

# Devaluing Truth: Unverified Health Claims in the Aftermath of *Pearson v. Shalala*

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## I. INTRODUCTION

For more than twenty years, the regulation of dietary supplements has been the third rail of food and drug policy.<sup>1</sup> Efforts to regulate the industry generate such fierce political opposition that the industry receives delicate treatment from both Congress and the Food and Drug Administration (FDA).<sup>2</sup> As a result, unsubstantiated health claims have proliferated in the marketing of dietary supplements. Dietary supplement marketers claim that supplements prevent cancer, lower the risk of heart disease, treat anxiety and depression, boost immune system function, and even enhance sexual performance. Most of these claims are made in the absence of significant scientific proof. In marked contrast to drugs and food additives, which are subject to rigorous FDA review prior to marketing, dietary supplements ordinarily are marketed without any prior FDA screening. FDA occasionally brought enforcement actions to enjoin egregiously false health claims, arguing that a disease prevention, mitigation, or cure claim was an unapproved, and therefore forbidden “drug” claim. The agency’s regulatory power with respect to dietary supplements, however, was uncertain. To make matters worse, agency enforcement actions invariably generated a political backlash, which in turn made the agency more cautious in trying to rein in the industry.<sup>3</sup>

In part to stem the rising tide of unsubstantiated health claims, Congress enacted the Nutritional Labeling and Education Act (NLEA)<sup>4</sup> in 1990. To ensure that health claims regarding dietary supplements are reliable, the NLEA directs FDA to screen health claims to ensure that they are based on sound science. To implement the NLEA, marketers of dietary supplements must show that there is “significant scientific agreement” that a health claim is, in fact, scientifically valid to obtain FDA clearance to make the claim.<sup>5</sup> The NLEA also confirms FDA’s authority to bring enforcement actions when supplements are marketed with claims unapproved by FDA.<sup>6</sup>

The marketing restrictions in the NLEA did not sit well with the dietary supplement industry, which responded by filing a number of lawsuits on First Amendment

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<sup>1</sup> As defined in the FDCA, a dietary supplement is a “product (other than tobacco) intended to supplement the diet that bears or contains . . . a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any [of the above ingredients].” 21 U.S.C. § 321(ff)(1) (1994).

<sup>2</sup> See, e.g., Mark A. Kassel, *From A History of Near Misses: The Future of Dietary Supplement Regulation*, 49 FOOD & DRUG L.J. 237, 254-61 (1994) (chronicling the history of congressional and FDA efforts to regulate dietary supplements); see also Note, *Where There’s Smoke There’s Fire: The Dangers of the Unregulated Dietary Supplement Industry*, 42 N.Y.L. SCH. L. REV. 261, 268-71 (1998).

<sup>3</sup> See Kassel, *supra* note 2, at 254-61.

<sup>4</sup> Pub. L. No. 101-535, 104 Stat. 1213 (codified at 49 U.S.C. § 521 (1994); 49 U.S.C. App. §§ 1814, 2501 note, 2801 notes, 2802-12 (1994)).

<sup>5</sup> 21 C.F.R. § 101.14 (1996).

<sup>6</sup> 21 U.S.C. § 343(r)(1)(B).

grounds,<sup>7</sup> challenging the constitutionality of FDA implementing regulations. The industry claimed that FDA's regime infringed the rights of the sellers of dietary supplements to make health claims that are not misleading or false, although the claims cannot meet the significant scientific agreement standard.<sup>8</sup> The industry lost the first round of the litigation.<sup>9</sup>

On January 15, 1999, the tide turned. The U.S. Court of Appeals for the District of Columbia held that FDA's regulatory scheme for approving health claims for dietary supplements was unconstitutional on First Amendment grounds.<sup>10</sup> In its ruling, the court disagreed with FDA that claims lacking significant scientific agreement are "inherently misleading" and may be forbidden categorically under the First Amendment.<sup>11</sup> Although the court recognized that "some" health claims will mislead consumers, it reasoned that FDA's regulations nonetheless are impermissibly restrictive because they do not allow manufacturers to make health claims accompanied by clarifying disclaimers where significant scientific agreement is lacking.<sup>12</sup> The court suggested that disclaimers referring to the absence of FDA approval, or the "inconclusive" nature of the scientific evidence, might be sufficient to safeguard against consumer deception.<sup>13</sup> Thus, the panel held that FDA either must "demonstrate with empirical evidence" that a disclaimer "would bewilder consumers and fail to correct for deceptiveness," or permit the claim to go forward, accompanied by a reasonable disclaimer.<sup>14</sup>

FDA petitioned the court for rehearing *en banc*, but in an order issued April 2, 1999, the petition was denied.<sup>15</sup> FDA did not seek review by the Supreme Court, and currently is considering approaches to implement the ruling of the D.C. Circuit.<sup>16</sup>

This article explains why the reasoning of *Pearson* misconceives basic First Amendment commercial speech principles and places the public at undue risk. Although the Supreme Court, on occasion, has approved the use of government-required disclaimers to guard against potentially confusing or deceptive speech,<sup>17</sup> the Court never has directed a governmental agency to permit potentially deceptive speech so long as it is accompanied by a disclaimer. Nor do any of the precedents cited in *Pearson* support its ruling with respect to marketing claims about products that can, and too often do, pose real health threats to consumers. The Supreme Court has not suggested that where the public's health and safety are concerned, the government may not err on the side of caution. The tragic result of the *Pearson* court's misstep is that consumers again will be exploited by health claims riddled with half-truths and distortions and duped into taking products that may jeopardize their health. Nothing in the First Amendment compels that result.

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<sup>7</sup> *Nutritional Health Alliance v. Shalala*, 144 F.3d 220 (2d Cir. 1998), *cert. denied*, 119 S. Ct. 589 (1998); *National Council for Improved Health v. Shalala*, 122 F.3d 878 (10th Cir. 1997); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

<sup>8</sup> *Id.*

<sup>9</sup> *Nutritional Health*, 144 F.3d 220; *National Council*, 122 F.3d 878.

<sup>10</sup> *Pearson*, 164 F.3d 650.

<sup>11</sup> *Id.* at 655.

<sup>12</sup> *Id.* at 657.

<sup>13</sup> *Id.* at 659.

<sup>14</sup> *Id.* at 659-60.

<sup>15</sup> *Pearson v. Shalala*, 172 F.3d 72 (D.C. Cir. 1999).

<sup>16</sup> See Jenna Greene, *FDA Waging War of Words: Definition of "Disease" Sparks Furor*, XXII (10) LEGAL TIMES WASH. I (July 19, 1999).

<sup>17</sup> See, e.g., *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985).

## II. THE NLEA

Congress passed the NLEA to prohibit “unfounded,” “inaccurate,” or “insupportable health claims” that have “great potential for defrauding consumers” and, at the same time, to “permit health claims based on scientifically valid information.”<sup>18</sup> Congress enacted the NLEA in response to a long history of abusive marketing practices by food and dietary supplement manufacturers. Prior to the NLEA’s passage, the multi-billion-dollar-a-year food and dietary supplement marketplace was rife with misleading and unsubstantiated health claims that jeopardized consumers’ health and well-being. For example, marketing claims of products ranging from “Stone Free Kidney and Gall Formula” to “Fat Burners,” suggested treatments of afflictions ranging from kidney stones to obesity. Some of these health claims lacked even minimal scientific support. Congress recognized that consumers are ill-equipped to evaluate the accuracy of health claims on their own, and therefore often fall prey to unprincipled sales tactics.<sup>19</sup>

Enacted as an amendment to the Federal Food, Drug, and Cosmetic Act (FDCA),<sup>20</sup> the NLEA authorizes the dissemination of health claims that characterize the “relationship of any nutrient . . . to a disease or a health-related condition,”<sup>21</sup> on food labels, but only where FDA has found that such claims are reliable. The NLEA thus establishes a system for permitting claims that are not misleading, while clarifying and strengthening the prohibition against making unapproved claims.<sup>22</sup> To distinguish between reliable and dubious claims, Congress directed FDA to promulgate regulations for evaluating health claims for both foods and dietary supplements. For conventional food products, Congress required that FDA determine whether, based on the totality of the available scientific evidence, there is “significant scientific agreement” among experts qualified by scientific training and experience to evaluate such claims.<sup>23</sup> For dietary supplement claims, Congress did not prescribe a substantive standard, but rather delegated to FDA the task of establishing a standard “respecting the validity of such claim[s].”<sup>24</sup> Nonetheless, the legislative history of the NLEA makes

<sup>18</sup> 136 CONG. REC. H12953 (daily ed. Oct. 26, 1990) (remarks of Rep. Waxman); *see also* H.R. REP. NO. 538, 101st Cong., 2d Sess. 7, *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337.

<sup>19</sup> It can be argued that the NLEA actually weakened FDA’s authority over dietary supplements. Prior to the passage of the NLEA, a food or dietary supplement that carried a health claim was subject to regulation as a drug under the Federal Food, Drug, and Cosmetic Act (FDCA). A health claim is, in fact, a disease prevention claim, and all products claiming to prevent disease are classified as “drugs” under the FDCA. *See* 21 U.S.C. § 321(g) (1972 & Supp. 1997). Such claims were forbidden unless the “drug” had been tested extensively by the manufacturer (*see* 21 U.S.C. § 355) and either approved by FDA or generally recognized as safe and effective. Accordingly, before the NLEA, a food or dietary supplement making an unsubstantiated health claim would be subject to an FDA seizure action, because it would be both “misbranded” under 21 U.S.C. §§ 331(a), 352(a), and an unapproved “new drug” under 21 U.S.C. § 355(a). *See Kellogg v. Mattox*, 763 F. Supp. 1369 (N.D. Tex. 1991), *aff’d without opinion sub nom.*, *Kellogg v. Morales*, 940 F.2d 1530 (5th Cir. 1991) (upholding the complete prohibition of health claims against First Amendment attack). *See Kassel, supra* note 2, at 249-53.

<sup>20</sup> Pub. L. No. 75-717, 52 Stat. 1040 (1938) (as amended 21 U.S.C. §§ 301 et seq.).

<sup>21</sup> 21 U.S.C. § 343(r)(1)(B).

<sup>22</sup> The NLEA applies to health claims made on actual product labels and on “labeling,” i.e., other written materials distributed by manufacturers or retailers in conjunction with the promotion and sale of dietary supplements. This requirement is consistent with a long-standing provision in the FDCA that defines “labeling” as “all labels and *other written, printed, or graphic matter* (1) upon any article or its containers or wrappers, or (2) *accompanying such article*.” 21 U.S.C. § 321(m) (emphasis added). FDA’s regulations under § 321(m) do not apply to the dissemination of scientific or other literature in non-commercial fora. Moreover, Congress amended the NLEA in 1994 to permit dietary supplement manufacturers and retailers to distribute such literature in limited situations, 21 U.S.C. § 343-2(a).

<sup>23</sup> *Id.* § 343(r)(3)(B).

<sup>24</sup> *Id.* § 343(r)(5)(D).

evident that Congress intended the standard for dietary supplements to be as strong as or stronger than the standard for foods.<sup>25</sup>

Following an extensive notice and comment rulemaking proceeding, FDA determined that the same standards and procedures should be applied to dietary supplements as Congress established for conventional foods.<sup>26</sup> Thus, FDA will permit a health claim for a dietary supplement only where "significant scientific agreement" supports the claim.<sup>27</sup> In the absence of such agreement, the claim is deemed unreliable. Any product bearing an unapproved claim is misbranded and subject to FDA regulatory action, including seizure.<sup>28</sup>

Under FDA regulations implementing these NLEA requirements, members of the food or dietary supplement industry may petition FDA to permit a health claim.<sup>29</sup> These claims may include "third party references" to the dietary recommendations of government agencies, such as the National Cancer Institute, and private organizations, such as the American Heart Association.<sup>30</sup> Within 100 days following the receipt of the petition, FDA must notify the petitioner whether the petition will be "filed" for further review or denied because it fails to meet the regulatory standards.<sup>31</sup> If the petition is filed, within ninety days FDA must publish a proposed regulation either authorizing the health claim or denying the petition.<sup>32</sup> Within 270 days after the publication of a proposed rule, FDA must publish a final regulation either authorizing the claim or explaining why the claim will not be authorized.<sup>33</sup> Using these procedures, FDA has approved ten health claims thus far.<sup>34</sup> Two of these claims involve calcium and folate, nutrients available in both food and supplement form. As a result, they can be used on dietary supplement labels.

In 1994, the dietary supplement industry urged Congress to overrule FDA's implementing regulations by amending the NLEA. In response, Congress enacted the Dietary Supplement Health and Education Act (DSHEA)<sup>35</sup> which modifies the regulation of dietary supplement safety and labeling. DSHEA also gives the industry one of the prizes it had long sought; FDA no longer may assert "drug" authority over supplements.<sup>36</sup> To the industry's disappointment, however, the legislation left FDA's health claim regulations intact.<sup>37</sup> DSHEA also established the Commission on Dietary

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<sup>25</sup> See 136 CONG. REC. H12953 (daily ed. Oct. 26, 1990) (statements of the House Floor Managers of both parties that dietary supplements "covered by this provision should be subject to at least as strong a standard as is applicable to other foods"); see also 136 CONG. REC. S16608 (daily ed. Oct. 24, 1990) (statement of Sen. Metzenbaum, sponsor of the bill).

<sup>26</sup> 21 C.F.R. §§ 101.14, 101.70.

<sup>27</sup> Although there are semantic differences, the "significant scientific agreement" standard is not significantly different than the standard that applies to new drugs, and the health claims that can be made for drugs. The FDCA does not define what constitutes general recognition of a drug's safety and effectiveness under § 201(p)(1). Based on the structure and purpose of the statutory scheme, however, the Supreme Court in *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 629-34 (1973), interpreted § 201(p)(1) to require an "expert consensus" on safety and effectiveness founded upon "substantial evidence" as defined in FDCA § 505(d), 21 U.S.C. § 355(d). Health claims are forbidden for unapproved new drugs, as well as for unapproved indications for approved drugs.

<sup>28</sup> 21 U.S.C. § 343(r)(1)(B).

<sup>29</sup> 21 C.F.R. § 101.70.

<sup>30</sup> *Id.* § 101.14(a)(1).

<sup>31</sup> *Id.* § 101.70(j)(2).

<sup>32</sup> *Id.* § 101.70(j)(3).

<sup>33</sup> *Id.* § 101.70(j)(4).

<sup>34</sup> See *id.* §§ 101.72-101.81.

<sup>35</sup> Pub. L. No. 103-417, 108 Stat. 4325 (codified at 21 U.S.C. § 301 note).

<sup>36</sup> 21 U.S.C. § 201(ff)(3)(B).

<sup>37</sup> See *id.*

Supplement Labels to study how health claims should be regulated and required FDA to conduct a rulemaking in response to the Commission's findings.<sup>38</sup>

The Commission's Report only fortified FDA's position. The Report notes that "Commission members agree that a high standard of evidence is appropriate for health claims," and that this standard "serves the public interest."<sup>39</sup> The Commission based its conclusion on the difficulties inherent in scientifically proving any link between dietary supplements and health benefits:

Many of the diet-disease associations of potential relevance for health claims relate to chronic disease processes for which diet is one of many possible causes and which, for both ethical and practical reasons, are often not subject to direct experimentation. Thus, different types of evidence are usually considered in attempting to establish that a causal association actually exists and that dietary change would have preventive value.<sup>40</sup>

The Report goes on to say that a "high standard is appropriate for health claims" because conclusions about safety are, "by definition, a matter of judgment, and must rest on a body of evidence considered adequate to support such agreement (i.e., more than preliminary studies or a few emerging studies, even if the evidence seems convincing)."<sup>41</sup>

### III. THE PEARSON LITIGATION — THE DISTRICT COURT'S RULING

Durk Pearson and Sandy Shaw manufacture and distribute dietary supplements. Along with two non-profit lobbying organizations, the American Preventative Medical Association and Citizens for Health, they brought what is known as the *Pearson* case.<sup>42</sup> Plaintiffs contended that FDA's regulations implementing the NLEA, and certain decisions FDA made regarding specific health claims, violated their First Amendment rights.<sup>43</sup> The district court rejected plaintiffs' First Amendment claims. The court initially addressed plaintiffs' claim that the NLEA and its implementing regulations violate the First Amendment because they impermissibly restrict the dissemination of truthful and non-misleading information about dietary supplements.<sup>44</sup> This argument, the court noted, was wrong because the claims, in fact, were not truthful. Rather, as the court put it, "failure to meet the [significant scientific agreement] standard makes the claims misleading because they have not been scientifically validated."<sup>45</sup> Health

<sup>38</sup> Under DSHEA, dietary supplement manufacturers may make claims, without FDA approval, concerning how a supplement affects the structure or function of the human body (e.g., calcium helps build strong bones). 21 U.S.C. § 343(r)(6). Unlike health claims (e.g., calcium may prevent osteoporosis), structure and function claims do not promise to prevent, mitigate, or cure disease; indeed, a structure or function claim may not even mention a disease. See 63 Fed. Reg. 23,624 (Apr. 29, 1998).

<sup>39</sup> Commission on Dietary Supplement Labels, *Report to the President, the Congress and the Secretary of the Department of Health and Human Services* 31, 35 (Nov. 1997) (visited Nov. 12, 1999) <web.health.gov/dietsupp/>.

<sup>40</sup> *Id.*

<sup>41</sup> *Id.* These recommendations were echoed by the Congressional Commission on Risk Assessment and Risk Management, in its examination of the standards imposed by the NLEA and FDA's implementing rules. The Commission informed Congress that "FDA's authority to require scientific evidence to justify manufacturers' claims of safety and health benefits from nutritional supplements should be reaffirmed and strengthened." Presidential/Congressional Commission on Risk Assessment and Management, *Risk Assessment and Risk Management in Regulatory Decision-Making*, 139 (Washington, D.C. 1997).

<sup>42</sup> *Pearson v. Shalala*, 14 F. Supp. 2d 10 (D.D.C. 1998).

<sup>43</sup> *Id.* at 17.

<sup>44</sup> *Id.* at 18.

<sup>45</sup> *Id.*

claims inherently are misleading “when the public lacks the necessary knowledge to evaluate” them or when the claims are “not subject to reliable verification through a consumer’s personal experience.”<sup>46</sup> Because unverified health claims are misleading, they are not protected by the First Amendment.<sup>47</sup>

The district court also addressed whether the First Amendment would be violated where a dietary supplement manufacturer was “able to propose health claims that were not misleading, even though they could not meet the ‘significant scientific agreement’ standard.”<sup>48</sup> Although the court thought that this scenario was unlikely,<sup>49</sup> it held that, even in that case, application of the significant scientific agreement standard would not transgress the First Amendment.<sup>50</sup> According to the court, the government has a substantial interest in “ensuring that labels on dietary supplements are truthful and non-misleading to protect the health and safety of consumers.”<sup>51</sup> The court also reasoned that the regulations directly advance the government’s interest because “[c]onsumers cannot be expected to do research and analyze preliminary and often conflicting scientific studies to determine whether a health claim is valid.”<sup>52</sup> That task, the court ruled, Congress properly assigned to FDA, and “the substance of the ‘significant scientific agreement’ standard is designed to accomplish precisely that goal.”<sup>53</sup> The court found that FDA’s regulation “is no broader than necessary to protect the public health and prevent consumer fraud.”<sup>54</sup> After all, the court pointed out, FDA’s regulations apply only to health claims made on labeling. They do not cover, for example, reports of scientific research, journal articles, newspapers, magazines, and any other publications that are disseminated to the public apart from the selling efforts of a dietary supplement manufacturer aimed directly at consumers.<sup>55</sup> For these reasons, the court held that the regulations are “sufficiently narrow,” and entered summary judgment in FDA’s favor.<sup>56</sup>

#### IV. THE COURT OF APPEALS’ RULING

As noted earlier, the court of appeals’ decision in *Pearson* reversed the judgment entered by the district court. The difference in outcomes stems directly from the different ways the courts viewed the case. As the district court saw it, the pivotal issue was whether the strong interest consumers have in obtaining truthful and reliable information on health care products outweighs the dietary supplement industry’s interest in using unverified health claims to tout its products. Applying the balancing test prescribed by the Supreme Court for commercial speech cases, the district court readily concluded that the public’s interest in not being exposed to potentially misleading information about health care products overshadows the industry’s right to use unproven information in its sales efforts.

What led the court of appeals to the opposite conclusion? A close reading of *Pearson* demonstrates that the outcome in the court of appeals was dictated by three

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<sup>46</sup> *Id.*

<sup>47</sup> *Id.* at 19.

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> *Id.* at 20-21.

<sup>54</sup> *Id.* at 20.

<sup>55</sup> *Id.*

<sup>56</sup> *Id.* at 21.

factors. First, the court saw *Pearson* mainly as a First Amendment case, rather than a food and drug case implicating serious public health issues. Moreover, the court read the commercial speech doctrine as requiring government to respond to potential marketplace fraud with almost surgical precision — excising only speech that is demonstrably false or misleading.<sup>57</sup> Second, the court rejected the judgment made by Congress in the NLEA and carried forward by FDA that unverified health claims pose a serious public health risk and inherently are misleading.<sup>58</sup> Finally, the court mistakenly concluded that disclaimers and warnings that generally are required to provide the consumer with factual, objectively verifiable information, will solve the problem of consumer deception here.<sup>59</sup> The problem posed by dietary supplements, however, is the absence of sufficiently reliable data to form a judgment about the product's safety and efficacy. Disclaimers, no matter how carefully worded, cannot fill that void. Thus, the disclaimers envisioned by the court only will heighten the consumers' dilemma because they say nothing to help consumers evaluate the product's safety and efficacy. Rather, the disclaimers will tell consumers only that the government does not vouch for the product, that the product may pose some risk, and ultimately, that consumers are on their own in selecting health care products. Therefore, consumers will be left in the predicament Congress enacted the NLEA to avoid — having to make purchasing decisions about products claiming to prevent, cure, or mitigate a disease, without the government's assistance, and on the basis of unreliable information.

#### A. *The Pearson Opinion Misapplied the Commercial Speech Doctrine*

No longer is there any question that commercial speech is entitled to considerable protection under the First Amendment.<sup>60</sup> Since the Court's landmark opinion in *Virginia State Board of Pharmacy*, the question is not whether commercial speech falls within the protective shield of the First Amendment, but rather the extent to which government can place limits on commercial speech in the service of important governmental objectives, such as combating fraud or preserving personal privacy. Contrary to the court's ruling in *Pearson*, FDA's health claim regulations do not raise insurmountable First Amendment questions principally because the governmental interests they serve are compelling, and the restrictions they impose are calibrated carefully to advance those interests without unduly suppressing the supplement industry's free speech rights. As the Supreme Court often has stressed, nothing in the First Amendment forbids the government from ensuring "that the stream of commercial information flow[s] cleanly as well as freely."<sup>61</sup>

To comprehend the significance of the governmental interests served by the NLEA, it is important to understand precisely what is and what is not at issue in *Pearson*. Academic and public debate over the scientific merit of health claims is not at issue. Nothing in the NLEA subjects academic and public discourse on the merits or drawbacks of dietary supplements to FDA regulation; only promotional claims on labeling are regulated.<sup>62</sup> Also not at issue is the sort of puffery that ordinarily is used to sell food and nutrition products, such as claims regarding taste, purity, appearance, cost, odor, or other product attributes relating to whether a food product will be pleasing to

<sup>57</sup> 164 F.3d at 657-58.

<sup>58</sup> *Id.* at 656-57.

<sup>59</sup> *Id.* at 659-60.

<sup>60</sup> *See, e.g.,* *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976); *Edenfield v. Fane*, 507 U.S. 761 (1993); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996).

<sup>61</sup> *Edenfield*, 507 U.S. at 770.

<sup>62</sup> 21 U.S.C. § 343-2(a).

the consumer.<sup>63</sup> Those statements largely are subjective, or mere hyperbole, and they are not regulated by the NLEA.

The health and nutrition claims regulated by NLEA are sales messages that claim that dietary supplements actually improve one's health or prevent, mitigate, or cure disease, such as:

- beta carotene prevents cancer;
- zinc boosts immune system function;
- omega-3 fatty acids reduce the risk of heart disease;
- SAM-e treats depression and arthritis; and
- vitamin C reduces the risk of influenza.<sup>64</sup>

Unlike puffery, these claims imply a high degree of scientific reliability and encourage purchases based on promises of disease prevention or cure. These claims also play on the public's fear of diseases, such as cancer and heart disease. Thus, the NLEA seeks to distinguish health claims that have been accepted by the scientific community from those that have not received general acceptance or have been repudiated by the vast majority of scientists and, therefore, inherently are misleading or downright false.

The court of appeals, as did the district court, evaluated the constitutionality of the significant scientific agreement standard under the analysis laid down by the Supreme Court in *Central Hudson Gas & Electric Corporation v. Public Service Commission of New York*.<sup>65</sup> In *Central Hudson*, the Court declined to apply the strict scrutiny it applies to political or ideological speech, choosing instead to apply a more deferential intermediate standard of review. The Court established a four-part test for assessing the constitutionality of regulations of commercial speech — a test that repeatedly has been reaffirmed.<sup>66</sup> That test inquires, in relevant part:

- first, whether the speech is *misleading*;
- second, whether the government's asserted interest in regulating the speech is *substantial*;
- third, whether the restraint *directly advances* the government's interest;
- fourth, whether the legislation is *no more extensive than necessary* to serve the government's interest.<sup>67</sup>

The NLEA passes muster under each prong of this test.

### 1. *Unverified Health Claims Inherently Are Misleading*

The most glaring flaw in *Pearson* is the court's failure to grapple with the fundamental judgment embodied in the NLEA and FDA's regulations. Namely, that health and nutrition claims unsupported by "significant scientific agreement" are unreliable and misleading. As noted above, the first inquiry required under *Central Hudson* is whether the proposed speech is misleading. If it is, the speech may be suppressed by

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<sup>63</sup> For a detailed discussion of the limits on the use of "puffery" by advertisers, see Ivan L. Preston, *Puffery and Other "Loophole" Claims: How the Law's "Don't Ask Don't Tell" Policy Condones Falsity in Advertising*, 18 J.L. & COM. 49 (1998).

<sup>64</sup> See Brief of Amici Curiae American Cancer Society, et al., in *Pearson*, 14 F. Supp. 2d at 10-11.

<sup>65</sup> 447 U.S. 557 (1980).

<sup>66</sup> *Id.* at 563-64. *Accord* Florida Bar v. Went for It, Inc., 515 U.S. 618, 623-24 (1995); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 482 (1995).

<sup>67</sup> *Central Hudson*, 447 U.S. at 563-64.

the government in its entirety, without further inquiry under the First Amendment. As the Court has emphasized time and again:

Obviously, much commercial speech is not probably 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 insuring that the stream of commercial information flows cleanly as well as freely.<sup>68</sup>

Thus, the issue presented in *Pearson* is the extent to which government may regulate commercial speech, which has not been determined either true or false because the scientific jury is still out, and therefore, the government views it as inherently misleading.

In its court submissions, FDA strongly argued that unsubstantiated health claims inherently were misleading for three reasons. First, FDA asserted that there was a long and well-documented history of unfounded health claims for dietary supplements.<sup>69</sup> Prior to the passage of the NLEA, misleading and fraudulent health claims about dietary supplements were widespread.<sup>70</sup> FDA asserted that history provided a solid anchor for its judgment that consumers would continue to be at risk from deceptive health claims in the absence of vigorous government regulation. Moreover, FDA contended that the attributes of health claims on supplement labels make the claims inherently misleading. They address matters of great importance to consumer health (such as ways to treat depression or reduce cancer risk), exploit the public's fear about disease, and exert substantial influence on purchasing decisions.<sup>71</sup> Finally, the claims rest on scientific information "that the average consumer would have trouble verifying independently."<sup>72</sup> For these reasons, FDA argued, "the high potential for health claims to be misleading" led Congress "to permit only those health claims . . . that FDA determines to be scientifically valid."<sup>73</sup> The government urged the court not to disturb Congress' judgment.

The court of appeals peremptorily dismissed FDA's "inherently misleading" argument, going so far as to suggest that "this contention is almost frivolous."<sup>74</sup> While

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<sup>68</sup> *Friedman v. Rogers*, 440 U.S. 1, 9-10 (1979) (citations omitted). *Accord Florida Bar*, 515 U.S. at 623-24 ("[T]he government may freely regulate commercial speech that . . . is misleading."); *Edenfield*, 507 U.S. at 768 ("[O]ur cases make clear that the State may ban commercial expression that is fraudulent or deceptive without further justification."). Courts repeatedly have upheld government prohibitions on deceptive advertising and labeling of foods and drugs against First Amendment challenges. *See, e.g.*, *Kraft, Inc. v. Federal Trade Comm'n*, 970 F.2d 311, 324-26 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993) (upholding Federal Trade Commission (FTC) ban on deceptive calcium claims for processed cheese products); *Bristol-Myers Co. v. Federal Trade Comm'n*, 738 F.2d 554, 562 (2d Cir. 1984), *cert. denied*, 469 U.S. 1189 (1985) (sustaining FTC prohibition against certain advertising claims for analgesics); *United States v. General Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986) (upholding FDA prohibition of certain nutritional claims on the product label).

<sup>69</sup> Brief for Appellees in *Pearson v. Shalala*, Nos. 98-5043 & 98-5084, at 24-25 (citing H.R. REP. NO. 101-538 (1990); 136 CONG. REC. H12,953 (1990); 136 CONG. REC. H5844 (1990); *Disease-Specific Health Claims on Food Labels: An Unhealthy Idea*, H.R. REP. NO. 100-561 (1988); *FDA's Continuing Failure to Regulate Health Claims for Foods: Hearings Before the Human Resources and Intergovernmental Relations Subcomm. on the House Comm. on Governmental Affairs*, 101st Cong. (1990); *Health and Nutrition Claims in Food Advertising and Labeling: Hearings Before the Senate Comm. on Governmental Affairs*, 101st Cong. (1990)).

<sup>70</sup> Brief for Appellees, *supra* note 69, at 16, 24-25.

<sup>71</sup> *Id.* at 25.

<sup>72</sup> *Id.*

<sup>73</sup> *Id.* (citing 58 Fed. Reg. 2562 (Jan. 6, 1993)).

<sup>74</sup> *Pearson*, 164 F.3d at 655.

the court was quick to condemn FDA's argument, it offered no explanation for its harsh conclusion.<sup>75</sup> The only clue the court offers comes later in the opinion, when the court rejects FDA's contentions about the nature and magnitude of the risks posed by unproven health claims for dietary supplements. Whatever the court's rationale, it was wrong to reject FDA's "inherently misleading" argument for three reasons.

First, the *Pearson* court assumes that the commercial speech doctrine extends to claims about the quality or characteristics of a product that are unverifiable, as long as a disclaimer can be employed to alert the consumer to that fact. But no Supreme Court case endorses that view. To the extent that the Court addressed the question of unverifiable claims, it has suggested that they may be banned altogether. An example of this was the Court's decision in *Bates v. State Bar of Arizona*.<sup>76</sup> There the Court emphasized that while the First Amendment protects the right of lawyers to advertise the services they render and the fees they charge, it was wary about "the peculiar problems associated with advertising claims relating to the quality of legal services," because such claims "are not susceptible of precise measurement or verification," and hence may be "deceptive or misleading."<sup>77</sup> The Court repeated this concern in *Zauderer v. Office of Disciplinary Counsel*,<sup>78</sup> observing that "our decisions have left open the possibility that States may prevent attorneys from making non-verifiable claims regarding the quality of their services."<sup>79</sup> In neither instance did the Court suggest that the potential deception created by non-verifiable claims must be cured through the use of a disclaimer that said, for example, that the state bar does not endorse the claim, or that quality claims inherently are incapable of verification.<sup>80</sup> In keeping with the view that unverified claims are outside the protection of the First Amendment, the Federal Trade Commission (FTC) long has required "substantiation" of claims regarding a product's characteristics, and for health claims, insisted that the advertiser produce "competent and reliable scientific evidence" supporting its claims.<sup>81</sup> Under *Pearson*, the FTC might be compelled to permit a health claim lacking "competent and reliable" evidence, so long as the seller could point to some scientific evidence and affix a curative disclaimer. Yet there appears to be no precedent for the *Pearson* court's conclusion that the First Amendment commands this result.

Second, as a matter of settled First Amendment jurisprudence, courts owe considerable deference to legislative judgments in the realm of commercial speech.<sup>82</sup> Here,

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<sup>75</sup> The *Pearson* court's dismissal of FDA's "inherently false" argument contrasts sharply with the routine acceptance of the argument that "if FDA does not endorse a claim, then it must be false" in other contexts. Under the Lanham Act, for example, courts have held that a drug claim not approved by FDA — even if supported by scientific studies and journal arguments — is false under the Act and hence actionable. To take one recent example, in *Zeneca Inc. v. Eli Lilly & Co.*, No. 99 CIV. 1452(JGK), 1999 WL 509471 (S.D.N.Y. July 19, 1999), the district court entered an injunction barring Eli Lilly from suggesting that its drug Evista<sup>®</sup> reduces the risk of breast cancer because, although there is some scientific evidence supporting Lilly's claim, the evidence is inconclusive and thus FDA has not approved Evista<sup>®</sup> for that use. And as explained above, the necessity of FDA premarketing approval for drug claims long has been accepted, even though FDA requires an "expert consensus" that the drug is safe and effective for its intended use. See, e.g., *Weinberger*, 412 U.S. at 629-34.

<sup>76</sup> 433 U.S. 350 (1976).

<sup>77</sup> *Id.* at 366.

<sup>78</sup> 471 U.S. 626 (1985).

<sup>79</sup> *Id.* at 641 n.9.

<sup>80</sup> Indeed, the lower courts have upheld state bans on lawyers making quality claims in their advertisements, unless the claim is subject to objective substantiation. See, e.g., *Texans Against Censorship v. State Bar*, 888 F. Supp. 1328 (E.D. Tex. 1995), *aff'd without opinion*, 100 F.3d 953 (5th Cir. 1996).

<sup>81</sup> C. Lee Peeler & Susan Cohn, *The Federal Trade Commission's Regulation of Advertising Claims for Dietary Supplements*, 50 FOOD & DRUG L.J. 349, 350-51 (1995).

<sup>82</sup> See, e.g., *United States v. Edge Broad. Co.*, 509 U.S. 418, 434 (1993); *Board of Trustees of the State Univ. of New York v. Fox*, 492 U.S. 469, 480 (1989).

the *Pearson* court paid no deference to Congress' judgment in the NLEA — this was serious error. Had the court grappled forthrightly with the policy judgment that lies at the core of the NLEA, it certainly would have reached the opposite conclusion.

Indeed, Congress' judgment — that unverified health claims pose too great a risk of harm to consumers to be permitted in the marketplace — is unassailable. Because of the complexity of health claims, consumers cannot conceivably evaluate them on their own.<sup>83</sup> No one realistically expects consumers to wade through volumes of preliminary and often conflicting and inconclusive scientific literature involving clinical trials, laboratory animal experiments, and epidemiological studies to assess whether a particular health claim is well-founded. That task often confounds experts. Even the most well-informed, health-conscious consumer easily could fall prey to preliminary scientific findings disseminated as part of a sales pitch.<sup>84</sup> Congress reasonably decided that this scientific review is FDA's function, not the job of consumers in the United States. The significant scientific agreement standard assures consumers reliable information when they are making purchasing decisions that affect their health and well-being. Congress was entitled to make the judgment that consumers should not be solely responsible for making decisions of this importance, and the court was wrong to so blithely disregard Congress' judgment on this score.<sup>85</sup>

Third, the court disregarded considerable precedent that supports the FDA's position. Most remarkably, the court does not address *Ohralik v. Ohio State Bar Association*,<sup>86</sup> where the Supreme Court upheld a categorical ban on direct, in-person solicitation of clients by lawyers. *Ohralik* is important because it makes clear that the *Pearson* court's concern — that FDA's regulation might ensnare truthful claims as well as misleading ones — is overstated. The First Amendment tolerates a degree of over-inclusiveness in restrictions on commercial speech, and *Ohralik* is a prime example of the extent of that tolerance. *Ohralik* confronted virtually the same over-inclusiveness problem that vexed the *Pearson* court. The *Ohralik* Court recognized that an all-out ban on in-person solicitation by lawyers would deter not only improperly coercive speech, but also truthful speech that was not coercive, but in fact, was valuable to the prospective client. Nonetheless, the Court upheld the ban, emphasizing that, where a restriction on commercial speech was based on extensive historical evidence of abuse, and imposed to prevent serious harm to consumers, broad prophylactic restraints could be upheld.<sup>87</sup> The Court justified the breadth of its ruling by pointing out that, in the absence of an outright ban, there would be no way to prevent consumer harm, that it would be difficult, if not impossible, to repair the damage that could result from overreaching by soliciting lawyers, and that the harms that could befall prospective clients were substantial.<sup>88</sup> In 1995, the Supreme Court reaffirmed

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<sup>83</sup> See, e.g., *American Home Prods. Corp. v. Federal Trade Comm'n*, 698 F.2d 681, 695 (3d Cir. 1982); *United States v. Rutherford*, 442 U.S. 544 (1979).

<sup>84</sup> *Id.*

<sup>85</sup> See, e.g., *Rutherford*, 442 U.S. at 555-57. Nor was the Court correct in trivializing the risks from dietary supplements. The court proclaims that "the government does not assert that appellants' dietary supplements in any fashion threaten consumer's health and safety." *Pearson*, 164 F.3d at 656 (emphasis in original; footnote omitted). This statement is wrong because, as discussed below, FDA in fact argued that the health claims appellants wanted to make for their folate products did jeopardize public health. More disquieting, however, is the court's implication that dietary supplements generally pose little health risks to the public — a suggestion that is quite wide of the mark. See, e.g., Kassel, *supra* note 2, at 241-50 (canvassing serious public health risks posed by use of dietary supplements).

<sup>86</sup> 436 U.S. 447 (1978).

<sup>87</sup> *Id.* at 466 (assuming "that in-person solicitation by lawyers more often than not will be injurious to the person solicited").

<sup>88</sup> *Id.* at 465-67; see also *In re R.M.J.*, 455 U.S. 191, 202 (1982); *Friedman v. Rogers*, 440 U.S. 1 (1979).

the *Ohralik* principle unaddressed in *Pearson — The Florida Bar v. Went for It, Inc.*,<sup>89</sup> where it upheld a Florida court rule forbidding lawyers from sending solicitation letters to recent accident victims and their families, in large measure because of the record of abuse.<sup>90</sup>

Relying on this line of cases, FDA demonstrated in *Pearson* that the history of misleading and fraudulent health claims for dietary supplements justified Congress' decision to let only reliable claims on the market.<sup>91</sup> As FDA maintained, the same factors that impelled the *Ohralik* Court to uphold the solicitation ban apply with equal force here — there is a strong historical basis for concluding that overreaching in the sale of dietary supplements is commonplace; there is no way beside a prophylactic ban to prevent consumers from being deceived; and there is no way to repair the harm to consumers once they rely on an ineffective (or dangerous) dietary supplement to prevent, mitigate or cure an illness that could be treated with a different product.<sup>92</sup> Although this argument was at the core of FDA's submission, the *Pearson* court did not address it.<sup>93</sup>

## 2. Assuming That Unproven Health Claims Are "Potentially Misleading," *Pearson* Still Is Decided Wrongly

Having given the back of its hand to FDA's argument that unproven health claims are "inherently misleading," the court next turned to the agency's contention that, at the very least, unverified health claims potentially are misleading "because the consumer would have difficulty in independently verifying these claims," and could be restricted on this basis.<sup>94</sup> Nowhere did the court take issue with FDA's submission that consumers generally are incapable of assessing the scientific data on which health claims purportedly are based. Nonetheless, the court rejected FDA's "potentially misleading" argument, because, in its view, FDA's regulatory scheme was not sufficiently tailored to address the problem of consumer deception. The court believed that FDA could cure the problem of consumer deception through the use of disclaimers and warnings instead of banning unverified claims outright.<sup>95</sup>

The court's reasoning was based on its rejection of FDA's arguments about the nature of the risks posed by dietary supplements. FDA made two main submissions. First, it urged that the ban on unverified health claims was needed to protect the public's health. FDA contended that dietary supplements pose a risk to human health both because some of the products themselves may pose dangers to consumers, and because some consumers will rely on ineffective supplements and pass up more reliable therapies, thus delaying treatment or foregoing it

<sup>89</sup> 515 U.S. 618 (1995).

<sup>90</sup> Once again, there was no question in *Florida Bar* that the anti-solicitation rule would bar valuable, non-intrusive communications as well as invasive ones, and hence was considerably overinclusive. Nonetheless, as both *Ohralik* and *Florida Bar* show, the Court's commercial speech cases make it clear that, contrary to the implication in *Pearson*, the Court will sustain restrictions on commercial speech that are significantly overinclusive, so long as they are "reasonable." *Accord Fox*, 492 U.S. at 480; *Edge Broadcasting*, 509 U.S. at 429.

<sup>91</sup> Brief for Appellees, *supra* note 69, at 24-26.

<sup>92</sup> *Id.*

<sup>93</sup> The court's silence on this issue is especially puzzling in light of the judgment made in the FDCA that, until proven to FDA's satisfaction, health claims for drugs flatly are prohibited because of the health risks unverified claims pose to consumers. *See, e.g., Rutherford*, 442 U.S. at 555-57, and *Zeneca*, 1999 WL 509471. Why a categorical, prophylactic ban is acceptable for unverified health claims for drugs but is wholly unacceptable for dietary supplements is left unanswered.

<sup>94</sup> Brief for Appellees, *supra* note 69, at 25.

<sup>95</sup> *Pearson*, 164 F.3d at 659-60.

altogether.<sup>96</sup> And second, FDA argued that unproven health claims resulted in economic loss to consumers, who were spending millions of dollars on products that did not deliver the health benefits promised.<sup>97</sup> Although the court agreed that in principle these were legitimate governmental interests, it trivialized each one in rejecting FDA's argument.

The court first took aim at FDA's public health argument, suggesting, wrongly, "that the government does not assert that . . . dietary supplements in any fashion threaten consumer's health and safety."<sup>98</sup> In a footnote, the court remarked that "[d]rugs, on the other hand, appear to be in an entirely different category — the potential for harm presumably is much greater."<sup>99</sup> This passage of the court's opinion betrays its confusion over the risks posed by supplements and the relationship between supplements and drugs.

Congress and FDA plainly have a powerful interest in limiting the dissemination of information that could lead consumers to choose unproven or dangerous therapies in lieu of more reliable remedies.<sup>100</sup> Dietary supplements often are sold to treat ailments such as depression, anxiety, osteoporosis, arthritis, high cholesterol, and sleeping disorders — diseases and illnesses for which well-studied and reliable therapies are available. Consumers are urged not to substitute unproven therapies for tested ones, but to engage in self-medication, which presents a host of other risks. Unlike drugs, supplements are not subject to exacting testing requirements, so their safety and efficacy is uncertain. And unlike drugs, the manufacturing of dietary supplements is unregulated by FDA, increasing the risk of product contamination. Thus, when a consumer takes a dietary supplement to prevent, cure, or treat a disease, he or she often is passing up a more reliable therapy, eschewing the advice of a physician, and taking a product manufactured without FDA oversight.

The laissez-faire regulatory scheme advocated by the dietary supplement industry and endorsed by the court of appeals will have significant public health consequences. Suppose that *Pearson* had been the law a few years ago, when dietary supplement manufacturers sought to promote the use of anti-oxidant supplements, including beta-carotene, by claiming that these products reduced the risk of cancer. These claims would have been based on preliminary scientific studies and, therefore, could not have been, and were not, approved by FDA under the "significant scientific agreement" standard.<sup>101</sup> The wisdom of FDA's decision not to approve these claims was confirmed by further research. Although preliminary studies suggested that anti-oxidant supple-

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<sup>96</sup> *Id.* This later point was echoed in an editorial in the *New England Journal of Medicine*:

[B]efore we lend our imprimatur to the widespread use of a still unproved treatment, one that requires the patient only to pop a few pills, we should ask how many patients will slack off on their adherence to better-established, but somewhat more onerous, preventative measures such as a cholesterol-lowering diet, regular exercise, and smoking cessation.

Daniel Steinberg, M.D., Ph.D., *Anti-Oxidant Vitamins and Coronary Heart Disease*, 328 *NEW ENG. J. MED.* 1487 (1993). See also C. Hennekens, M.D., *Antioxidant Vitamins — Benefits Not Yet Proven*, 330 *NEW ENG. J. MED.* 1080 (1994) ("Despite the lack of reliable evidence, exaggerated health claims are being made for antioxidant vitamins.").

<sup>97</sup> Brief for Appellees, *supra* note 69, at 33, 35.

<sup>98</sup> *Pearson*, 164 F.3d at 656 (emphasis in original).

<sup>99</sup> *Id.* n.6.

<sup>100</sup> Indeed, the Supreme Court's opinion in *Rutherford* rests mainly on this consumer-protective function of the food and drug laws. Yet the *Pearson* court never mentions *Rutherford*, let alone grapples with FDA's contention that unverified and overblown health claims for dietary supplements will lead some consumers to forego conventional and effective treatments in favor of unproven remedies.

<sup>101</sup> See 58 Fed. Reg. 54,595 (Oct. 22, 1993) (rejecting health claim petition on anti-oxidants); see also 58 Fed. Reg. 2622 (Jan. 6, 1993).

ments might be beneficial, more definitive studies demonstrated that even large doses do not reduce the risk of cancer and actually may increase the incidence of cancer in high risk individuals, such as smokers.<sup>102</sup> Nonetheless, in the post-*Pearson* marketing free-for-all, it is hard to see how FDA would have been able to shield consumers from these misleading claims.

Consider a second example. FDA's brief in *Pearson* pointed out that one of the plaintiffs wanted to market its high-dose folic acid supplement by claiming that high doses of folic acid are superior to low doses in helping to reduce neural tube defects.<sup>103</sup> Although the agency authorized claims that folic acid limited to one milligram daily has been shown to reduce neural tube defects,<sup>104</sup> FDA refused to authorize "comparative" claims touting the efficacy of high doses because they can mask the symptoms of pernicious anemia, thereby impeding diagnosis while its effects — including irreversible nerve damage — continue undetected and untreated.<sup>105</sup> It is likely that *Pearson* will unleash these claims on the public, as long as they are accompanied by a disclaimer of some sort. Nowhere does the *Pearson* court explain why consumers are served by permitting this kind of unreliable and potentially dangerous marketing claim.

Equally unsettling is the court's effort to contrast the risk of dietary supplements and drugs, suggesting that dietary supplement usage generally is benign and that the potential risk from drugs is "presumably much greater."<sup>106</sup> The court's observation is fraught with problems. Drugs are tested extensively prior to marketing, FDA has a clear-cut appreciation of the risks prior to the drug entering the market, and the agency has made a cost-benefit determination that the benefits of the drug outweigh the known risks. No such determination has been made, let alone could be made, for dietary supplements because they are not approved by FDA and they rarely are subject to rigorous testing — even when serious adverse health effects have been noted.<sup>107</sup> Dietary supplements also are not subject to the rigorous quality-control requirements FDA imposes on drug manufacturers. As the L-tryptophan debacle drives home, the absence of tight regulation of the production of dietary supplements poses its own substantial public health risk.<sup>108</sup> Moreover, the court seems to forget that risk is a relative concept. Taking a drug for which there is a known benefit but that carries some risk

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<sup>102</sup> Press Statement of the National Cancer Institute, National Institutes of Health, *Beta Carotene and Vitamin A Halted in Lung Cancer Prevention Trial*, Jan. 18, 1996.

<sup>103</sup> Brief for Appellees, *supra* note 69, at 52.

<sup>104</sup> *Id.*

<sup>105</sup> *Id.* at 10-12, 51-53. Without belaboring the point, it is astonishing how little attention the court paid to the public health imperative that lies at the core of the NLEA. The examples cited in the text are just the tip of the iceberg. One need only recall the 38 deaths and 1500 injuries associated with L-tryptophan to understand the risks that indiscriminate use of untested dietary supplements pose to public health. See, e.g., Stuart L. Nightingale, *Update on EMS and L-Tryptophan*, 268 JAMA 1828 (1992); see also Kassel, *supra* note 2, at 241-43 (recounting health problems posed by a wide range of dietary supplements).

<sup>106</sup> *Pearson*, 164 F.3d at 656 n.6.

<sup>107</sup> See, e.g., Comment, *Melatonin Mania: Can the FDA Regulate Hormonal Dietary Supplements to Protect Consumer Interests in Light of the Dietary Supplement Health and Education Act of 1994?*, 22 DAYTON L. REV. 77, 81 (1996) (pointing out the widespread usage of melatonin to combat sleeping disorders and to reduce jet lag, despite the fact that it is a powerful hormone whose "long-term effects . . . are completely unknown"); Kassel, *supra* note 2, at 243 (observing that for many of the 24 amino acids taken as dietary supplements, that the Federation of American Societies for Experimental Biology, working under a contract from FDA, concluded that there "no safe level of intake exists," in large measure because of uncertainties over the public health risk).

<sup>108</sup> See generally *supra* note 101; see also Huijeong Hahm, et al., *Comparison of Melatonin Products Against UPS's Nutritional Supplements Standard and Other Criteria*, 39(1) J. AM. PHARM. ASS'N 27 (Jan./Feb. 1999) (concluding that significant quality control problems persist in the formulation and manufacturing of dietary supplements).

does not pose a greater risk than taking a supplement the benefits of which are uncertain and risks of which are unknown.<sup>109</sup>

Nor is the court's discussion of the fraud issue more on target. According to the court, it is fair to assume "that some health claims on dietary supplements will mislead consumers" and, for that reason, FDA has a right to regulate to prevent deception from taking place.<sup>110</sup> But the court sidesteps that acknowledgment, and takes FDA to task for trying to prevent deception by insisting that health claims be verified, instead of using disclaimers.

Apart from the court's misperception about the utility of disclaimers, the rejection of FDA's position is incompatible with the commercial speech jurisprudence on which it purports to rely. The court acknowledges that, under *Board of Trustees of the State University of New York v. Fox*,<sup>111</sup> the pivotal question was whether Congress' and FDA's regulatory scheme was "reasonable," not whether it was the least restrictive approach possible.<sup>112</sup> As the Court stated in *Fox*, the fit between the legislature's ends and the means chosen to accomplish those ends "represents not necessarily the single best disposition but one whose scope is in 'proportion to the interest served' . . . that employs not necessarily the least restrictive means but . . . a means narrowly tailored to achieve the desired objective."<sup>113</sup> As long as the fit between the challenged statute and regulations and the legislature's goals is "reasonable," a court should find them constitutional.<sup>114</sup>

<sup>109</sup> Perhaps most problematic is the court's assumption that there is a clear dividing line between supplements on the one hand and drugs on the other. That is not the case. Many dietary supplements that have potent pharmacological effects are also sold as prescription medications. For instance, the herbal product *Atropa Belladonna* is used to treat a variety of heart problems, including arrhythmia and cardiac insufficiency, and liver and gallbladder complaints; *Ephedra Sinica* (often sold as *Ma-Huang*) is used for respiratory tract ailments and as a stimulant. See PHYSICIAN'S DESK REFERENCE FOR HERBAL PRODUCTS at 677-80, 826-27 (1998 ed.). Both are also the main ingredients in prescription medications; *Atropa Belladonna* is an active ingredient in *Bellatol* and *Donnatol*, and *Ephedra Sinica* is an active ingredient in *Marax*. See PHYSICIAN'S DESK REFERENCE at 2211 (*Bellatol*), 2234 (*Donnatol*), and 2015 (*Marax*) (1997 ed.).

<sup>110</sup> *Pearson*, 164 F.3d at 656.

<sup>111</sup> 492 U.S. 469 (1989).

<sup>112</sup> *Fox* is a pivotal case in commercial speech jurisprudence. There the Court laid to rest any argument that states were obligated to impose the "least restrictive measure" or less "drastic" means in regulating commercial speech to safeguard against deception. Rather, the Court emphasized that "reasonableness," not perfection, is the touchstone of analysis under the commercial speech doctrine. *Id.* at 480. The Court recognized that ordinarily "reasonableness" is the touchstone of rational basis review, the least stringent constitutional review the Court applies. *Id.* The difference, the Court observed, is that, unlike rational basis review, intermediate scrutiny demands that "the State bears the burden of justifying its restrictions . . . [and] it must establish the reasonable fit we require." *Id.* (citations omitted).

<sup>113</sup> *Id.* at 480 (citations omitted). The *Pearson* court's quick trigger in rejecting the legislative judgments underlying the NLEA and FDA's implementing rule may pose a real dilemma for agencies engaged in health and safety regulation. Most statutes that delegate authority to set health and safety standards direct agencies to apply a "precautionary principle" — namely to err on the side of over-regulation when addressing risks that are not well understood. As one commentator has put it, the "precautionary principle simply reflects the classic adage: Better safe than sorry." Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 851 (1996); see also Richard C. Revesz, *Environmental Regulation, Cost Benefit Analysis, and the Discounting of Human Lives*, 99 COLUM. L. REV. 941, 1013 (1999). But *Pearson* suggests that when an agency engages in health and safety regulation by limiting expressive activity, the precautionary goal of the regulation will count little in assessing the regulation's validity under the First Amendment.

<sup>114</sup> See *Fox*, 492 U.S. at 480; see also *Edge Broadcasting*, 509 U.S. at 434 ("Within the bounds of the general protection provided by the Constitution to commercial speech, we allow room for legislative judgments."). Congress' judgment in the NLEA was informed by an enormous record amassed before the passage of the Act. See, e.g., *FDA Proposals to Permit the Use of Disease-Specific Health Claims on Food Labels: Hearing Before a Subcomm. of the House Comm. on Government Operations*, 100th Cong., 1st Sess. (1987); *House Comm. on Government 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 Government Opera-*

Had the court measured the significant scientific agreement standard against the test of "reasonableness," it easily would have passed muster. Here, the nexus between the goals Congress set forth in the NLEA and the means Congress and FDA chose to achieve those goals, is close. The NLEA's goal was to prohibit manufacturers from making unreliable health claims about dietary supplements, while permitting claims that are, in fact, truthful and dependable to be made.<sup>115</sup> Remarkably, however, in invalidating this scheme, the *Pearson* court paid no attention to Congress' judgment in the NLEA about the risk posed to consumers by unproven health claims. Instead, the court substituted its own notions about the informational needs of consumers and the safety of dietary supplements, although the court's views wholly were at odds with those of Congress and the expert agency.<sup>116</sup> The result, paradoxically, is that the court has placed consumers in precisely the position that the NLEA was enacted to avoid, and deprived them of the Act's assurance that only verifiable health claims would be permitted in the marketplace.

### B. *Disclaimers Are No Panacea*

The court of appeals concluded that the First Amendment precluded FDA's approach because disclaimers are available to mitigate consumer deception.<sup>117</sup> According to the court, instead of forbidding unproven health claims outright, FDA simply could require dietary supplement sellers to place on labeling disclaimers saying that "[t]he evidence in support of this claim is inconclusive," "[t]he FDA does not approve this claim," or FDA does not believe that the product is effective for its claimed use.<sup>118</sup> At the heart of the court's ruling is its faith that, so long as a disclaimer can be added to the product label informing the public that the product lacks FDA approval, or that FDA is skeptical about the product's efficacy, consumers are protected against deception.

The court's ruling breaks new legal ground. Until *Pearson*, no court had held that the First Amendment requires the government to use disclaimers to mitigate the adverse effects of misleading commercial speech. In fact, long-standing Supreme Court precedent suggests the opposite.<sup>119</sup> In *Friedman*, for instance, the Court admonished that "there is no First Amendment rule . . . requiring 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."<sup>120</sup> Nor is it appropriate for a court to arrogate to itself the judgment of how best to cure misleading speech; at least in the first instance, that determination is the province of the legislative branch of government. For precisely that reason, all Supreme Court cases concerning disclaimers involve efforts by regulatory authorities to require disclaimers; not disclaimers imposed by the judiciary.

*Zauderer v. Office of Disciplinary Counsel*<sup>121</sup> is the textbook disclaimer case. Zauderer was charged with engaging in deceptive practices by advertising that he accepted cases on a contingent fee basis, with "no cost" to the client in the event that

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tions, *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 Governmental Affairs*, 101st Cong., 2d Sess. (1990). The evidence compiled by FDA when it promulgated its implementing regulations is equally substantial and compelling. See 59 Fed. Reg. 395 (Jan. 4, 1994).

<sup>115</sup> 21 U.S.C. § 343(r)(1)(B).

<sup>116</sup> *Pearson*, 164 F.3d at 659-60.

<sup>117</sup> *Id.* at 658-59.

<sup>118</sup> *Id.*

<sup>119</sup> *Friedman*, 440 U.S. 1.

<sup>120</sup> *Id.* at 12 n.11.

<sup>121</sup> 471 U.S. 626 (1985).

the litigation was unsuccessful.<sup>122</sup> The Ohio Supreme Court found Zauderer's advertisement misleading because it failed to disclose to clients that they would nonetheless remain liable for costs, as required by Ohio's disciplinary rules.<sup>123</sup> The Court upheld the validity of the Ohio disclosure rule, remarking that "warning[s] and disclaimer[s] might be appropriately required . . . in order to dissipate the possibility of consumer confusion or deception."<sup>124</sup> *Zauderer* and its progeny undercut, not support, the D.C. Circuit's conclusion in *Pearson*. For one thing, *Zauderer* upheld a state bar rule requiring a disclaimer; the disclaimer was not the invention of the Court. For another, the function of the disclaimer in *Zauderer* was to provide information to ensure that the public understood exactly how legal fees are charged. The information mandated by the bar rule in *Zauderer* was indisputably relevant to a consumer's evaluation of which lawyer to hire and the fee the consumer would be assessed. The First Amendment theory underlying *Zauderer* is that, in combating potential consumer deception, the preferred remedy is more speech, more information, and hence better informed consumers, rather than suppression.<sup>125</sup>

That rationale does not apply in *Pearson*. Nothing in the disclaimers mandated by *Pearson* help dispel consumer confusion because, in contrast to the disclaimer in *Zauderer*, the disclaimers envisioned in *Pearson* contain no information to help in the consumer's appraisal of a product.<sup>126</sup> The key question is not, as the court suggest, whether FDA stands behind the product's safety and efficacy, the more pressing question is whether the product in fact is safe and effective for its intended use. In conflating these very separate questions, the *Pearson* court wrongly concludes that answering the first question is tantamount to answering them both. But that is not the case.

The dilemma that *Pearson* studiously overlooks is the sheer paucity of evidence concerning the safety and efficacy of most dietary supplements. And the virtue of the significant scientific agreement standard is that it ensures that there is sufficient, consistent, replicable data such that experts reasonably are certain that a claim thought to be valid today will not be disproved tomorrow. Disclaimers serve no role in filling this informational void. Indeed, nothing in the disclaimers envisioned by the *Pearson* court:

- tell the consumer whether the product is safe — that fact is unknown;
- alert the consumer to the product's risks — the risks are unknown;

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<sup>122</sup> The main issue presented in *Zauderer* was whether the Ohio Bar could punish a lawyer for running an advertisement seeking clients injured by the Dalkon Shield. To distinguish between the Shield and other intra-uterine devices, the lawyer's advertisement included a drawing of the Dalkon Shield. The Ohio courts had sustained disciplinary action against Zauderer because the advertisement — and especially the drawing — solicited a particular client group and therefore sought to stir up litigation. The Supreme Court reversed, holding that, because of its expressive content, the drawing was just as entitled to First Amendment protection as verbal commercial speech. *Id.* at 647-49.

<sup>123</sup> *Id.* at 650.

<sup>124</sup> *Id.* at 651 (quoting *In re R.M.J.*, 455 U.S. at 201).

<sup>125</sup> The Court's decision in *44 Liquormart, Inc. v. Rhode Island* also rests on the pro-information goal of the First Amendment, and does not support the *Pearson* decision. The *Pearson* court says that *44 Liquormart* undermined "the proposition that a court should not second guess a legislative decision to restrict speech rather than to require more speech." 164 F.3d at 658. To be sure, the *44 Liquormart* Court criticized a prior Supreme Court ruling, *Posadas de Puerto Rico Assocs. v. Tourism Co. of Puerto Rico*, 478 U.S. 328 (1986), for failing to review the rationality of the legislature's judgment that all casino gambling advertising directed toward Puerto Rican residents should be banned outright. But nothing in *44 Liquormart* goes as far as the *Pearson* court suggests and counsels disregard for legislative judgments. Indeed, in post-*44 Liquormart* commercial speech decisions, the Court again emphasized the need for deference, albeit not blind deference, to legislative judgments. See *Greater New Orleans Broad. Ass'n v. United States*, 119 S. Ct. 1923 (1999).

<sup>126</sup> Applying the logic of *Pearson*, the disclaimers in *Ohralik* might have read as follows: "The Ohio State Bar takes no position on whether the statement concerning fees and costs is accurate" or "The Ohio State Bar does not approve this claim."

- tell the consumer whether the product works — that fact is unknown; and
- tell the consumer whether the product is more or less effective than a conventional remedy — that fact is unknown.

Rather than arm consumers with useful information, the disclaimers contemplated in *Pearson* serve only to inform consumers that FDA does not take a position on the safety or efficacy of the product, or is skeptical about the seller's health claims.<sup>127</sup> There is a vast gulf between providing useful information and disclaiming responsibility. Because the disclaimers envisioned by the Court of Appeals will not assist consumers in distinguishing between truthful and deceptive claims, the *Pearson* court was wrong to believe that disclaimers will cure consumer deception. By relegating consumers to a marketplace that will be rife with unproven and unreliable health claims, the court's ruling poses a real threat to the health and well-being of our nation's consumers.

#### V. CONCLUSION: MARKETING DIETARY SUPPLEMENTS POST-PEARSON

Although it is too early to evaluate the full effect of *Pearson*, the consequences of the ruling are certain to be substantial and far-reaching. In *Pearson*'s aftermath, FDA is struggling with how it can police a marketplace where deceptive conduct abounds while handcuffed by the court's ruling. The options open to FDA are limited. At the very least, FDA will be hard-pressed to take action to prevent sellers of dietary supplements from using any study that even arguably supports a health claim as part of their promotional efforts. So long as a disclaimer can be added that informs consumers that the product is not FDA-approved, it is likely that virtually any claim will be permitted to go forward unless FDA can show that the product is harmful. Making matters worse, nothing in the *Pearson* court's ruling distinguishes among studies that are tentative, inconclusive, preliminary, non-replicable, or even out of step with mainstream science. So long as a study suggests a link between a dietary supplement and the prevention, mitigation or cure of a disease, and so long as the seller tags on a disclaimer, *Pearson* suggests that the First Amendment entitles sellers to use health claims based on that study to market their product.<sup>128</sup>

The other foreseeable consequence of *Pearson* is the likelihood, perhaps certainty, that some manufacturers will forego the new drug approval process and market what plainly are new drug products as dietary supplements. In the post-*Pearson* era, there no longer may be any meaningful advantage of having a product designated a "drug." Dietary supplements may make the same therapeutic claims as drugs, but with far fewer restrictions. What rational manufacturer would willingly endure the time, expense, and uncertainty of FDA's new drug approval process when it immediately could put its product on the market as a supplement, make disease prevention, mitigation, and cure

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<sup>127</sup> *Pearson*, 164 F.3d at 658-59.

<sup>128</sup> The same conclusion almost certainly will apply to food products. Although *Pearson* involved only dietary supplements, it is hard to see how FDA will be able to enforce its parallel restrictions on health claims for food products. The court's opinion suggests that it might treat drugs differently, but nothing in the opinion indicates that the court would reach a different outcome for health claims for food products. Indeed, because foods are seen to pose even less risk than dietary supplements, foods might be an *a fortiori* case. Although to date the question has not been the subject of litigation, it is reasonable to assume that post-*Pearson* food sellers will be permitted to make disease prevention, mitigation, and cure claims based on unverified data, as long as the claims are accompanied by a suitable disclaimer.

claims, and paste on a brief disclaimer to satisfy FDA? Although only the early returns are in, it appears that the answer may be few or none.<sup>129</sup>

If indeed *Pearson* authorizes this easy path to the marketplace, the main casualty will be the new drug approval process itself — long the consumers' first line of defense against ineffective or dangerous drugs reaching the market. Any erosion of that process is a body blow to the safety of American consumers, yet that may be the consequence of *Pearson*. FDA now has the unenviable task of trying to protect the American people while adhering to *Pearson*. It may be an unmeetable challenge. For consumers, however, the message of *Pearson* is unmistakable — buyer beware.

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<sup>129</sup> See, e.g., *Pharmanex, Inc. v. Shalala*, 35 F. Supp. 2d 1341 (D. Utah) (rejecting FDA's contention that Cholestin, a dietary supplement consisting of red yeast rice marketed to lower cholesterol, was a "drug" subject to the new drug requirements of the FDCA because Cholestin's active ingredients are identical to those in prescription medication used to reduce cholesterol levels; Sheryl Gay Stolberg, *FDA Issues a Health Warning on Weight-Loss Supplement*, N.Y. TIMES, NOV. 12, 1999, at A19 (reporting FDA warning that Triax Metabolic Accelerator, a dietary supplement made from a derivative of thyroid hormone and sold for weight loss, should be considered an unapproved new "drug").

Perhaps the best-known illustration of this point is the extraordinary success of the supplement called SAM-e (S-adenosylmethionine), which is touted as a treatment for both depression and arthritis. See, e.g., Karen S. Peterson, *Self-Prescribed Antidepressant Highly Touted But Untested*, USA TODAY, Aug. 10, 1999, at 5D; Shari Roan, *A Wonder Pill Raises Doubt As Well As Hope*, THE RECORD (Bergen County NJ), July 12, 1999, at H1; Jenny Deam, *Problem or Solution? Medical Professionals Debate the Safety of Supplements*, DENVER ROCKY MOUNTAIN NEWS, Aug. 24, 1999, at 3D. SAM-e was briefly studied as an anti-depressant in the United States, but FDA halted trials because of concerns about the compound's stability. Despite FDA's concerns, and a hefty price-tag of \$1 per pill, SAM-e appears to be the fastest growing supplement on the market. Thus far, SAM-e's manufacturers have not made explicit health claims on the product's label, but instead have maintained, among other things, that it helps "mental well-being." Elsewhere, however, the supplement is being touted as a treatment for depression, arthritis, and a host of other ailments. After *Pearson*, however, it is only a matter of time before SAM-e is marketed to consumers as a treatment for depression, arthritis, and who knows what else.

This illustration brings into focus two problems triggered by *Pearson*. First, where the product in question is a naturally occurring one that can be sold as a dietary supplement, manufacturers no longer will bother to undergo the NDA process. As a result, neither the scientific community nor the public will have access to basic and reliable scientific information about the safety and efficacy of the product because none will be produced. Second, and equally troubling, SAM-e is being sold to treat depression. Self-medication to treat a disease as complex and debilitating as depression introduces an entirely separate layer of complex concerns, especially because physical illnesses, such as anemia or malfunctioning thyroid, often present themselves as depression. Even assuming that SAM-e shows promise in treating depression, one must ask whether consumers are really better off in having this product available in health food stores instead of through a prescription, which ensures the intervention of a trained health care professional and guarantees that the product will be made subject to FDA manufacturing rules.

