. NOTICE-AND-COMMENT RULEMAKING WAS REQUIRED BEFORE THE AGENCY ISSUED GUIDANCE INSTITUTING A NEW REGULATORY REGIME.

When an agency promulgates a substantive rule, "effect[ing] a dramatic change in the agency's established regulatory regime," the agency must follow the notice-and-comment procedure of the Administrative Procedure Act ("APA"). *Croplife Am. v. EPA*, 329 F.3d 876, 884 (D.C. Cir. 2003). Failure to do so requires that the rule be vacated. *Id.* Because the July Guidance is a substantive rule, issued without notice-and-comment rulemaking, Plaintiffs are entitled to summary judgment on their fifth cause of action.

Notice-and-comment rulemaking was also required because the July Guidance contradicts prior FDA statements made during the course of the notice-and-comment rulemaking that culminated in an existing FDA regulation. *See Sprint Corp. v FCC*, 315 F.3d 369, 374 (D.C. Cir. 2003) (describing as a "'maxim of administrative law' the proposition that, '[i]f a second rule repudiates or is irreconcilable with [a prior legislative rule], the second rule must be an amendment of the first; and, of course, an amendment to a legislative rule must itself be legislative.'") (citation omitted); *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 586-87 (D.C. Cir. 1997). Accordingly, the FDA erred in issuing the July Guidance without notice-and-comment rulemaking.

The FDA has argued that the Guidance did not require notice-and-comment rulemaking because it is a "policy statement." FDA Motion to Dismiss 37. However, the effect of the Guidance shows that the FDA's characterization is incorrect. *See Croplife Am.*, 329 F.3d at 883 (agency's characterization of its action not controlling); *General Elec. Co. v. EPA*, 290 F.3d 377, 383-34 (D.C. Cir. 2002) (effect of agency action most significant for determining its nature); *Community Nutrition Inst. v. Young*, 818 F.2d 943, 946-47 (D.C. Cir. 1987) (same).

The July Guidance "is certainly in part an exercise in policy," as are substantive rules generally. *See Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 95 (D.C. Cir. 1997). "But the crucial distinction . . . is that a substantive rule *modifies* or *adds* to a legal norm based on the agency's *own authority*. That authority flows from a congressional delegation to promulgate substantive rules, to engage in supplementary lawmaking. And, it is because the agency is engaged in lawmaking that the APA requires it to comply with notice and comment." *Id.* (emphasis in original). The July Guidance fundamentally modifies the legal norm: Prior to the Guidance, qualified health claims on foods were forbidden; under the Guidance, procedures and standards are in place to allow them. The FDA's plan for considering and authorizing qualified health claims does not just "extend its regulatory reach," *id.*; the plan creates a regulatory scheme that modifies both the procedures and substantive standards of the NLEA and of FDA regulations. The Guidance also sets forth procedures that bind the FDA with respect to timing, such that the FDA can grant itself an extension of time to consider a petition for authorization to make a qualified claim only for 30 to 60 days and only "upon good cause." Interv. SJ Motion, Exh. A at 5. And the FDA is now following the procedures of the July Guidance, giving them "present, binding effect." *Community Nutrition Inst*, 818 F.2d at 949; *see Croplife Am.*, 329 F.3d at 881.

Moreover, after the agency has authorized a qualified claim pursuant to the Guidance, "it would be daunting indeed to try to convince a court that the agency could appropriately prosecute" a company for making that qualified claim. *Community Nutrition Inst.*, 818 F.2d at 948. Indeed, the FDA has implicitly conceded that authorization of a health claim under the July Guidance binds the agency as to that claim. FDA Reply, Motion to Dismiss, 13. "[T]his type of cabining of the agency's prosecutorial discretion can in fact rise to the level of a substantive, legislative rule." *Community Nutrition Inst.*, 818 F.2d at 948. Further, the FDA's contention that the Guidance merely "announces the agency's tentative intentions for the future," FDA Motion to Dismiss 37, is contradicted by the facts that the Guidance has already gone into effect and that the FDA is *currently* considering three food claims under the procedures announced in the Guidance. *See* www.cfsan.fda.gov/~dms/lab-qhc.html#petition.

Exceptions to notice-and-comment requirements are recognized to "accommodate situations where the policies promoted by public participation in rulemaking are outweighed by the countervailing considerations of effectiveness, efficiency, expedition, and reduction in expense." *Guardian Fed. Sav. & Loan Ass'n v. Federal Sav. & Loan Ins. Corp*., 589 F.2d 658, 662 (D.C. Cir. 1978). None of these considerations applies here. Indeed, although the FDA listed them in its Motion to Dismiss (at 37), it did not even argue that any apply. The fact that the agency has so far been asked to review only three qualified food claims under the July Guidance also demonstrates that a need for expedition did not excuse the FDA from following the APA. Moreover, even where an exception to notice-and-comment rulemaking may be warranted, the Administrative Procedure Act requires the agency to make express findings on the need for one. 5 U.S.C. § 553(b).

Furthermore, the FDA's November 2003 ANPR implicitly recognizes that rulemaking is necessary to institute the broad procedural and substantive changes outlined in the Guidance. Thus, it states that one option for regulating qualified health claims in the long term would be a regulation, issued pursuant to notice-and-comment rulemaking, "to codify the current interim procedures." 68 Fed. Reg. 66042 (Interv. SJ Motion, Exh. G). The ANPR's statement that the agency may some day either supersede the July Guidance with a notice-and-comment rulemaking or revoke the Guidance in favor of postmarket enforcement, *see id.* (listing options), does not relieve the agency of its APA obligations today. *See General Elec. Co.*, 290 F.3d at 380. Indeed, it only serves to emphasize that such a dramatic change in the regulatory regime is properly pursued, if at all, through rulemaking.

III. PLAINTIFFS HAVE STANDING.

Plaintiffs have addressed the bulk of Intervenors' argument that Plaintiffs lack standing in their opposition to the FDA's motion to dismiss and will not repeat here all of that discussion. *See* Pltf. Opp. 16-24. Intervenors' principal argument is that Plaintiffs' members lack injury because qualified health claims are not misleading and are protected by the First Amendment, *see* Interv. SJ Motion 20-23, but that argument goes to the merits, not to standing. In essence, Intervenors contend that Plaintiffs are not injured because the FDA's new regulatory regime for qualified health claims is constitutionally required. However, "[f]or purposes of ruling on a motion to dismiss for want of standing, both the trial and reviewing courts must accept as true all material allegations of the complaint, and must construe the complaint in favor of the complaining party." *Warth v. Seldin*, 422 U.S. 490, 500-01 (1975). "[S]tanding in no way depends on the merits of the plaintiff's contention that particular conduct is illegal . . . ." *McConnell v. FEC*, 124 S. Ct. 219, 709 (2003) (quoting *Warth*, 422 U.S. at 500).

In addition, Intervenors' constitutional argument does not in any way affect Plaintiffs' standing to raise their third, fourth, and fifth causes of action, which allege violations of procedural requirements of the NLEA and of FDA regulations and a violation of the Administrative Procedure Act. *See* Complaint at 13. Accordingly, Intervenors' contention that Plaintiffs are not injured because qualified health claims are not inherently misleading, even if true, does not call into question Plaintiffs' standing to bring this case.

Finally, Intervenors argue that Plaintiffs do not have standing on behalf of themselves because they have not been denied an opportunity to comment on pending petitions for approval of qualified health claims for foods. As discussed in Plaintiffs' opposition to the FDA's motion to dismiss and recognized by the FDA, notice and comment "following publication of proposed rules is a critical step in determining whether a proposed regulation is appropriate for adoption." 58 Fed. Reg. 2478, 2523 (1993). Under the FDA's new regime—and contrary to statute and regulation—the FDA is not publishing proposed rules with respect to qualified health claims. Accordingly, although the regime announced in the July Guidance allows the public to submit comments on qualified health claim petitions, the FDA is not providing the public with a proposed rule on which to comment. The difference is significant, for the petition sets forth a company's view of the claim, not the FDA's objective assessment and explanation of its intent with regard to the disposition of the petition (for example, what category of claim the FDA is tentatively inclined to approve). Indeed, under the new regime, the comment period ends before the FDA even undertakes its own

evaluation. *See supra* p.5. As discussed in Plaintiffs' opposition to the FDA's motion, the procedural injury is sufficient to confer standing. *See* Pltf. Opp. 17-19.[5]

IV. THIS CASE IS RIPE FOR JUDICIAL REVIEW AND DOES NOT CHALLENGE FDA ENFORCEMENT DISCRETION.

Intervenors' arguments (at 25-28 & 33-34) with respect to ripeness and enforcement discretion repeat arguments made in the FDA's motion to dismiss. For the reasons stated in Plaintiffs' opposition to the FDA's motion, Intervenors' arguments lack merit. This case is ripe for review because the FDA's implementation of the July Guidance is final agency action under the Administrative Procedure Act and the lawsuit presents a purely legal issue that is appropriate for immediate resolution. *See* Pltf. Opp. 12-16*; General Elec. Co.*, 290 F.3d at 380; *cf. Office of the Communication of the United Church of Christ v. FCC*, 826 F.2d 101, 105 (D.C. Cir. 1987) (although purely legal, "issue not fit for review, because the agency had not bound itself to follow the course of conduct challenged, but had stated only that it might do so.") (citing *Toilet Goods Ass'n v. Gardner*, 387 U.S. 158, 163-64 (1967)). Moreover, this case does not ask the Court to second-guess the FDA's use of enforcement discretion. *See* Pltf. Opp. 24-26.

V. PLAINTIFFS HAVE NOT FAILED TO EXHAUST ADMINISTRATIVE REMEDIES.

Plaintiffs challenge a new FDA regulatory regime, instituted through "guidance." Intervenors make a cursory argument that Plaintiffs failed to exhaust their administrative remedies. There were, however, no administrative remedies for Plaintiffs to exhaust. *See*, *e.g.*, *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90 (D.C. Cir. 1997) (considering challenge to FDA guidance). The provision cited by Intervenors, 21 C.F.R. § 10.45(b), does not apply to cases such as this one, but

[5]Intervenors also raise as a standing point their contention that Plaintiffs seek to force the FDA to take enforcement action. That contention misunderstands this case. *See* Pltf. Opp. 24-26.

rather to challenges to FDA decisions with respect to citizen petitions or matters as to which the agency provides a right to an administrative review hearing under 21 C.F.R. § 16.1(b). Moreover, the very regulation on which Intervenors rely makes plain that Plaintiffs have satisfied any exhaustion requirements here: Section 10.45(d)(1)(i) states the FDA's position that "Final agency action exhausts all administrative remedies." Because this case challenges "final agency action," *see* Pltf. Opp. 14-16, the agency deems Plaintiffs' remedies exhausted in this case.

In addition, exhaustion is not a jurisdictional doctrine and should be applied "flexibly, with an eye toward its underlying purposes." *Cutler v. Hayes*, 818 F.2d 879, 890 (D.C. Cir. 1987). "Since the doctrine is not linked to the power of the court to entertain actions, but instead implicates prudential considerations, the exhaustion requirement may be waived by the agency, or disregarded by the court when application of the doctrine would be futile." *Id.* at 891. Here, consistent with its regulation, 21 C.F.R. § 10.45(b), the FDA has waived the argument, as its 45-page motion to dismiss did not mention exhaustion. Moreover, application of an exhaustion requirement would be futile. First, the FDA has made clear, through the July 2003 Guidance and the November 2003 ANPR, that it has made a decision to allow health claims that do not meet the statutory and regulatory requirements. Intervenors do not suggest that the FDA's position is realistically open to change. To be sure, the ANPR asks for comment on various options for regulating health claims that violate the NLEA, but the premise of the ANPR is that the FDA *is* going to allow them. More importantly, the July Guidance is currently in effect, the FDA is processing petitions for authorization of qualified health claims under its procedures, and the Guidance will be in effect for the foreseeable future. In these circumstances, it would be pointless to impose an exhaustion requirement.

Finally, even if an exhaustion requirement somehow applied in this case, Plaintiffs should be deemed to have satisfied it. In an April 10, 2003 letter to the FDA, Plaintiffs challenged the FDA's authority to adopt its own regulatory scheme, in lieu of the scheme mandated by Congress. *See* FDA Motion to Dismiss, Tab 2. Plaintiffs' letter expressly addressed the statute's procedural requirements and the FDA's obligation to undertake notice-and-comment rulemaking if it sought to alter its regulatory requirements, to the extent the NLEA permitted the FDA to alter them. Although this letter was written in response to a Guidance issued by the FDA in December 2002, Plaintiffs' challenge to the July Guidance, as stated in the third through fifth causes of action of their complaint, is identical to the issues raised in the April letter. The agency never responded to that letter, except by issuing the July Guidance, which rejects the views expressed in Plaintiffs' letter.

CONCLUSION

For the foregoing reasons and those set forth in Plaintiffs' opposition to the FDA's motion to dismiss, Plaintiffs' motion for summary judgment should be granted and Intervenors' motion for summary judgment should be denied.

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Respectfully submitted,

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