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 MAKERS OF THE WORLD'S FAVORITE BRANDS OF
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 Food and Drug Administration
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CITIZEN PETITION

The Grocery Manufacturers of America (GMA) submits this petition to request that the Food and Drug Administration (FDA) apply the First Amendment principles enunciated in *Pearson v. Shalala*¹ to all food, not just to dietary supplements. GMA submits this petition under 21 C.F.R. § 10.30, sections 201(n) and 403(r) of the Federal Food, Drug, and Cosmetic Act (FD&C Act),² 21 C.F.R. § 101.14, and 21 C.F.R. Subpart E to request that the Commissioner of Food and Drugs withdraw and completely revise FDA's strategy for implementation of the *Pearson* decision.

GMA is the world's largest association of food, beverage, and consumer brand companies. GMA member companies sell more the \$460 billion in consumer food and other products each year and employ more than 2.5 million workers in all 50 states. GMA speaks for food and consumer brand manufacturers at the state, federal, and international levels on legislative and regulatory issues. These manufacturers have

¹ 164 F.3d 650 (D.C. Cir.), *rehearing denied*, 172 F.3d 72 (D.C. Cir. 1999).

² 21 U.S.C. §§ 321(n), 343(r).

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a deep interest in using truthful and nonmisleading claims for their food products. The *Pearson* case establishes that GMA's members have a constitutionally protected right to do so. In the nine months since *Pearson* became final and binding on FDA in July 1999, FDA has done virtually nothing to implement it and has taken steps to exclude conventional food from the reach of *Pearson's* First Amendment mandate.

In a notice published on December 1, 1999, FDA announced what it called a strategy to "implement" the *Pearson* decision.³ FDA said it will first obtain all scientific data relevant to the four claims involved in the *Pearson* case, then hold a public meeting, and then determine its course of action specifically with respect to the four requested claims for dietary supplements. In a subsequent notice announcing the public meeting, FDA acknowledges that "Any decision [concerning disease claims] with respect to dietary supplements . . . will also affect the use of such claims for conventional foods."⁴ Nevertheless, the same notice expressly restricts FDA's implementation of *Pearson* to dietary supplement labeling:

"FDA may authorize health claims on conventional foods only when there is significant scientific agreement among qualified experts that the totality of publicly available scientific evidence supports the claim. As a result of this statutory requirement for conventional foods and because the *Pearson* case involved only dietary supplements, this portion of the public meeting [to discuss possible changes in light of the *Pearson* decision to FDA's general health claim regulations as they apply to dietary supplements] will be restricted to health claims on dietary supplements."⁵

Thus, FDA has made it clear that it will not begin to consider either the application of the *Pearson* decision to conventional food or the broader impact of the decision on all FDA-

³ 64 Fed. Reg. 67289 (December 1, 1999)

⁴ 65 Fed. Reg. 14219, 14221 (March 16, 2000).

⁵ *Id.*

regulated labeling until after FDA finishes the current strategy, which only addresses dietary supplement labeling. Thus, FDA implementation of *Pearson* is years away.

There is no reason for this delay. *Pearson* arose under the same standard for approval of disease claims⁶ as applies to all food under the Nutrition Labeling and Education Act of 1990 (NLEA). FDA simply extended that standard to dietary supplements by regulation. *Pearson* then held unambiguously that FDA's application of that standard to bar proposed disease claims was unconstitutional.

FDA's misnamed "implementation" strategy perpetuates FDA's suppression of truthful and nonmisleading information about food and dietary supplements and inhibits GMA members from disseminating important nutrition and health information to consumers. The First Amendment leaves FDA no constitutional choice other than to withdraw and revise its *Pearson* strategy and its disease claims regulations and related guidances immediately.

A. Action Requested

GMA requests that FDA conform FDA's regulation of food labeling to *Pearson's* First Amendment standards.⁷ To do so, FDA must take the following steps:

1. FDA must immediately withdraw and revise its proposed strategy to implement the *Pearson* decision.
2. FDA must apply *Pearson* to all food, including but not limited to dietary supplements, because the *Pearson* case interpreted the NLEA standard for approval of disease claims for food (which FDA extended without change to dietary supplements).

⁶ FDA generally refers to all claims authorized by section 403(r)(1)(B) of the FD&C Act as "health claims." This petition refers to them as "disease claims" to distinguish them from structure/function claims and because section 403(r)(1)(B) defines such claims as characterizing "the relationship of any nutrient . . . to a disease."

⁷ FDA's Federal Register notice publishing the *Pearson* implementation strategy did not solicit public comment, as might reasonably have been expected, given that the strategy concerns a fundamental constitutional right.

3. FDA must withdraw the significant scientific agreement guidance because it does not permit FDA to authorize all truthful, nonmisleading claims (including claims for which the level of scientific support can be set forth meaningfully in disclaimers or other explanatory information).
4. FDA must withdraw the authoritative statement guidance because it indicates that FDA will use its unconstitutional interpretation of "significant scientific agreement" to determine whether a statement is "authoritative."
5. FDA must amend all existing disease claim regulations (both procedural and substantive) in 21 C.F.R. § 101.14 and 21 C.F.R. Part E to comply with *Pearson*.
6. FDA must immediately suspend all enforcement action against claims that are truthful, accurate, and not misleading.

B. Statement of Grounds

I. Background

A. Congress Has Repeatedly Directed FDA to Permit Communication of Disease-Related Information on Food Labeling

Congress has taken legislative action three times in less than a decade to compel FDA to authorize dissemination to the American public of important information about the relationship between diet and disease. Because FDA did not heed the direction of the legislature, its actions were challenged in the courts, culminating in the *Pearson* holding, which FDA continues to resist.

The disease claim controversy dates back to the 1938 FD&C Act, under which a food labeled with a disease claim was regulated as a drug. Over time, advances in the nutritional sciences demonstrated an array of disease-related benefits of food. In light of these developments, what was in effect a flat statutory prohibition of disease claims for food became completely untenable.

In 1987 and 1990, FDA attempted to liberalize its disease claim policy under the 1938 FD&C Act.⁸ FDA's effort was triggered both by a recognition that there was valuable information concerning diet/disease relationships that should be communicated to consumers and by the fact that food manufacturers were in fact using disease claims without meaningful FDA guidance or oversight. Congress ultimately preempted FDA's efforts by enacting the NLEA in 1990 and expressly authorizing manufacturers to make disease claims for food.

The NLEA directed FDA to approve all disease claims for conventional foods that were substantiated under the statutory "significant scientific agreement" standard and gave FDA discretion to develop a standard and procedure for dietary supplement disease claims. FDA by regulation adopted the same procedures and substantiation standard for dietary supplement disease claims. In the ten years since the enactment of the NLEA, only eleven disease claims have been approved under the NLEA.⁹ The few claims that FDA has approved by regulation have little value in food labeling. They are wordy and cumbersome and therefore largely unsuitable for mass communication or for presentation as part of product labels or labeling. For that reason, even the approved claims are not widely used. Thus, even diet/disease information that FDA has found to be substantiated is still not being communicated to consumers.

Only four years later, Congress enacted the Dietary Supplement Health and Education Act of 1994 (DSHEA), which further expanded the scope of disease-related information that could be provided for dietary supplements.¹⁰ DSHEA allowed

⁸ 52 Fed. Reg. 28843 (August 4, 1987); 55 Fed. Reg. 5176 (February 13, 1990).

⁹ 21 C.F.R. §§ 101.73-101.81; 64 Fed. Reg. 57700 (October 26, 1999), *to be codified at* 21 C.F.R. § 101.82.

¹⁰ Section 403(r)(6) of the FD&C Act, 21 U.S.C. § 343(r)(6).

manufacturers to make structure/function claims without premarket approval by or premarket notification to FDA. But even this signal from Congress did not prompt FDA to reevaluate its food labeling policies.

The NLEA disease claim approval process as implemented by FDA gave rise to major problems. First, it was a premarket approval scheme, under which the claim could not be made unless authorized by FDA. Second, as applied by FDA, even the few claims that were permitted were subject to burdensome limitations (including prescribed wording) that made their use impractical. Third, the approval process itself delayed the use of any claim and the communication of the diet/disease relationship by years. All three problems raise constitutional issues and all three played a role in Congress' decision to revisit the NLEA disease claims process.¹¹ In 1996, the Senate Committee on Labor and Human Resources observed:

"Unfortunately, the promised benefits of the original health claims provisions of the NLEA have not been fully realized. The FDA has established unduly stringent criteria for approving health claims for food, resulting in the approval of very few health claims available for use in only limited circumstances. In addition, as is true with other areas of premarket approval, the health claims process has become a regulatory bottleneck, preventing useful claims from entering the market without undue delay."¹²

Congress was very concerned that this regulatory bottleneck, which was standing in the way of consumer access to meaningful disease information, already had had adverse public health consequences. It cited as an example the fact that the

¹¹ The Commerce Committee of the House of Representatives noted that, under the NLEA, "it often takes an estimated two years following submission of a health or nutrient content claim petition before . . . FDA . . . is able to approve a claim, thereby delaying the provision of important dietary information to consumers." H.R. Rep. No. 105-306, 105th Cong., 1st Sess. 6 (October 6, 1997). The Committee added, "The perception of a time-consuming process without predictability of endpoint is widely believed to serve as a disincentive to the proposal of new claims." *Id.* at 7.

¹² S. Rep. 104-284, 104th Cong., 2d Sess. 63 (June 20, 1996).

Centers for Disease Control and Prevention (CDC) had recommended in 1992 that women of childbearing age consume 0.4 mg of folic acid per day to prevent spinal bifida and other neural tube defects. Despite the CDC position, FDA refused to approve this disease information for use in labeling, finding that the evidence did not satisfy the FDA "significant scientific agreement" standard. Ultimately, bowing to the public outcry over this information ban, FDA finally authorized the use of a folic acid/neural tube defect claim in March 1996.¹³ This was *four years* after the CDC recommendation was issued, and many more years after the claim had been fully substantiated and after meaningful information about the folic acid/neural tube defect connection could have been communicated to consumers.

In 1997, Congress attempted to rectify the failure of the FDA implementation of the NLEA disease claim provisions by creating an alternative. The Food and Drug Administration Modernization Act of 1997 (FDAMA) included a new disease claims provision that: (a) permitted manufacturers to make such claims for food based on "authoritative statements" of qualified federal scientific bodies, including the CDC, (b) replaced prior FDA approval of such disease claims with a process of premarket notification, (c) did not require FDA to prescribe the language of the permitted disease claims, and (d) did not require FDA to promulgate a regulation, thereby dramatically shortening the "waiting period" before the manufacturer could market foods bearing the authoritative statement claim. In so doing, Congress emphasized the importance of disease claims on food in promoting public health: "[Disease] claims serve the public health by helping to disseminate important health information to the public promptly, and at the point of purchase where they can help

¹³ *Id.* at 63-64.

shape healthful consumer food choices."¹⁴ But even this far less restrictive mechanism has not dramatically increased the use of disease claims on food labeling. Only one "authoritative statement" claim has been permitted by FDA; nine have been rejected.

In all, FDA has permitted only twelve disease claims for food products. That figure alone indicates that, due to FDA's overly restrictive approach, the NLEA and FDAMA disease claims provisions have not achieved their public health objectives.

B. Constitutional Protections for Claims on Food Labeling

FDA's restrictions on claims in food labeling and other forms of speech have been struck down by the courts several times in the past three years on the ground that they are unconstitutional restrictions of commercial speech. The principles established in *Pearson* and in United States Supreme Court commercial speech cases mandate a complete overhaul of FDA's regulation of claims in food labeling to bring it into compliance with the First Amendment.

The First Amendment to the United States Constitution protects "commercial speech," including food and dietary supplement labeling. It prohibits the government from restricting commercial speech unless the government's regulations satisfy the four-part *Central Hudson Gas & Electric Corp. v. Public Service Commission* test.¹⁵ The *Central Hudson* test can be distilled into two simple principles. First, "only

¹⁴ S. Rep. 105-43, 105th Cong., 1st Sess. at 49 (July 1, 1997).

¹⁵ 447 U.S. 557 (1980). The *Central Hudson* analysis runs as follows:

1. Is the speech false or misleading or does it propose an unlawful transaction?
2. If the commercial speech at issue is true, not misleading, and concerns a legal activity, does the government assert a substantial interest that the restriction on commercial speech is intended to further?
3. Does the restriction of commercial speech "directly advance" the interests involved?
4. Is the restriction more extensive than necessary?

false, deceptive or misleading commercial speech may be banned."¹⁶ Second, commercial speech that is not false, deceptive, or misleading may be restricted, but only if the State shows that there is a "reasonable fit" between the government's objectives and the degree of restriction that the government uses to achieve its objectives.¹⁷

The government has the burden "of identifying a substantial interest and justifying the challenged restriction."¹⁸ The restriction must be "narrowly tailored."¹⁹ The "cost" of the restriction -- that is, the burden it imposes on the speech -- must be "carefully calculated."²⁰ That cost/benefit assessment in turn requires that "the regulation not 'burden substantially more speech than is necessary to further the government's legitimate interests."²¹ FDA's restrictive approach to disease claims -- in particular, its complete suppression of claims -- does not pass constitutional muster.

The purpose of the NLEA and implementing regulations is not to prohibit false and misleading speech, but to permit truthful, nonmisleading, and substantiated claims on food labeling. FDA already has the power to prohibit or punish false and misleading speech that is not within the protection of the First Amendment. False and misleading labeling violates the FD&C Act and subjects a manufacturer to potential criminal penalties for misbranding.²² The Federal Trade Commission similarly prohibits false, misleading, deceptive, and/or unsubstantiated claims in food product

¹⁶ *Ibanez v. Florida Dep't of Business and Professional Regulation*, 512 U.S. 136, 142 (1994) (citing *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 638 (1985)).

¹⁷ *Board of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (U.S. 1989).

¹⁸ *Greater New Orleans Broadcasting Ass'n, Inc. v. United States*, 527 U.S. 173, 174 (U.S. 1999).

¹⁹ *Fox*, 492 U.S. at 480.

²⁰ *Id.* at 480.

²¹ *Id.* at 478.

²² Sections 301(a), 303(a), 403(a) of the FD&C Act, 21 U.S.C. §§ 331(a), 333(a), 343(a).

advertising.²³ Thus, FDA's restrictive approach to disease claims is not needed to prevent the use of false or misleading claims.

In *Pearson*, FDA argued that FDA approval (pursuant to the significant scientific agreement standard) was the dividing line between inherently misleading (and, by implication, not constitutionally protected) commercial speech and constitutionally protected speech. The court flatly rejected that position, describing it "almost frivolous."²⁴ Thus, under *Central Hudson*, FDA does not have the authority categorically to ban claims that do not meet the significant scientific agreement standard. Further, FDA has a heavy burden to justify a restriction on such claims. It is beyond dispute that absolute suppression does not satisfy that burden when there are less restrictive means available.

The Supreme Court has repeatedly and emphatically rejected what it calls the "paternalistic" suppression of commercial speech. As the Court has explained, "*The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good. That teaching applies equally to state attempts to deprive consumers of accurate information about their chosen products.*"²⁵ To the contrary, the Supreme Court clearly directs the government to give consumers information on which they can base their own decisions: "*information is not in itself harmful . . . people will perceive their own best interest if only they are well enough informed . . . the best means to that end is to open the channels of*

²³ See generally Federal Trade Commission, *Enforcement Policy Statement on Food Advertising*, Part II (May 1994) (available at <http://www.ftc.gov/bcp/policystmt/ad-food.htm>).

²⁴ *Pearson*, 164 F.3d at 655.

²⁵ *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) (emphasis added).

communication rather than to close them."²⁶ The Court made the same point in *Central Hudson*: "Even when advertising communicates only an incomplete version of the relevant facts, *the First Amendment presumes that some accurate information is better than no information at all.*"²⁷

C. FDA's Restriction of Disease Claims Violates the First Amendment

FDA has tried to avoid the reach of the First Amendment for decades. It has argued that it is constitutionally permitted to restrict FDA-regulated speech more heavily than other commercial speech because it involves an area of comprehensive governmental regulation or because FDA's mission is to protect the public health.²⁸ Three recent cases establish that speech regulated by the FDA is entitled to the same constitutional protection as other commercial speech. More importantly, these cases clearly show that the courts have lost all patience with FDA's notion that it can regulate in defiance of the First Amendment.

In *Pearson*, a unanimous panel of the United States Court of Appeals for the District of Columbia Circuit struck down FDA's rejection of four petitions by dietary supplement manufacturers to use disease claims under the NLEA. FDA had refused to approve the claims because the scientific evidence supporting them was inconclusive and therefore did not satisfy the significant scientific agreement standard.²⁹ FDA argued to the court that health claims lacking "significant scientific agreement" are

²⁶ *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 770 (1976) (emphasis added).

²⁷ *Central Hudson*, 447 U.S. at 562 (emphasis added)

²⁸ See, e.g., 62 Fed. Reg. 64074, 64077 (December 3, 1997); 58 Fed. Reg. 2478, 2524-2525 (January 6, 1993).

²⁹ *Pearson*, 164 F.3d at 653.

inherently misleading and thus entirely outside the protection of the First Amendment.

The Court disposed of this point as follows:

"As best we understand the government, [the government's] first argument runs along the following lines: that health claims lacking 'significant scientific agreement' are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment at the point of sale We think this contention is almost frivolous."³⁰

The Court directed FDA to consider disclaimers or other explanatory information that would cure the potential for each claim to mislead consumers. Similarly, the court in *Western States Medical Center Pharmacy v. Shalala*,³¹ also held that FDA could achieve its public health objectives by a less restrictive approach (again, a disclaimer), when it ruled that the provisions of FDAMA that prohibit a compounding pharmacy from advertising or promoting the compounding of any particular drug violate the First Amendment.³²

In *Washington Legal Foundation v. Friedman (WLF)*, the District Court for the District of Columbia enjoined FDA's policies prohibiting dissemination of off-label use information to physicians on the ground that these policies violated the manufacturers' First Amendment rights.³³ The court wrote:

³⁰ *Pearson*, 164 F.3d at 655.

³¹ 69 F. Supp.2d 1288 (D. Nev. 1999).

³² *Id.* at 1300-1301, 1307-1308 (discussing section 503A(c) of the FD&C Act, 21 U.S.C. § 353a(c)).

³³ 13 F. Supp.2d 51, 72-74 (D.D.C. 1998), *amended*, 36 F. Supp.2d 16 (D.D.C. 1999), *amended*, 36 F. Supp.2d 418 (D.D.C. 1999), *appeal dismissed, injunction vacated in part*, 202 F.3d 331 (D.C. Cir. 2000). FDA appealed only one of the three parts of the District Court injunction. The United States Court of Appeals for the District of Columbia Circuit – the same court that wrote the *Pearson* decision – dismissed the appeal and vacated the part of the District Court's injunction that had been appealed only because FDA reversed its position on appeal and took the new position that the FDAMA and guidance document provisions gave FDA no independent authority to regulate speech thus making the case moot. It is critical to note that the *WLF* court simply assumed without discussion that FDA's regulation of speech, whether pursuant to a statute or guidance document, must comply with the First Amendment.

"In asserting that any and all scientific claims about the safety, effectiveness, contraindications, side effects, and the like regarding prescription drugs are presumptively untruthful or misleading until the FDA has had the opportunity to evaluate them, FDA exaggerates its overall place in the universe."³⁴

These recent cases should have sent a very clear signal to FDA that its entire approach to regulating labeling and other speech is wrongheaded. Yet FDA continues to assume that speech is *prohibited* unless FDA affirmatively allows it. In the words of the *WLF* court, this assumption, which underlies FDA's entire approach to food labeling, is simply "preposterous. The First Amendment is premised upon the idea that people do not need the government's permission to engage in truthful, nonmisleading speech about lawful activity."³⁵ All the cases teach that FDA may not prohibit truthful and nonmisleading speech and cannot restrict such speech unless its restriction is narrowly tailored to accomplish the FDA's objectives and does not burden substantially more speech than is necessary. This presumption of a free flow of truthful and nonmisleading information to consumers must guide FDA's strategy to implement *Pearson*. Unless FDA embraces that principle, it will face constant First Amendment challenges that will further undermine the respect and authority that FDA commands in its role as the protector of public health.

II. FDA's Regulation of Food and Dietary Supplement Labeling Must Comport With the First Amendment

The request of this citizen petition is a simple one. FDA should make a public commitment to embrace the *Pearson* decision fully and to apply it to all food and

³⁴ *Id.* at 67.

³⁵ *Id.* at 85.

other labeling, not just to dietary supplements. This theme underlies all the actions that GMA requests.

A. FDA Must Embrace *Pearson*

FDA's "Strategy for Implementation of *Pearson* Court Decision" has the following components:

"(1) Update the scientific evidence on the four claims at issue in *Pearson*; (2) issue guidance clarifying the 'significant scientific agreement' standard; (3) hold a public meeting to solicit input on changes to FDA's general health claim regulations for dietary supplements that may be warranted in light of the *Pearson* decision; (4) conduct a rulemaking to reconsider the general health claims regulation for dietary supplements in light of the *Pearson* decision; and (5) conduct rulemakings on the four *Pearson* health claims."³⁶

The first and most basic problem is what this strategy does not include. Nowhere does it state that FDA commits to adopt the teachings of the First Amendment and to apply them to its regulation of all food, not just dietary supplements, as well as to all other FDA regulated products. It is past time for FDA to give up its resistance to the First Amendment and to make a commitment to ensuring that consumers receive the truthful and nonmisleading information to which they are constitutionally entitled.

B. FDA Must Apply *Pearson* To Food as Well as to Dietary Supplements

FDA clearly intends to read *Pearson* as narrowly as possible. The only reference to *Pearson* in the Center for Food Safety and Applied Nutrition's 2000 Program Priorities is under the "Dietary Supplements" heading.³⁷ Similarly, CFSAN lists *Pearson* as a component of a *ten-year* "Dietary Supplement Strategy" which states only

³⁶ 64 Fed. Reg. at 67290.

³⁷ CFSAN 2000 Program Priorities, at 1 (available at <http://vm.cfsan.fda.gov/~dms/cfsan200.html>).

"Pearson v. Shalala. Implement court decision as outlined in December 1, 1999, strategy notice."³⁸ This limited reading of *Pearson* is inconsistent with both *Pearson* and the FD&C Act.

First, dietary supplements are "food" under the FD&C Act. Thus, the rules that apply to dietary supplement disease claims also must apply to disease claims for food. The disease claims regulation makes this point expressly when it states: "The requirements of this section apply to foods intended for human consumption that are offered for sale, regardless of whether the foods are in conventional food form or dietary supplement form."³⁹

Second, although the *Pearson* case arose as a challenge to FDA's suppression of dietary supplement disease claims, the statutory and regulatory standards for disease claims -- whether for dietary supplements or for conventional food -- are the same. By enacting the NLEA in 1990, Congress authorized disease claims to be made for conventional food and permitted FDA to extend that principle to dietary supplements. FDA did so by regulation. In fact, FDA recognized that the same standard applies to disease claims for dietary supplement and conventional foods when it issued the significant scientific agreement guidance following the *Pearson* decision. There is nothing to suggest that disease claims for dietary supplements and conventional food are subject to differing degrees of constitutional protection. Yet FDA inexplicably attempts to confine its implementation of *Pearson* to dietary supplement

³⁸ CFSAN Dietary Supplement Strategy (Ten Year Plan), ¶ II.A (available at <http://vm.cfsan.fda.gov/~dms/ds-strat.html>).

³⁹ 21 C.F.R. § 101.14(g). This has been FDA's position since FDA first proposed health claims regulations in 1987, before the enactment of the NLEA. 52 Fed. Reg. at 28846 (August 4, 1987).

disease claims. At a minimum, FDA's implementation strategy must apply the *Pearson* mandate to FDA regulation of food labeling.

C. FDA Cannot Suppress All Claims While It Reevaluates its Policies

FDA's *Pearson* strategy also states that FDA will "*deny, without prejudice,*" any petition for a dietary supplement health claim that does not meet the significant scientific agreement standard "[u]ntil the rulemaking to reconsider the general health claims regulations for dietary supplements is complete."⁴⁰ There are a host of constitutional and other legal problems with this pronouncement.

First, neither section 403(r)(4) of the FD&C Act (as amended by FDAMA),⁴¹ nor the procedure for petitions for disease claims set forth in the regulations,⁴² authorizes a "denial without prejudice" of a disease claim petition.⁴³ Second, this blanket denial without prejudice is simply a euphemism for the complete suspension of FDA review of disease claims -- in other words, stonewalling. There is nothing in the FD&C Act or the regulations that authorizes FDA to suspend the review of disease claims petitions. Third, the blanket denial of all claims pending FDA's reevaluation of its policies indicates that FDA is making no effort whatever to review

⁴⁰ 64 Fed. Reg. at 67290 (emphasis added). In January 2000, CFSAN represented that it would "Meet statutory obligations by responding to health claim petitions within statutory timeframes." *Dietary Supplement Strategy (Ten Year Plan)*, at ¶ II.B. (available at <http://vm.cfsan.fda.gov/~dms/ds-strat.html>). If "denial without prejudice" is FDA's idea of responding within a statutory timeframe, FDA's Dietary Supplement Strategy is more than a little disingenuous.

⁴¹ 21 U.S.C. § 343(r)(4)(A)(i).

⁴² 21 C.F.R. § 101.70.

⁴³ FDA could take the position that its "denial without prejudice" is intended to fit within the language added by FDAMA in 1997 under which a petition is "deemed to be denied" if the Secretary of Health and Human Services has not acted on it within 100 days of filing. 21 U.S.C. § 343(r)(4)(A)(i). As discussed in the text, FDA represents that it is following the procedure it adopted when the NLEA was enacted. At the time, the FD&C Act did not "deem" a disease claim petition denied by FDA inaction within the 100-day period. Thus, "denial without prejudice" might have been intended to mean something other than "deemed to be denied." Were that the case, it would place the proposed disease claims in a procedural limbo. Consequently, a denial -- whether "without prejudice" or "deemed" -- must still be a denial. In this case, it is a denial without any agency consideration of the merits of the petition.

individual disease claims and is simply prohibiting all disease claims of a similar type, without distinguishing between truthful and nonmisleading (and therefore constitutionally protected speech) and speech that has no constitutional protection.⁴⁴ Fourth, there is no deadline for FDA to complete this process. Thus, FDA clearly intends to suppress disease claims that do not meet the significant scientific agreement standard indefinitely. Such indefinite suppression of disease claims pending FDA review already has been rejected as an unconstitutional burden on protected commercial speech. In *Nutritional Health Alliance v. Shalala*, the federal district held that FDA could not suppress dietary supplement disease claims (which were then undergoing FDA review) without a reasonable deadline.⁴⁵ Similarly, the United States Court of Appeals for the Second Circuit stated that "It is established that *'[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.'*"⁴⁶ Not only is the significant scientific agreement standard unconstitutional as applied by FDA, but suppressing disease claims indefinitely while FDA reviews its policies for applying that standard is in itself a constitutional violation.

⁴⁴ This "blanket" approach stands in stark contrast to agency enforcement policy with respect to disease claims, as described in 1990, when FDA was still grappling with the initial disease claims regulations. The Acting Director of the Office of Nutrition and Applied Food Sciences of CFSAN stated, "The basic principle of the policy is a careful scrutiny of health messages on a case-by-case basis." F. Edward Scarbrough, Ph.D., *Under the Reproposed Rule, How Much Scientific Evidence Does a Company Need to Justify its Claim and What are the Food and Drug Administration's Interim Rules*, 45 Food Drug Cosmetic L. J. 647, 649 (1990)(footnote omitted).

⁴⁵ 953 F. Supp. 526, 530 (S.D.N.Y. 1997), *affirmed in part, vacated and dismissed in part (on other grounds)*, 144 F.3d 220 (2d Cir. 1998), *cert denied*, 525 U.S. 1040 (1998).

⁴⁶ *International Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 71 (2nd Cir. 1996) (emphasis added, citations omitted). The court issued a preliminary injunction against enforcement of a Vermont law requiring certain statements on milk labels concerning synthetic hormones used to increase milk production and held that this "compelled speech" was an impermissible burden on First Amendment rights.

Although FDA describes this "denial without prejudice" as an "interim process,"⁴⁷ it is in fact a moratorium rather than a process. FDA has made two points to support this wholesale suppression of disease claims in the face of *Pearson*. First, FDA thought this would be more "efficient":

"The agency believes that the fastest and most efficient way to fully implement the [*Pearson*] decision is to conduct a rulemaking to reconsider the general procedures and standards governing health claims for dietary supplements before ruling on individual petitions that do not meet the current regulatory standard for health claim authorization."⁴⁸

Second, FDA noted that this is the same approach it used when implementing the NLEA's statutory authority for disease claims for conventional food and dietary supplements.⁴⁹ Simply put, it is administratively convenient for FDA to suspend free speech and FDA has gotten away with it before.

FDA must abandon this "interim process" immediately and must evaluate individual disease claims petitions on their merits as they are received. There is no statutory, regulatory, or constitutional basis to suspend indefinitely the review of all disease claims petitions and, in so doing, to suppress truthful and nonmisleading speech in violation of the *Pearson* mandate.

⁴⁷ 64 Fed. Reg. at 67290.

⁴⁸ *Id.*

⁴⁹ *Id.* at 67290-67291. Given that the NLEA was the first express Congressional authorization of disease claims, it is not surprising that there was no constitutional challenge to FDA's interim denial of claims while FDA was implementing a statute designed to facilitate the use of disease claims. But FDA's implementation of the statute failed to achieve that purpose. As noted above, in the ten years since the passage of the NLEA, FDA has issued regulations authorizing only 11 disease claims. In fact, at the time the NLEA was enacted, Congress directed FDA to consider authorizing seven of those claims. Thus, the NLEA experience does not suggest that temporary suppression ultimately will open the channels of communication, as Congress intended. In no way does the NLEA precedent warrant repeating.

D. FDA Must Withdraw the Significant Scientific Agreement Guidance

The *Pearson* case arose because FDA had denied four proposed dietary supplement disease claims on the ground that they did not satisfy the significant scientific agreement standard. That standard appears in both the NLEA (which applies it to food) and in FDA regulations (which apply it to dietary supplements). Neither the statute nor the regulations define the term "significant scientific agreement." Nevertheless, FDA applied that undefined standard and denied outright claims that did not meet the standard.

In reviewing FDA's application of the significant scientific agreement standard, the *Pearson* court did a surprising thing: it began its analysis by considering the constitutionality of FDA's actions. Ordinarily, a reviewing court would not reach a constitutional question unless it were absolutely necessary to do so. The *Pearson* court acknowledged that it was reversing the normal analysis because of the importance of the constitutional question at issue:

"Normally we would discuss the non-constitutional argument first We invert the normal order here to discuss first appellants' most powerful constitutional claim, that the government has violated the First Amendment by declining to employ a less draconian method -- the use of disclaimers -- to serve the government's interest, because the requested remedy stands apart from appellants' request under the [Administrative Procedure Act] that the FDA flesh out its standards. That is to say, *even if 'significant scientific agreement' were given a more concrete meaning, appellants might be entitled to make health claims that do not meet that standard -- with proper disclaimers.*"⁵⁰

It is a fundamental rule of constitutional law and of statutory interpretation that a statute must be interpreted in a manner that is consistent with the constitution, if

⁵⁰ *Pearson*, 164 F.3d at 654 (emphasis added)

at all possible. FDA's interpretation of the statutory standard is that claims not supported by significant scientific agreement are inherently misleading. *Pearson* characterized this interpretation as "almost frivolous."⁵¹

Because they are not, by definition, misleading, disease claims lacking significant scientific agreement do not inherently fall outside the zone of protected commercial speech. *Pearson* teaches that, when interpreted by FDA as a categorical bar to disease claims that do not yet have widespread or uniform support in the scientific community, the statutory standard is unconstitutional. Thus, FDA's task is to interpret the statutory standard in a manner that is consistent with the First Amendment -- in other words, in such a way as not to place impermissible restrictions on truthful and nonmisleading speech.

Following the direction of the *Pearson* court, FDA did issue a guidance explaining the significant scientific agreement standard. The draft guidance fails to cure the constitutional problems that were identified by *Pearson*.

First, FDA continues to interpret the significant scientific agreement standard to preclude disease claims unless there is significant scientific agreement about the diet/disease relationship that is the subject of the claim rather than significant scientific agreement about the claim itself, which is what the statute explicitly requires. FDA's interpretation is more restrictive than the statutory language, which states:

"The Secretary *shall* promulgate regulations authorizing claims of the type described in subparagraph (1) (B) [health claims] only if the Secretary determines, based on the totality of publicly available scientific evidence. . . .that there is significant scientific agreement, among experts qualified by

⁵¹ *Id.* at 655.

scientific training and experience to evaluate such claims, that *the claim* is supported by such evidence."⁵²

The statute further provides that FDA must authorize a claim that "is an accurate representation" of the diet/disease relationship and which "enables the public to comprehend . . . the relative significance of such information in the context of a total daily diet."⁵³

There is a clear difference between (a) a claim that describes the diet/disease relationship as established and (b) a claim that described the diet/disease relationship in terms of preliminary data or emerging science or consists of a factual statement about the current status of scientific research or reports on the findings and recommendations of authoritative nongovernmental scientific bodies. By requiring that the diet/disease relationship itself be supported by significant scientific agreement, FDA imposes a greater restriction on speech than Congress contemplated or than the constitution permits. Both Congress and *Pearson* intended that a claim should be permitted if it is truthful, accurate, and nonmisleading.

The draft significant scientific agreement guidance clarifies FDA's interpretation of the significant scientific agreement standard. In so doing, it confirms that FDA's interpretation is unconstitutional. The guidance states:

"The significant scientific agreement standard is intended to be a strong standard that provides a high level of confidence in the validity of a substance/disease relationship. Significant scientific agreement means that the validity of the relationship is not likely to be reversed by new and evolving

⁵² Section 403(r)(3)(B)(i) of the FD&C Act, 21 U.S.C. § 343(r)(3)(B)(i) (emphasis added).

⁵³ Section 403(r)(3)(B)(iii) of the FD&C Act, 21 U.S.C. § 343(r)(3)(B)(iii).

science, although the exact nature of the relationship may need to be refined."⁵⁴

The guidance also made clear that "emerging science" cannot constitute "significant scientific agreement":

"In the process of scientific discovery, significant scientific agreement occurs well after the stage of emerging science, where data and information permit an inference, but before the point of unanimous agreement within the relevant scientific community that the inference is valid."

* * *

"Significant scientific agreement cannot be reached without a strong, relevant, and consistent body of evidence on which experts in the field may base a conclusion that a substance/disease relationship exists. There is considerable potential for incorrect conclusions if only preliminary evidence (emerging science) is available for review."⁵⁵

In general, the guidance shows that the significant scientific agreement standard remains a difficult one to meet. This makes it more likely that many claims will fall below that threshold and therefore will be disallowed by FDA although they would be permitted by the *Pearson* court with appropriate disclaimers or other explanatory information. In 1990, an FDA official criticized a similarly restrictive approach embodied in a bill then being debated by Congress on the ground that it would have permitted disease claims only for a miniscule universe of "perfectly balanced" foods. The Acting Director of the Office of Nutrition and Applied Food Sciences of CFSAN stated: "It is being overly paternalistic to completely forbid health discussions, except on only those few perfect foods."⁵⁶ FDA's unduly restrictive interpretation of the significant scientific

⁵⁴ FDA Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements; Availability, at ii-iii (December 20, 1999).

⁵⁵ *Id.* at 16-17.

⁵⁶ Scarbrough, note 44 supra, 45 Food Drug Cosmetic L. J., at 653.

agreement standard achieves a similarly paternalistic result that flies in the face of *Pearson* and other commercial speech cases.

FDA must revise the significant scientific agreement guidance to indicate that (a) FDA's focus is on whether there is significant scientific agreement about the claim rather than about the diet/disease relationship that is the subject of the claim and (b) FDA will consider disclaimers or other explanatory language in determining whether the proposed claim is truthful and nonmisleading and accurately reflects the level of scientific support for the diet/disease relationship that is the subject of the claim. To do otherwise is to continue to apply a standard that *Pearson* expressly held unconstitutional.

E. FDA Must Withdraw the Authoritative Statement Guidance

FDA also must withdraw its guidance concerning disease claims based on authoritative statements to the extent that that guidance incorporates FDA's unconstitutional interpretation of significant scientific agreement.

In 1997, FDAMA enlarged the scope of disease claims for conventional food by permitting such claims based on an authoritative statement of a government scientific body or the National Academy of Sciences (NAS) with prior notice to (but not approval by) FDA.⁵⁷ In so doing, Congress reacted strongly against FDA's restrictive approach to disease claims under the NLEA. In describing an authoritative statement, FDAMA did not adopt the NLEA significant scientific agreement standard.⁵⁸

⁵⁷ Section 403(r)(3)(C) of the FD&C Act, 21 U.S.C. § 343(r)(3)(C). Although FDAMA permits nutrient content claims based on authoritative statements for both conventional food and dietary supplements, its provisions permitting disease claims apply only to conventional food. Under FDAMA, the disease prevention claim need not be authorized by regulation, but the manufacturer must give FDA 120 days' notice before marketing a food with the claim. *Id.*

⁵⁸ *Id.* FDA has stated that other federal agencies may qualify as sources of authoritative statements, specifically "the CDC, the NIH, and the Surgeon General within the Department of Health and (continued...)"

FDA dramatically undercut the expansive force of FDAMA by narrowly interpreting "authoritative statement" in a guidance document. FDA specifically said that it would apply the NLEA significant scientific agreement standard to disease claims under FDAMA.⁵⁹ FDA stated that, when evaluating a proposed disease claim based on an authoritative statement, "FDA intends to determine whether the standard of significant scientific agreement is met by a health claim based on an authoritative statement."⁶⁰

FDA's authoritative statement guidance is inconsistent with FDAMA (which does not adopt the significant scientific agreement standard) and with *Pearson*, which has held FDA's interpretation of significant scientific agreement inconsistent with the First Amendment. Given that FDA applies the same standard to disease claims made under the authoritative statement provision of FDAMA, its authoritative statement guidance also is unconstitutional and should be withdrawn.

F. FDA Must Amend the Disease Claims Regulations to Conform to *Pearson*

Pearson makes it abundantly clear that GMA's members have a constitutional right to make truthful and nonmisleading claims concerning the relationship between food and disease even if there is not significant scientific agreement about the diet/disease relationship that is the subject of the claim. *Pearson* also indicates that FDA's disease claims regulations violate the First Amendment to the

Human Services; and the Food and Nutrition Service, the Food Safety and Inspection Service, and the Agricultural Research Service within the Department of Agriculture." Food and Drug Administration, Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body (1998) ("FDA Authoritative Statement Guidance") (available at <http://www.cfsan.fda.gov/~dms/guidance.html>).

⁵⁹ FDA Authoritative Statement Guidance, at 2.

⁶⁰ *Id.*

extent that the regulations defining disease claims (a) prohibit claims on the grounds that the underlying diet/disease relationship has not been proved by significant scientific agreement and (b) do not require FDA to consider disclaimers or other explanatory information in determining whether the claim is truthful and nonsmisleading. To address these constitutional violations, FDA should make the following changes to the disease claims regulations.

The regulations define "health claim" as:

"any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including 'third party' references, written statements (e.g., a brand name including a term such as 'heart'), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition."⁶¹

This definition should be revised in the following manner. First, it must require that the claim is truthful and not misleading or that it does not violate section 403(a) of the FD&C Act.⁶² Second, the definition must include claims that accurately describe the level of scientific support for the diet/disease relationship that is the subject of the claim.

FDA also must revise the portion of the regulation describing the "validity requirement" for a disease claim. The current provision states:

"FDA will promulgate regulations authorizing a health claim only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-

⁶¹ 21 C.F.R. § 101.14(a)(1).

⁶² In proposing health claims regulations in 1987, FDA noted that the requirement that health claims be truthful and nonmisleading is "the fundamental principle underlying FDA's evaluation of health messages on food labels." 52. Fed. Reg. at 28846.

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."⁶³

To comply with *Pearson*, this provision must be revised to indicate that FDA will promulgate a regulation authorizing a disease claim when the claim is truthful and nonmisleading and *either* (a) the diet/disease relationship that is the subject of the claim is supported by significant scientific evidence or (b) the claim accurately describes the level of scientific support for the diet/disease relationship that is the subject of the claim. The section also must state that FDA will consider whether disclaimers or other explanatory language accurately describe the level of scientific support for the proposed claim.

These changes in the substantive standard also must be reflected in the review procedure described in 21 C.F.R. § 101.70, which sets out the disease claim petition process. The current regulation requires that the disease claim petition include evidence of significant scientific agreement and provides that a claim that does not satisfy that standard will be rejected.⁶⁴ GMA believes that virtually all existing provisions of section 101.70 are suspect under *Pearson*. To comply with *Pearson*, that section must be revised to eliminate requirements that do not pertain directly to the substantiation of the proposed claim.

This change in the process and standard employed in evaluating disease claims under section 101.70 also will compel FDA to reevaluate claims that were

⁶³ 21 C.F.R. § 101.14(c).

⁶⁴ 21 C.F.R. §§ 101.70(f), 101.70(j)(2).

rejected under that pre-*Pearson* approach. Thus, FDA must revoke immediately the regulations that categorically prohibit claims (21 C.F.R. § 101.71).⁶⁵

III. Conclusion

By failing to incorporate the *Pearson* mandate into its regulatory approach, FDA threatens the market with chaos and threatens to undermine its own guardianship of public health. FDA now prohibits -- and intends to prohibit for some undefined period -- truthful and nonmisleading disease claims. These claims would provide valuable information to the public. *Pearson* and other precedents indicate that further attempts by FDA to prohibit such claims (including but not limited to the current *Pearson* implementation strategy) would not survive a First Amendment challenge. Thus, manufacturers could bypass the FDA petition process on the assumption that FDA either would not challenge the claim or that FDA's challenge might well fail, as it did in *Pearson*. Therefore, unless FDA brings its regulatory policy in line with *Pearson*, the market will be flooded with unapproved claims and FDA in effect will forfeit its role in protecting public health through its oversight of food labeling.⁶⁶

⁶⁵ The prohibited claims pertain to:

- (a) Dietary fiber and cancer.
- (b) Dietary fiber and cardiovascular disease.
- (c) Antioxidant vitamins and cancer.
- (d) Zinc and immune function in the elderly.
- (e) Omega-3 fatty acids and coronary heart disease.

21 C.F.R. § 101.71.

⁶⁶ This is precisely the situation that confronts FDA in the aftermath of the *WLF* decisions. Three opinions held that FDA's restrictive policies concerning the dissemination of off-label use information to physicians violated the First Amendment. On appeal, FDA argued for the first time that the challenged provisions did not provide it with independent authority to regulate speech. Consequently, the appellate court vacated portions of the existing injunction. Since that time, there has been a raging public debate about what the appellate court's decision means. It is likely that many drug and device manufacturers will follow the constitutional limitations set forth in the district court's opinions rather than the FDA regulations and guidances that the court held to violate the First Amendment. This clearly undermines FDA's (continued...)

In light of the potential consequences of its current actions, FDA must immediately withdraw and revise its strategy to implement *Pearson* and must apply the principles set forth in *Pearson* to its regulation of food labeling.

C. Environmental Impact

The actions requested herein are subject to categorical exclusion under 21 C.F.R. §§ 25.30 and 25.32.

D. Economic Impact

GMA will submit an economic impact statement at the request of the Commissioner.

E. Certification

The undersigned certifies that, to the best of his knowledge and belief, this petition includes all information and views on which the petition relies, and there are no data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,



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authority and shows, in yet another context, the urgent need for FDA to issue regulations and guidances that are consistent with the First Amendment.