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The FDA Knows Best . . Or Does It? First Amendment Protection Of Health Claims On Dietary Supplements: *Pearson v. Shalala*

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The FDA Knows Best. . . Or Does It? First Amendment Protection of Health Claims on Dietary Supplements: *Pearson v. Shalala*[*]

I. INTRODUCTION

Early decisions of the U.S. Supreme Court in the area of the First Amendment guarantee of free speech recognized the American devotion to the concept of the free flow of ideas.[1] As these cases articulate, the democratic ideal rests on the belief that the people are sovereign in their ability to sift through the varying expressions of their fellow citizens—whatever the motivation of the speaker—in order to glean true information from among the deceptive chaff of blatantly false or merely misleading communication. Many scholars note, however, that the Founders seem to have adopted the Bill of Rights as a quick expediency in order to convince the states to adopt the Constitution, which was viewed as a harbinger of the immense power to be exercised by the federal government, and, as a consequence, did not clearly consider the meaning and nature of "speech" and other rights protected therein.[2]

As a result of this lack of thoughtful intent, the definitional development of these rights has been, by necessity, created through the constitutional determinations of the Supreme Court. Jurisprudence in the First Amendment freedom of speech analysis has been particularly dynamic, as the courts have had to decide how to regulate the increasing avenues of communications provided to the average U.S. citizen in the information age. In recent decades, the Court has attempted to define "speech" more concretely, or more expansively, and has created classifications of speech that are accorded varying levels of First Amendment protection based on the social value of the speech.[3]

As the Supreme Court has developed this hierarchy of speech protection under the First Amendment, regulation has become

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1. *See* Phillip J. Cooper, *Rusty Pipes: The Rust Decision and the Supreme Court's Free Flow Theory of the first Amendement*, 6 NOTRE DAME J.L. ETHICS & PUB. POL'Y 359 (1992). *See also* Abrams v. United States, 250 U.S. 616, 630 (1919) (Holmes, J., dissenting).

2. *See* Robert Bork, *Neutral Principles and Some Fundamental First Amendment Problems*, 47 MD. L.J. 1,22 (1971).

3. *See generally* Virginia State Bd. of Pharmacy v. Va. Citizens Consumer Council, 425 U.S. 748 (1976).

increasingly complex, intruding in the ordinary affairs of U.S. domestic life. The 'awe of the expert,' characteristic of the New Deal era, created a system of administrative agencies interested in protecting the public from the dangers of modern society, including dangers to public health and safety. Ultimately, some argue that the administrative state has taken this duty of protection to the extreme of protecting the individual citizen even from himself or herself. Critics of the administrative state note that the elevation of the 'expert' leads to the degradation of democracy and diminishes the individual's ability to act in his or her own best interests by making informed choices.[4] These critics note that the goal of regulatory agencies ought to first be to "ensure genuinely informed choices, 'rather than to dictate outcome from Washington'" and that the administrative state should establish a priority to be more dedicated to "educative, rather than regulatory" functions.[5]

The FDA's regulation of health claims on labels of dietary supplements sits at the intersection of these two areas of debate—the evolution of First Amendment speech protection and the effects of the administrative state on democracy. The Dietary Supplement Health and Education Act (DSHEA) does not require dietary manufacturers to prove the safety of the product before it reaches the shelf. Supplements are placed in the same category as foods under the FDA regulatory scheme; however, the health claim labeling requirements of the Dietary Labeling and Education Act applying to dietary supplements were not repealed with the DSHEA, and strict limitations on labeling remain in place.

Section II of this note focuses on the relevant history of the FDA regulation of health claims on the labels of dietary supplements, as well as the evolution of the commercial free speech strand of First Amendment jurisprudence. Section III focuses on the facts of *Pearson v. Shalala,* a 1999 decision in the D.C. Circuit Court of Appeals, that focuses the debate on commercial free speech and FDA regulation of health claims. Section III outlines the facts and reasoning of the court in *Pearson.* Sections IV and V explain the application of the Supreme Court's *Central Hudson* test and its failure to encompass the complexity of interests involved in this regulatory/free speech analysis. This section will also explain why the Supreme Court should use the failure of the *Central Hudson* test in this context to revise its notion of commercial speech protection to better suit the government and public interests involved. Section VI provides a summary of the author's reasons why the agency should revise its standard of regulation in such cases in order to

4. *See* Cass R. Sunstein, *Informing America: Risk, Disclosure, and the First Amendment*, 20 FLA. ST. U. L. REV. 653 (1993).

5. *Id.*

comply with the First Amendment, and why the agency should reconsider its determination that mixed categories of speech, such as health claims, should be provided a lower degree of First Amendment protection than other categories of speech. The section will close by suggesting that dietary supplements should be subjected to safety approval by the FDA, while health claims should be permitted without prior restraint and removal upon proof of falsity. Section VII concludes the article.

II. BACKGROUND

A. The First Amendment and the Commercial Speech Doctrine

As noted earlier, the Bill of Rights was added as a quick addendum to the Constitution in order to assuage fears of an overbearing federal government and thereby to coax the states to ratify the Constitution.[6] Consequently, the Founders did not fully explicate the meaning of the terms used therein.[7] The First Amendment provides that "Congress shall make no law . . . abridging the freedom of speech," and the definition of the term "speech" is continuously evolving through the Supreme Court's analysis in relevant cases.

Although the definition of speech, therefore, must by necessity be a creation of the Court, one thing is clear: neither the plain language of the Constitution nor the debates of the Founders differentiate between the full First Amendment protection of "pure" speech and the lesser degree of protection used for subcategories such as commercial speech, deemed by the Court to be of less social worth.[8] This valuation of speech is purely a creation of the Court.[9]

While the Court has long recognized that, at times, a government interest may justify the restriction of speech based on time, place and manner, several justices, most notably Holmes and Brandeis, warned against the evils of an over-censoring, patronistic government.[10] Scholars and jurists alike, however, almost unanimously concede that the ability

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6. *See* Bork, *supra* note 2, at 22.

7. *See id.*

8. Richard A. Posner, *Free Speech in an Economic Perspective*, 20 SUFFOLK U. L. REV. 1, 6–7 (1986).

9. Some scholars even suggest the Founders did not ignore the high value of commercial speech at all but valued it as highly as political expression. *See* Brian J. Waters, *A Doctrine in Disarray: Why the First Amendment Demands the Abandonment of the Central Hudson Test for Commercial Speech*, 27 SETON HALL L. REV. 1626, 1647 (1997).

10. *See* Brandeis' discussion in Whitney v. California, 274 U.S. 357, 375–76 (1927) (Brandeis, J., concurring), *cited in* John M. Blim, *Free Speech and Health Claims under the NLEA of 1990*, 88 NW. U. L. REV. 733, 749 n.127 (1994); *see also Whitney*, 274 U.S. at 371; *Abrams*, 250 U.S. at 624 (Holmes, J., dissenting).

of the government to restrain free speech does not merely exist when "an immediate check is required to save the country."[11] Government interests such as the protection of public health and safety have traditionally justified extensions of government regulatory authority.[12]

As Richard Posner noted in a Suffolk University Law Review article, "the state must be allowed to restrain speech if necessary in order to avert lesser catastrophes."[13] To 'avert' these 'lesser catastrophes,' the Court has attempted to create a value system with core speech most strongly exhibit[ing] the qualities of a public good at the top of the First Amendment protection scheme with other lesser categories of speech less protected.[14] The Court first recognized commercial speech as a distinct category worthy of limited protection in a case addressing the publication of pharmaceutical prices by Virginia pharmacies.[15] The Virginia Citizens Consumer Council brought a suit in 1974 to invalidate a Virginia law prohibiting pharmacists in the state from advertising the prices of the drugs. The penalty for advertising drug prices was to be found guilty of "unprofessional conduct" for the publication.[16]

The Court defined commercial speech as speech that does "no more than propose a commercial transaction."[17] Justice Blackmun, writing for the court, relied mainly on the 'free flow of information' theory and the notion that if we assume that the First Amendment is "primarily an instrument to enlighten public decision-making in a democracy," the Court could not devalue "concededly truthful information about entirely lawful activity."[18] With this decision, the Court noted that both the speaker and the recipients of speech have a right at stake in the free flow of commercial information.[19] The Court weighed the competing government and public interests at issue and invalidated the Virginia statute, determining that the court's patronistic reasons for restraining communication were unacceptable.[20]

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11. *Abrams*, 250 U.S. at 630 (Holmes, J., dissenting).

12. *See* Posadas de Puerto Rico Assoc. v. Tourism Co. of Puerto Rico, 478 U.S. 328, 340 (1986); Rubin v. Coors Brewing Co., 514 U.S. 476, 485 (1995).

13. Posner, *supra* note 8, at 6.

14. *See* Daniel A. Farber, *Free Speech Without Romance: Public Choice and the First Amendment*, 105 HARV. L. REV. 554, 562 (1991).

15. *Virginia State Bd. of Pharmacy*, 425 U.S. at 748.

16. *See id.* at 752.

17. *Id.* at 752 n.2.

18. *Id.* at 773.

19. *See id.* at 756.

20. See Blackmun's statement that

> the State's protectiveness of its citizens rests in large measure on the advantages of their being kept in ignorance . . . There is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that

While the Court deemed commercial speech worthy of limited protection under the First Amendment in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council,* Justice Blackmun was quick to assert that the time, place and manner restrictions imposed on pure speech were equally applicable, if not more so, in determining whether a regulation improperly abridges a commercial free speech right.[21] In addition, Justice Blackmun presented two reasons why the Court was choosing to provide a lesser degree of protection to commercial speech than to other forms of expression: (1) commercial speech is "more easily verifiable by its disseminator" and (2) commercial speech may be "more durable than other kinds [of speech]."[22] As a result of this objective verifiability and hardiness of commercial speech, Justice Blackmun clearly stated that commercial speech is not entitled to the usual prohibition against prior restraint, and that a speaker may be required to attach disclaimers or other counter information to the speech in order to combat possible deceptive effects.[23] Notwithstanding this lesser protection, however, the Court forcibly agreed with the lower court's determination that a State may not "completely suppress the dissemination of concededly truthful information about entirely lawful activity, fearful of that information's effect upon its disseminators and its recipients."[24]

While the Court clearly recognized commercial speech as a category deserving some degree of First Amendment protection in *Virginia State Board of Pharmacy*, Justice Blackmun's opinion did not formulate a clear standard of scrutiny for evaluating regulations that abridge commercial speech. However, in 1980, in the case of *Central Hudson Gas v. Public Service Commission,* the court formulated an intermediate standard of scrutiny it would apply to regulations of commercial speech.[25] The *Central Hudson* controversy arose during a severe fuel shortage during which the New York Public Service Commission prohibited electrical utilities from publishing promotional advertising that heightened the aggregate demand for electricity. [26] In this case, the government interest in regulation was substantially higher than the patronistic interest asserted by the state of Virginia in *Virginia State*

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the best means to that end is to open the channels of communication rather than to close them.

Id. at 769-70.

21. *See id.* at 771.
22. *Id.* at 772 n.24.
23. *See id.*
24. *Id.* at 773.
25. 447 U.S. 557 (1980).
26. *See id.* at 560.

Board of Pharmacy. Before setting out the standard, the Court noted that "[t]he protection available for particular commercial expression turns on the nature both of the expression and of the governmental interests served by the regulation."[27] The Court then stated the test as follows: (1) Is the communication worthy of First Amendment protection because it is concerning lawful activity and not misleading? (2) Is the asserted governmental interest substantial? (3) Does the regulation directly advance the governmental interest asserted? (4) Is the regulation not more extensive than is necessary to serve that interest?[28] If the answers to prongs one and two are yes, the court will proceed to prongs three and four. Otherwise, the analysis ends at prong two. The court determined in *Central Hudson* that the Public Service Commission regulation did not pass this test and was therefore invalid as a violation of the First and Fourteenth Amendment.[29]

From the very adoption of the test in *Central Hudson*, however, several members of the Court noted the ambiguity inherent in its language[30] and the difficulty in justifying the difference in the level of protection accorded to commercial speech and that accorded to other forms of truthful, non-misleading speech. In a concurring opinion, Justice Blackmun stated that "[n]o differences between commercial speech and other protected speech justify suppression of commercial speech in order to influence public conduct through the manipulation of the availability of information."[31] In other words, the government should no more be able to suppress information in order to influence consumer choice in a situation involving commercial speech than it may suppress core speech, such as political speech, in order to influence public conduct.

Also in 1980, the Court decided *Posadas de Puerto Rico Assoc. v. Tourism Co. of Puerto Rico,* in which Justice Rehnquist made his much-debated statement that the "greater power to completely ban casino gambling necessarily includes the lesser power to ban advertising of casino gambling."[32] In this case, the Court determined under the *Central Hudson* scheme that the Puerto Rican legislature's regulation disallowing the advertisement of gambling in Puerto Rico was valid under the First Amendment.[33] The government interest asserted under the *Central Hudson* test was the legislature's belief that gambling would produce

27. *Id.* at 563.
28. *Id.* at 566.
29. *See id.* at 572.
30. *See also* Blim, *supra* note 10, at 747–49.
31. *Central Hudson,* 448 U.S. at 578.
32. 478 U.S. at 345–46.
33. *See id.* at 332.

"serious and harmful effects on the health, safety and welfare of the Puerto Rican citizens."[34] Although Justice Rehnquist's "greater/lesser" formulation seems excessively broad enough to encompass nearly all commercial speech, this logic has been limited in subsequent cases by the notion that this principle is applicable only when the commercial activity involved is never in the citizens' best interest.[35]

Further cases established the concept that while inherently misleading communication is not protected under the *Central Hudson* standard, potentially misleading information is protected to some extent. If truthful advertising related to lawful activities is potentially misleading, "the States may not place an absolute prohibition ... on potentially misleading information if the information also may be presented in a way that is not deceptive."[36] However, in *Board of Trustees of the State University of New York v. Fox,* a 1989 case, the Court determined that the fourth prong of the *Central Hudson* test, the appropriateness of the means to the government's asserted end, was to be evaluated under a "reasonable fit" standard and not a "least restrictive means" standard.[37]

The Court has recognized in subsequent cases that complete suppression is often not acceptable under the *Fox* "reasonable fit" standard. For instance, in *Bates v. State Bar of Arizona*[38], a 1977 case, the Supreme Court had disapproved of the State Bar's decision to discipline several attorneys who advertised their fees for certain legal services. The Court took this action because it disapproved of the notion that "the public is not sophisticated enough to realize the limitations of advertising, and that the public is better kept in ignorance than trusted with correct but incomplete information."[39] The Court went on to determine that the advertisement was not inherently misleading and therefore, the "preferred remedy is more disclosure rather than less."[40] In other words, if complete suppression is chosen over disclaimers, the government regulation is subject to question because it used the most restrictive means available to meet the government purpose. Later cases, such as *In Re R.M.J,* decided by the Court in 1982, further clarify the Court's position that the states may regulate commercial speech "in a

34. *Id.* at 341.
35. Blim, *supra* note 10, at 756.
36. Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999).
37. Board of Trustees v. Fox, 492 U.S. 469, 480 (1989).
38. 433 U.S. 350 (1977).
39. Bates v. State Bar of Arizona, 433 U.S. 350, 374–75 (1977).
40. *Id.* at 376.

manner no more extensive than reasonably necessary to further substantial interests."[41]

B. History of Congressional Legislation and FDA Regulation

The courts have held that health claims on dietary supplement labels fall under the rubric of commercial speech, according it a lesser level of scrutiny than 'pure' speech,[42] although the wisdom of this decision is questioned by many scholars who argue that health labels are partly informational and partly commercial and should therefore be protected under a more rigorous level of scrutiny.[43] The federal Food and Drug Administration (FDA) has long taken a hostile stance against the inclusion of health claims on dietary supplement labels. A dietary supplement was classified as a drug under the Pure Food and Drugs Act of 1906,[44] if it was "intended to be used for the cure, mitigation, or prevention of disease of either man or other animals."[45] However, the courts paid little heed to the food/drug classification and few health claims were litigated under the 1906 Act because the burden of proving falsity and fraudulence rested on the government.[46] With the federal Food, Drug, and Cosmetic Act of 1938,[47] however, the definition of a 'drug' was extended and the government's burden of proof was lessened to require only proof of falsity, and not fraudulence.[48]

The Drug Amendments of 1962 required pre-market approval of the effectiveness and safety of a drug with the burden of proof placed on the sponsor. The standard of proof was so high that it was nearly impossible for a health claim for a food or supplement to satisfy the required proof of a drug claim.[49] Because of this, health claims were virtually prohibited under the 1962 Amendments. The FDA determined in 1979, after holding joint hearings with the FTC on health claims, that scientific methods of verifying health claims were not sufficiently sophisticated at

41. *In re R.M.J.*, 455 U.S. 191, 207 (1982).

42. *See* Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 67–68 (1983).

43. *See* Martin H. Redish, *Product Health Claims and the First Amendment: Scientific Expression and the Twilight Zone of Commercial Speech*, 43 VAND. L. REV. 1433 (1990); R. George Wright, *Freedom and Culture: Why We Should Not Buy Commercial Speech*, 72 DENV. U. L. REV. 137 (1994); Edward Dunkelberger & Sarah E. Taylor, *The NLEA, Health Claims and the First Amendment*, 48 FOOD & DRUG L.J. 631 (1993).

44. Pub. L. No. 59-384, 34 Stat. 768 (1906).

45. *Id. See also* Richard M. Cooper, et al., *History of Health Claims Regulation*, 45 FOOD DRUG COSM. L.J. 655, 658.

46. *See id.*

47. Pub. L. No. 75-717, 52 Stat. 1040 (1938).

48. *See* Cooper, et al., *supra* note 45, at 658.

49. *See id.*

that time to justify the inclusion of health claims on products without misleading consumers.[50]

In 1984, Kelloggs opened the floodgates of health claims in advertising by placing a claim on boxes of All-Bran stating that the cereal was high in fiber and that the National Cancer Institute had established that a high-fiber diet could reduce the risk of some types of cancer.[51] Kelloggs did not consult with the FDA before attaching the claim to its cereal boxes, yet the agency took no action against Kelloggs. Other manufacturers interpreted this lack of FDA action as an invitation to flood the marketplace with health-related claims as a part of their marketing schemes.[52] While this led to an increase in healthier foods and more health information in the market, it also encouraged many companies to attach unsubstantiated and even misleading health claims to their products under the notion that the FDA would take no action.[53] In 1987, the FDA proposed a rule that would have permitted health claims relating to "diagnosis, cure, mitigation, treatment or prevention of human disease" to be used without requiring FDA pre-approval.[54] Although the flexibility apparent in the 1987 proposed rule and the outpouring of new health claims that followed the Kelloggs affair had the positive effect of increasing the number of healthful foods on the market, the proposed rule spurred industry concerns, and numerous comments were submitted to the FDA encouraging the agency to develop a definitive health claim policy.[55] In response to this outpouring of concern, the FDA prepared to propose new regulations in 1990 that would substantially return the approval of health claims to the hostile atmosphere that existed before the Kelloggs phenomenon.[56] This attempt, however, was cut short by Congress's passage of the Nutrition and Labeling Act of 1900.

In 1990, Congress anticipated the proposed system of policies under preparation by the FDA, and passed its own regulation, the Nutrition Labeling and Education Act of 1990 (NLEA).[57] Industry lobbyists and scholarly commentators who had cautioned about First Amendment problems during the notice and comment period for the FDA proposed regulations were virtually ignored by Congress during the debate preceding passage of the NLEA.[58] With the passage of the NLEA,

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50. *See id.* at 662.
51. *See* Blim, *supra* note 10, at 736; Cooper, et al., *supra* note 41, at 662–63.
52. *See* Cooper, et al., *supra* note 43, at 662-63 (1990).
53. H.R. Rep. 101-980, at 7 and 23 (1990).
54. *See* Cooper, et al., *supra* note 43, at 661.
55. *See id.* at 666.
56. *See id.* at 691.
57. Pub. L. 101-535, 104 Stat. 2353 (1990).
58. *See* Dunkelberger & Taylor, *supra* note 43, at 632-33. These cautions were presumably

Congress required the FDA to formulate regulations for health claims within twelve months under a "significant scientific agreement standard."[59] The FDA was directed to use a rulemaking process rather than a case-by-case, adjudicatory method to approve or disapprove of health claims, and Congress left the working definition of the "significant scientific agreement" standard to the FDA's discretion, leaving the agency free to "require near unanimity among scientists" regarding the validity of a claim before the agency would approve its use.[60]

Under the final FDA NLEA regulations, a dietary supplement manufacturer may only include a health claim on the label of the supplement if that health claim has been previously approved in FDA regulations.[61] If the health claim has not been approved in an FDA regulation, the organization may petition the FDA for an allowance, abandon the claim, or seek judicial review of the agency's decision.[62] The FDA has only approved eight health claims to date, and only one seems to be applicable to dietary supplements,[63] thus illustrating the agency's immense power to limit access to health information.[64] The agency codified its "procedure" for authorizing health claims in 21 C.F.R. § 101.14(c) as follows:

> [T]he FDA will establish a regulation approving a health claim only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.[65]

In practice, this standard of "significant scientific agreement" has proven to be ill-defined and virtually impossible to satisfy, as will be seen below.[66] In addition, if a company attaches an unapproved health claim to a label, this "exposes the company and its officials to criminal

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overlooked in an attempt to accommodate varying heated viewpoints among legislators regarding the policy at issue in health claim regulation. *See generally* H.R. Rep. No. 101-980 (1990), for a clear view of the partisan divisiveness in Congress regarding the NLEA and FDA health claims regulation in general.

59. Dunkelberger & Taylor, *supra* note 43, at 633.

60. Blim, *supra* note 10, at 739.

61. *See id.* at 740.

62. *See id.* at 742.

63. *See* Melinda Ledden Sidak, *Dietary Supplements and Commercial Speech*, 48 FOOD & DRUG L.J. 441, 450–51.

64. *See* Dunkelberger & Taylor, *supra* note 43, at 635.

65. Health Claims: General Requirements, 21 C.F.R. § 101.14(c).

66. *See* Sidak, *supra* note 63, at 452–61.

prosecution" even if the claim is "truthful and fully substantiated" but merely failed to meet the FDA's discretionary standard.[67] This result seems to stand in clear violation of First Amendment principles.

III. *PEARSON V. SHALALA*

Durk Peterson and Sandy Shaw, dietary supplement marketers, desired to present four health claims on their dietary supplement labels. The labels read as follows: (1) consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer; (2) consumption of fiber may reduce the risk of colorectal cancer; (3) consumption of fatty acids may reduce the risk of coronary heart disease; (4) .8 mg. of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form.[68] The FDA refused to certify any of these claims, although it later allowed a more general health claim regarding the foliate-neural tube defect claim purportedly because of political pressure, and not additional scientific justification.[69] The FDA explained that the rejection of these health claims was based, not on lack of scientific evidence of their verity, but rather because they "failed to give rise to 'significant scientific agreement.'" [70] The agency, however, failed to explain how it defined or measured "significant scientific agreement."[71]

Pearson and Shaw brought an action in federal district court seeking relief from this FDA decision based on three main theories: (1) the FDA violated their First Amendment rights by refusing to employ a less restrictive means of regulation, thus allowing them to include health claims on labels along with disclaimers stating that the FDA had not approved the claims; (2) the FDA failed to explain the meaning and measurement of "significant scientific agreement" and effectively imposed a prior restraint on communication that both violates the plaintiffs' First Amendment rights to free speech and deprives them of their liberty in violation of their Fifth Amendment right to due process; and (3) the FDA engaged in arbitrary and capricious action under the Administrative Procedure Act (APA) because it failed to "give some definitional content" to "significant scientific agreement."[72] The district court rejected all of these claims.[73]

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67. *See* Dunkelberger & Taylor, *supra* note 43, at 634–36.

68. *See Pearson*, 164 F.3d at 652.

69. *See id.* at 653. The FDA denies that mere political pressure caused the agency to approve the foliate-neural tube and asserts that new scientific studies justified the approval. *Id.* at 654.

70. *Id.* at 653.

71. *Id.*

72. *Id.* at 660.

73. *See id.* at 654.

While the D.C. Court of Appeals acknowledged the merits of the First and Fifth Amendment claims and extensively discussed the First Amendment argument in some detail, it declined to decide the case based on these theories. The agency action was a clear violation of the APA and, therefore, consideration of these more substantive claims was not necessary to reach the court's desired result in this case.[74] The court reversed the decision of the district court and remanded to the district court with instructions to remand to the FDA for reconsideration of Pearson and Shaw's health claims.[75]

The court did, however, lend credence to Pearson and Shaw's First and Fifth Amendment claims, noting the probability that these claims may have merit and may be reached in a case in which the APA claim does not exist. This case was the first seriously considered challenge of the NLEA based on First and Fifth Amendment claims to reach a U.S. Court of Appeals where the issues were ripe for decision and the parties had standing to sue. Thus, the fact that the D.C. Circuit Court of Appeals recognized the merit of these Constitutional challenges to the Act makes it more likely that similar challenges will be brought in the near future if the problems with the Act are not remedied through new legislation or FDA regulatory solutions.

IV. THE *CENTRAL HUDSON* TEST

A. First Amendment Violations

In its evaluation of the First Amendment claims, the court first noted that the health claims are to be evaluated under the commercial speech doctrine.[76] Therefore, the court's first inquiry was concerning the use of disclaimers as an effective but less restrictive means of regulation than the FDA's choice to completely suppress health claims on labeling. The court considered two arguments made by the government in this area: (1) the health claims are "inherently misleading" because they failed to pass the muster of the "significant scientific agreement" standard and therefore they are not entitled to any First Amendment protection and, in the alternative, (2) the health claims are merely potentially misleading under the *Central Hudson* analysis so the government may completely ban the publication of health claims, without even considering the less restrictive means of attaching disclaimers when the claims do not meet the "significant scientific agreement" standard.[77]

74. *See Pearson*, 164 F.3d at 660.
75. *See id.* at 661.
76. *See id.* at 655.
77. *See id.*

The court first derailed the government's argument that the health claims were inherently misleading, based on the notion that this was a patronistic argument underestimating the sophistication and ability of consumers to make choices based on the available information.[78] Then, turning to the possibility of characterizing the health claims as "potentially misleading" under the *Central Hudson* scheme, the court determined that commercial speech may be a proper classification of the health claims because of the difficulty that the independent consumer would face in trying to independently verify the claim and the possibility that the consumer might assume that the FDA had approved the claims attached to a label.[79]

Because the health claims could possibly be classified as "potentially misleading," the court was obliged to apply the next three parts of the *Central Hudson* test. The court determined that the "asserted government interests" in this instance, "protection of public health" and "protection of consumer fraud", were "substantial."[80] However, the court faced the last two steps of the test with more difficulty. At this point in the analysis, the test requires that the court determine whether the regulation "directly advances the government interest asserted"[81] and whether the government regulation is a "reasonable"[82]means to achieve the desired end.

As to the first asserted government interest, protection of public health, the court again noted that the dietary supplements at issue are not dangerous in themselves and the government cannot completely suppress a communication merely to cause the consumer to better spend his or her health dollars. Once again, this was based on the reasoning that the court should be wary of government regulations that attempt to hide information from the public as the government acts for 'the consumer's own good.'[83] Therefore, the court's analysis of the FDA's public health argument ended at the third step in the *Central Hudson* analysis. Here, however, the court saw more merit in the FDA's consumer fraud argument, that complete suppression of health claims would prevent consumer fraud and confusion, and thus "directly advance the

78. *See id.* The court cited the *Peel* opinion which states that this patronistic method of determining that a communication is inherently misleading is tantamount to a determination that consumers are "no more discriminating than the audience for children's television." *Id.* (quoting Peel v. Attorney Registration and Disciplinary Comm'n of Illinois, 496 U.S. 91, 105 (1990)).

79. *Pearson*, 164 F.3d at 655.

80. *Id.* at 656.

81. *Central Hudson*, 447 U.S. at 566.

82. *Fox*, 492 U.S. 469, 480 (1989).

83. *Pearson*, 164 F.3d at 656.

governmental interest asserted."[84] Therefore, the court subjected the consumer fraud argument to the "reasonable fit" standard of the fourth prong of the *Central Hudson* test.

As a part of the fourth prong analysis, the court noted that, under Supreme Court precedent, even when the court determines that the government's regulation "reasonably fits" its purpose, the regulation does not pass muster if it is "substantially excessive" and disregards a "far less restrictive and more precise means."[85] Under this reasoning, the court stated that the Supreme Court, in a series of commercial speech cases, has affirmed its dedication to the idea that the preference is for more communication rather than less, making a disclaimer preferable to complete suppression if this less restrictive means fulfills the government's purpose.[86] The court expressed confidence that disclaimers would meet the government's purpose in this instance, but left this decision to the discretion of the agency on remand.

The court next gave a cursory glance to Pearson and Shaw's argument that the regulations were a "prior restraint" on speech and, as such, were prohibited under the First Amendment. Appellants argued that the failure of the agency to sufficiently define the phrase "significant scientific agreement" was effectively a prior restraint because it does not inform labelers of the method by which the FDA determines that a label satisfies the "significant scientific agreement" standard.[87] In other words, the appellants had the burden of proving "significant scientific agreement," but they were unaware of the standard of proof required by the FDA. This argument was largely skimmed over because the appellants did not fully articulate their argument on this issue, but the court was quick to note that this may have been a fruitful claim if Pearson and Shaw had pursued this argument further.[88]

B. The Unarticulated Standard

Continuing its analysis that the FDA's failure to give some "content" to the "significant scientific agreement" standard, the court next turned to Pearson and Shaw's argument that they had been deprived of a liberty under the Fifth Amendment without due process.[89] Pearson and Shaw had argued that they had not been accorded sufficient due process

84. *Id.* at 656.
85. *Id.* at 658 (citing *Fox*, 492 U.S. at 479).
86. *See id.* at 657.
87. *Id.* at 660.
88. *See Pearson*, 164 F.3d at 660.
89. *See id.*

because of the vagueness of the agency's "significant scientific agreement" standard.[90] However, the court did not fully consider this argument because it determined that this vagueness also made the FDA's action "arbitrary and capricious" under the APA and that Pearson and Shaw would receive the same relief under the APA that they would be entitled to under the Fifth Amendment.[91]

Although the court required the FDA to give content to the term "significant scientific agreement" on remand, the court clearly stated that the FDA was not required to provide a complete definition in this one instance.[92] Congress had granted the FDA authority to regulate health claims on dietary supplements through a system of regulatory rulemaking, not adjudication, and this grant of authority presupposed that the agency could create a working definition on a "sub-regulation by sub-regulation" basis.[93] In the end, the court only required that the regulated class be able to "perceive the principles which are guiding agency action."[94]

V. ANALYSIS

Pearson highlights several of the problems with the current formulation of health claim regulation in the context of First Amendment analysis and the public interests involved in the publication of health claims. The DC Circuit Court of Appeals did not delve to the bottom of the situation in this instance to determine the constitutionality of the FDA's sub-regulations under the Nutritional Labeling and Education Act of 1990, because the relief sought by Pearson and Shaw was available through a less drastic method.[95] However, the dicta of the court's opinion lends credence to the idea that future litigation may invalidate the FDA's Nutritional Labeling and Education Act procedure if (1) the claimants fully explicate their First and Fifth Amendment causes of action and (2) the court chooses to afford relief under a constitutional rubric rather than an APA violation.[96] While there is clearly a need for FDA regulation of dietary supplements, the FDA's heavy-handed NLEA regulations both undermine the legislative purpose behind the NLEA and abridge the constitutional rights of those class members affected by the regulation, the speakers, and the public.

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90. *See Pearson*, 164 F.3d at 660.
91. *See id.*
92. *See id.* at 661.
93. *See id.*
94. *Id.*
95. *See id.* at 660.
96. *See id. See also* Pearson v. Shalala, 172 F.3d 72, 73 (D.C. Cir. 1999).

A. Trends in the Regulation of Dietary Supplement Health Claims

Congress clearly expressed the government's interest in regulating health claims in dietary supplements in its "findings and purposes" for the Dietary Supplement Health and Education Act of 1994. This piece of legislation clarified that health claims for dietary supplements under the NLEA are to be determined under the same standards as are health claims for foods.[97] According to national studies conducted in 1994, at least fifty percent of Americans consume dietary supplements with the purpose of improving their nutrition.[98] The proliferation of health claims following the Kelloggs claim in the 1980s itself substantiates the idea that healthy foods and supplements are big business in America.[99] In 1994, studies estimated that 600 dietary supplement manufacturers produce 4,000 products and account for annual sales of "at least four billion dollars."[100] This wide-scale use of supplements may be attributed in part to an increase in scientific validation of the health benefits of supplement use. While the FDA and the healthcare community have traditionally been hostile to the dietary supplement industry, scientific studies have shown links between supplement use and disease prevention.[101] These findings further emphasize the interests of the government and the public in "improv[ing] the health status of United States citizens" by supplementing traditional health care with more holistic health practices to reverse the increase in healthcare spending, which had reached one trillion dollars annually in 1994.[102] Indicators show that Americans will continue this escalated use of dietary supplements and therefore the government should have an interest in ensuring that the public is making health decisions based on the most reliable information available.

This governmental interest cuts both ways in the First Amendment debate over FDA approval of health claims. The question is whether the government should serve as the gatekeeper for health claims to better ensure their accuracy, or whether the government's role should be to protect the free flow of health information under the First Amendment and to proliferate reliable information about dietary supplements to counter less reliable claims that the free flow of information allows into

97. *See* S. REP. NO. 103-410, at 1.

98. *See* 140 Cong. Rec. H11173-02, H11173 (daily ed.).

99. *See* H.R. REP. NO. 101-980, at 7.

100. B. Clair Eliason, et al., *What Physicians Can Learn from Consumers of Dietary Supplements*, 48 J. FAM. PRAC., 459 (1999); 140 Cong. Rec. H11173-02, H11173.

101. *See* Sidak, *supra* note 63, at 441.

102. *See* 140 Cong. Rec. at H11173.

the public discourse. These competing interests are confronted in *Pearson* and the underlying legislation involved in this case.

While the notion that health claim based marketing is big business in America seems to validate the idea that the courts should apply the *Central Hudson* commercial speech test to health claims regulation, this conclusion is doubtful on closer analysis. If any speech with a relation to industry can be classified as commercial speech, one might asks where this places claims related to the science of traditional medicine. Clearly there is a conflict between two areas of big business in America, traditional and nontraditional healthcare, and the traditional medical community is now beginning to take note of the idea that they must be aware of nontraditional healthcare solutions, such as dietary supplements, if they are to remain as reliable sources of health information for their patients.[103] Congress, the FDA, and the courts must look to the medical model of information dissemination to determine whether the FDA's method of health claim sifting is appropriate under the First Amendment free-flow theory. Where science and commerce meet, the courts and the government, administrative and legislative, must establish a new concept of speech protection that is more thorough than the commercial speech standard in order to allow public access to the noncommercial, scientific component of such speech.[104] The remainder of this note will explore how this may be accomplished under the *Central Hudson* regime or under the First Amendment's protection of pure speech.

B. Commercial Speech Analysis

1. The first prong of the Central Hudson *Test*

The court in *Pearson* unquestioningly assumed that health claims should be evaluated under the commercial speech scheme based on the *Central Hudson* test.[105] The appropriateness of this categorization is questionable, but even under the commercial speech standard, the FDA NLEA regulation fails to meet the test on several grounds.

First, the *Central Hudson* test is intended to protect communications that are true and non-misleading. The Supreme Court's entire reason for creating the subcategory of commercial speech and providing it less protection than pure speech was based on the notion expressed by Justice

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103. *See* Eliason, et al., *supra* note 100, at 459.

104. *See* Lars Noah & Barbara A. Noah, *Liberating Commercial Speech: Product Labeling Controls and the First Amendment*, 47 FLA. L. REV. 63, 90 (1995).

105. *See Pearson*, 164 F.3d at 655.

Blackmun that commercial speech is somehow more objectively "verifiable by the disseminator."[106] As *Pearson* demonstrates, health claims may be objectively verifiable by the producer, Pearson and Shaw in this case, but the truth of the claim is of little import because the FDA imposes a subjective standard of verification on the health claim before it is even published. In *Pearson*, there was not a "dearth of evidence" to verify the health claim,[107] but, rather, the FDA imposed an arbitrary subjective standard of truth.

Pearson and Shaw's health claims failed to meet an impossibly high standard of "significant scientific agreement"—impossible because the FDA failed even to specify in this instance what quality and quantity of evidence would be required to objectively verify the health claim. The very idea of a "significant scientific agreement" standard without definition presupposes that the FDA is more capable of weighing the sources of scientific information than are the scientific community and the public.

This authority of the FDA to effectively declare the unreliability of a health claim places the FDA in the position of a "peer review mechanism for the scientific community."[108] This extreme grant of administrative authority is not consistent with either the concept of democracy or the modern skepticism that industry lobbyists control the administrative state. Scholars note that the New Deal notion of the 'all-knowing administrative expert' has been replaced with the idea of the agency as an educator that encourages "genuinely informed choices."[109] Arbitrarily determining supposed objective truth by sifting it through the sieve of subjective FDA review does not further the purpose of ensuring informed choice. An agency such as the FDA should not be given the authority to subjectively determine the truth of a statement under the lesser protective standard afforded to commercial speech, when the justification for the lesser protection substantially rests on the idea that commercial speech is more objectively verifiable than noncommercial speech. The responsibility of verifying the claims should fall on the shoulders of the supplement marketers and the experts in the traditional medical industry who are natural competitors in this situation. Otherwise, the disseminator is deprived of the right to prove truth in this instance, as Pearson and Shaw's experience demonstrates.

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106. *Virginia State Bd. of Pharmacy*, 425 U.S. at 751 n.2. Blackmun's footnote explanation, as discussed earlier in the Note, also specifies that the differentiation is due to the increased durability of commercial speech.

107. *See Pearson*, 164 F.3d at 653.

108. Noah, *supra* note 104, at 96.

109. Sunstein, *supra* note 4, at 653.

The FDA similarly fails to justify its regulation under the second notion inherent in the first prong of the *Central Hudson* test, the concept that misleading commercial communication is not worthy of protection. Clearly the health claims in this instance are not inherently misleading.[110] When the FDA can only make a subjective judgment about the truth of a claim, it should not declare the claim to be potentially misleading merely because the agency believes itself to be more capable than the average American to determine the value and accuracy of the claim. While the average citizen may not have the resources or expertise to independently verify a claim, the traditional medical industry and pharmaceutical industry do have the resources, expertise, and motive to destroy the credibility of false claims. When the same evidence of the claim's truth or falsity is available to both the FDA and the public, the individual, and not the FDA, should be considered to be the best judge of his or her own best interest.

2. *The final prongs of the* Central Hudson *test*

After the court determines that the speech is not false or inherently misleading, the remainder of the *Central Hudson* analysis is based on the nexus between the government interest and the regulation. This is where the health claims analysis is blurred because it appears that Congress had a different interest or purpose under its NLEA legislation than did the FDA in its NLEA regulations. The *Central Hudson* test doesn't account for the philosophical shift occurring somewhere between Congressional legislation and agency discretion. When it is unclear whether the purposes of the FDA and Congress coincide, Congress's purpose should preempt the agency's purpose because the agency is only acting under authority delegated by the legislative branch. Congress has repeatedly recognized in its legislation involving dietary supplements that (1) the FDA has historically disfavored dissemination regarding dietary supplement health claims, (2) the FDA's NLEA final regulations have slowed the flood of permissible health claims to less than a trickle, and (3) the FDA has not facilitated Congress's purpose to "provide more information to consumers about supplements."[111] In a Senate report regarding the DSHEA of 1994, Congress noted that FDA NLEA regulation and subsequent enforcement attempts have had a chilling

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110. Ironically, the Supreme Court's inclusion of merely potentially misleading speech in *Central Hudson* embodies the patronistic reasoning that the Supreme Court claims to abhor in its commercial speech jurisprudence, with *Bates* standing as the seminal case in recognizing this idea. *Bates*, 433 U.S. at 375.

111. S. REP. NO. 103-410, at 35.

effect on commercial communication that is based on a well-grounded belief in its verity.[112]

Clearly the FDA is not furthering the superior government interest with its NLEA regulations—consumers are being provided with less health claim information and producers are being subjected to a prior restraint on speech. The courts cannot allow the FDA's purely patronistic interest to suffice as a "substantial interest" under the *Central Hudson* test when it conflicts with the interest of Congress in increasing the flow of health information and the public's interest in receiving health information substantiated by a respectable degree of evidence. Therefore, the questions as to whether the regulation directly advances the government interest and uses a reasonable means to accomplish that end must be answered negatively in this instance. In fact, prior to health claim approval, dietary supplements are subject to safety approval if they contain a new ingredient.[113] The FDA can determine that the product itself is unsafe for sale and subsequently remove it from the market; thus, while supplements have been shown to be toxic at certain consumption levels, the FDA cannot claim that its NLEA health claims regulations are protecting the public from any real harm other than the consumer's own faulty judgment.[114]

3. The reasoning of Posadas de Puerto Rico Assoc. v. Tourism Co. of Puerto Rico *applied to this case*

While the FDA argues under the reasoning of *Posadas* that the greater power to regulate the product assumes the lesser power to regulate commercial speech about the product, the health claims scenario is easily distinguishable from the fact situation in *Posadas.*[115] In *Posadas,* the commercial activity, gambling, could have no positive

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112. *See id.* "FDA presently writes to companies warning that severe enforcement action may follow if a company does not cease . . . making claims that the FDA deems violative. Under current law, FDA may or may not do something further to enforce that opinion. A company wishing to challenge the assertion by FDA may not do so because the decision is not "final agency action" and therefore not ripe for review . . . A company is then forced to make possibly disastrous economic choices based upon a constant fear that enforcement may follow. A well-grounded belief in the viability of a claim . . . will often be overcome by the cost of defending an action that may not be filed." (Congress attempted to solve this problem by requiring that enforcement action occur within 60 days of receipt of the threat from the FDA.).

113. Stephen H. McNamara, *Dietary Supplements of Botanicals and Other Substances: A New Era of Regulation*, 50 FOOD & DRUG L.J. 341-48 (1995).

114. *See Pearson*, 164 F.3d at 659. (citing Ibanez v. Fla. Dep't. of Bus. and Prof'l Regulation, 512 U.S. 136, 146 (1994), "If the protections afforded commercial speech are to retain their force, we cannot allow rote invocation of the words 'potentially misleading' to supplant the [government's] burden to demonstrate that the harm it recites are real and that its restriction will in fact alleviate them to a material degree." *Ibanez*, 512 U.S. at 146.).

115. *See Pearson*, 172 F.3d at 73.

effects on public health and safety; therefore, restricting advertising for gambling would not withhold possibly beneficial information from the public. Here, however, both the product itself and the suppressed information have potential health benefits for the public. The *Posadas* approach is thus distinguished from this case. In fact, the idea that the FDA can prohibit the sale of dietary supplements if its ingredients do not meet safety standards further supports the proposition that the FDA is merely trying to protect the consumer from his own inefficient healthcare spending and not from any real harm threatened by the product itself. Thus, the *Central Hudson* test, accompanied by the clarification of its progeny, fails to consider competing government interests and to give sufficient weight to the interest of the listener—the public.

C. Inappropriateness of the Commercial Speech Classification

Not only does *Pearson* demonstrate that the *Central Hudson* test fails to sufficiently evaluate essential public and governmental interests involved in the regulation of health claims, it also illuminates the possibility that: (1) health claims may not be properly classified as commercial speech; and (2) the entire idea of the commercial speech classification recognized in *Virginia State Board of Pharmacy* may be faulty under First Amendment principles.

The D.C. Circuit in *Pearson* skimmed over the classification of health claims as commercial speech in one sentence, citing *Bolger v. Youngs Drug Products*[116] as support for this classification. The court in *Bolger* recognized that the core definition of commercial speech provided in *Virginia State Board of Pharmacy*, "speech which does 'no more than propose a commercial transaction'",[117] is problematic where noncommercial content is included with commercial content. However, it classified as commercial speech advertisements of contraceptives, which advertisements included information on public issues. The advertisements/informational brochures were classified as commercial speech based on a combination of three factors: (1) the concession that the pamphlets were advertisements, (2) the reference to a specific product in the pamphlets, and (3) the fact that the distributors had an economic motivation for mailing the pamphlets.[118] However, the Court's actual motivation in *Bolger* was to prevent advertisers from superficially

116. 463 U.S. at 66-67.

117. *Virginia State Bd. of Pharmacy*, 425 U.S. at 762 (quoting Pittsburgh Press Co. v. Human Relations Comm'n, 413 U.S. 376, 385 (1973)).

118. *See Bolger*, 463 U.S. at 66.

including information about public debate in order to latch onto the "constitutional protection afforded noncommercial speech."[119]

In the context of *Pearson* and the broader context of health claims regulation, the communication involved is of an entirely different nature than that which the *Bolger* court confronted. A health claim is in itself a statement of science, a statement of public health information and a statement with a commercial motivation; this more "pure" speech is not merely an appended piece of information but *is* the communication in question.

Critics have consistently noted that the mere fact that a scientific and public health statement is communicated for a commercial reason does not justify a lesser protection for that statement.[120] They cite a 1978 case, *Egg Nutrition v. FTC* to support this contention.[121] In this case, the court determined that an egg industry organization advertisement stating that there is no scientific link between egg consumption and heart disease was commercial speech because the purpose of the advertisement was to induce consumers to buy eggs.[122] Critics then noted that the exact same communication would be protected as "pure" speech under the First Amendment if it were merely communicated by someone without a profit-motive, such as a scientist or medical researcher.[123]

Health claims clearly fall within this category of communications of scientific information differentiated from pure speech because the speaker has something to gain—a profit-motive—by publishing the speech on a label. Thus, the motivations of the speaker, good or bad, that are so zealously guarded in the protection of ordinary speech are actually the sole reason that scientific communications such as health claims are provided less First Amendment protection. This scrutiny of motivation is irrational in the health claims context, and some fear that it will have the consequence of eroding the protection of "pure" speech, which has traditionally been rigorously guarded from suppression based on motivation.[124] In fact, some question the entire idea that commercial speech should be entitled less protection because it is profit-motivated, stating that enriching the public discourse and making money are not

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119. *Id.* at 68.

120. *See* Nat Stern, *In Defense of the Imprecise Definition of Commercial Speech*, 58 MD. L. REV. 55, 128 (1999); Alex Kozinski and Stuart Banner, *Who's Afraid of Commercial Speech?*, 76 VA. L. REV. 627, 642 (1990); Redish, *supra* note 43, at 1446.

121. Egg Nutrition v. FTC, 570 F.2d 157 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978); Kozinski, *supra* note 111, at 642; Stern, *supra* note 111, at 128.

122. *See* Kozinski, *supra* note 111, at 642.

123. *See id.*

124. *See id.*

"mutually exclusive."[125] The very notion that Blackmun expressed in *Virginia State Board of Pharmacy,* that commercial speech is entitled to less protection because it is more easily objectively verified, may damage his reasoning. If one assumes a reasonable and competent public, the dangers of commercial speech are far less than those posed by "pure" speech because the public is naturally more skeptical of commercial speech and has more objective tools to test its validity.[126]

In addition, if one believes that the market has a power to direct itself, it will only seem obvious that the profit-motive of a dietary supplement producer will be contrary to the profit-motive of another market player, such as a producer of a supplement with similar effects or a pharmaceutical producer, and this opposing market player will expose the misleading nature of a health claim in order to promote his own product. Thus, competition and profit-motive add an additional check in a commercial communication setting that is not necessarily present to such a degree in a noncommercial communication setting.

VI. ALTERNATIVE MODEL FOR HEALTH CLAIM PROTECTION AND REGULATION

The intent of this Note is not to suggest that Congress return the regulation of health claims back to the "snake oil" stage where anything is allowable. Instead, it is intended to suggest that the current system of FDA regulation is unduly restrictive when one considers the public interests involved and that judicial classification of health claims as commercial speech fails to adequately protect this category of mixed scientific and commercial communication. In order to create a more balanced approach, Congress should require that the FDA thoroughly describe its "significant scientific agreement" standard in order to ensure that it is not imposing a prior restraint by virtue of its vagueness, as Pearson and Shaw asserted in *Pearson.* In addition, the courts should reconsider their classification of mixed scientific and commercial communications, such as health claims on dietary supplements, as commercial speech and avoid dividing speech along motivational lines. Health claims are health information and, therefore, it seems appropriate to consider the traditional model of medical communication when

125. FREDERICK SCHAUER, FREE SPEECH: A PHILOSOPHICAL INQUIRY, 158 (University of Cambridge Press) (1982).

126. *See* Redish, *supra* note 43, at 1455; Kozinski, *supra* note 120, at 644. Kozinski, in particular, notes that the First Amendment assumes that the public is wise enough to filter the political communications of white supremacists and the neo-Nazis, so it is illogical to assume that the public would believe that a commercial speaker would take an impartial view of the health benefits of his or her product.

determining the appropriate method of regulation and judicial adjudication.

A. Medical Model of Communication in a Legal Context

Physicians have the legal duty to inform their patients of the dangers and benefits of proposed medical procedures, prescriptions, and recommendations. This notion of informed consent that is so intrinsic to the legal doctor/patient relationship is based on the assumption that the patient, although less scientifically sophisticated than the physician, should be the judge of his or her own best interest. The doctor is instructed to "first do no harm" but to provide the patient with all of the information material to his or her health. In the end, the party responsible for making a final determination as to the course of action is the patient; the patient is the final guardian of his or her own health. This paradigm should be carried over into the creation of health claims regulation and First Amendment protection of health claims.

Some may argue that Congress and the FDA have already adopted this concept by attempting to ensure that the information received by the public is accurate and not misleading. However, if we apply this analogy more closely, the physician is the dietary supplement producer, the supplier of the nontraditional healthcare, and the patient is the consumer. While it is true that a supplement producer may not be entitled to as much credibility as a physician because of lack of credentials, presence of profit-motive, and other factors, one cannot automatically assume that Congress and the agency are any more qualified or suited to sift health information and to determine the validity of health claims. This idea is strengthened by the notion that, although supplement producers are acting based on profit-motive, Congress and the agency are acting based on industry politics and lobbying efforts by the medical community and the pharmaceutical and nutraceutical industry.[127]

In addition, because the nature of health claims is often such that science cannot conclusively prove the validity of the claims beyond all doubt, the government should adopt the philosophy of "epistemological humility" and should recognize that it is no more the official determiner of "true science" than is the scientific community, the source of these health claims.[128] Therefore, the FDA should not set the level of proof inordinately high in order to preclude health claims as it has in the past.

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127. In fact, the court in *Pearson* noted that the eventual approval of the neural tube defect/folic acid health claim was purportedly based on the pressure of political figures such as Senator Hatch, who was undoubtedly influenced by nutraceutical lobbyists.

128. *See* Redish, *supra* note 43, at 1433.

Congress has clearly expressed that the purpose of its enabling legislation is to increase the flow of health information about dietary supplements to facilitate better consumer choice.[129] Any legislation, agency regulation, and judicial classification of health claims, should be reformed under the assumption that the consumer, the patient so to speak, is the final judge of his or her best interest and can only make accurate decisions if all of the information is before him or her. While the notion that the medical model of communication should be applied by analogy to dietary supplement health claims may seem contradictory, considering the fact that the FDA more tightly regulates cause and effect claims of pharmaceuticals than it does health claims in dietary supplements, this is not an insurmountable criticism. Pharmaceuticals rightly fit under a more restrictive standard than dietary supplements. First, the cause and effect of pharmaceuticals is intended to be more immediate and verifiable than the preventative or holistic effects of dietary supplements. Second, although dietary supplements may develop a toxic effect at extremely high levels of consumption, pharmaceuticals are generally more toxic and can have much more severe detrimental effects at a low level of use.[130]

B. FDA's "Significant Scientific Agreement" Standard and the First Amendment under a Medical Model of Communication

Because the health claim is merely a scientific statement published as a result of a profit-motive, it should be accorded the same First Amendment protection that the statement would be accorded if it were pronounced by someone, such as a scientist, with no underlying profit-motive. The most logical solution to the health claims problem is to require by regulation that producers desiring to make health claims on dietary supplements give notice of the intended claim to the FDA upon publication. The health claim would not be subject to the rigorous yet vague approval process that is now in place because this is, as Pearson and Shaw argued, a prior restraint under the First Amendment. The FDA then has access to any published health claims, and in cases where the health claim falls in the gray 'potentially misleading' area because it does not comport with the weight of available scientific evidence, the FDA should be authorized to take adjudicatory action against the publisher.

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129. 140 Cong. Rec. at H11173.

130. *See generally* Thomas D. Armsey & Gary A. Green, *Nutrition Supplements: Science vs. Hype*, 25 PHYSICIAN AND SPORTS MED.77 (1997); *Position of the American Dietetic Association: Vitamin and Mineral Supplementation*, 96 J. AM. DIETETIC ASS'N 73 (1996).

If the FDA finds that it can prove, to a degree that satisfies a court, that the claim is factually false or inherently misleading, then the agency can ask the court to enjoin the use of the claim and bring a charge of consumer fraud against the producer. The courts should apply a clear standard of scientific accuracy such as the judicial "reasonableness" standard in order to determine whether a reasonable individual in the light of total scientific evidence available could find this claim to be true. This "reasonableness" standard is consistent both with the government's interest in providing the average consumer with the most factual information possible about the dietary supplement and the need to have a clearly defined standard of proof that comports with standards of due process under the Fifth Amendment.

If, however, it is impracticable to reclassify health claims as pure speech because of the complexity of commercial speech jurisprudence and the unwillingness of the Court to rethink the commercial speech classification altogether, Congress should at least require the FDA to formulate a clear standard of proof and put the burden on the FDA to show that the communication would be found judicially false or fraudulent. This finding could be connected by statute to a particular standard of judicial review under section 706 of the APA. It is not commercially practicable for those in the class affected by the restraint on speech (i.e. dietary supplement producers) to guess the nature of the FDA's "significant scientific agreement" standard and determine whether their claim will survive FDA scrutiny based on a sub-regulation by sub-regulation analysis of past FDA action. FDA NLEA regulation as it now stands has a chilling effect on health claims communications and deprives the dietary supplement producers of their right to free expression and the public consumer of truthful and non-misleading health information. To provide some level of certainty, Congress should require the FDA to define the term "significant" and to give substantive content to the entirety of the term "significant scientific agreement" beyond the ad hoc, evolutionary sub-regulation approach approved of by the D.C. Circuit in *Pearson.*

C. Alternate Means to Protect Health and Safety

Regardless of the First Amendment conflicts inherent in the FDA NLEA regulations, the FDA is confronting a very real problem in the dietary supplement industry. The recent deaths caused by L-tryptophan and ephedrine illustrate that dietary supplements are not as harmless as their manufacturers may imply, labeling them as "natural" solutions to

health problems.[131] In these instances, the FDA was only permitted to step in and remove the suspect supplements from the shelf after the damage had already been done. In fact, as Dr. Richard Friedman, psychiatrist and director of the Psychopharmacology Clinic at New York Hospital-Cornell Medical Center, discovered, the FDA "couldn't stop [someone] from selling hemlock tea until the bodies piled up."[132]

While the Nutritional Supplements Health and Education Act did not amend the FDA's health claim requirements, it placed dietary supplements in a twilight zone between foods and drugs. Although both food and drug manufacturers have the burden of proving the safety of their products to the FDA before placing them on supermarket or pharmacy shelves, dietary supplement manufacturers need only prove the safety of their products if they contain ingredients that have not been present in the food supply prior to October 15, 1994, the date of NSHEA's enactment.[133] The FDA may remove a dietary supplement from the market if it is deemed adulterated, or poses "a significant or unreasonable risk of illness or injury," but the FDA bears the entire burden of proving supplement adulteration.[134] This places the FDA in a safety policing rather than a preemptive role. While it may be sufficient to limit the FDA's authority to regulate health claim communication to post publication action, the FDA should have more control over the actual sale of supplements. If the FDA has made a preliminary determination that the supplement is safe, the First Amendment argument that consumers should be able to evaluate published information about the product is not difficult to swallow. If, however, the agency has no control over the general safety of the product because it was on the market before the 1994 enactment of the DSHEA, then the First Amendment argument is less convincing.

While health claims may be difficult to substantiate, it is much easier to provide conclusive evidence that a dietary supplement is unsafe by subjecting it to pre-market studies. In addition, proof of safety in the case of supplements with a market history beginning prior to the 1994 enactment of DSHEA is even easier because a sufficient amount of time has elapsed to allow the dangers of the product to be revealed. Therefore, Rehnquist's argument in *Posadas*, that the power to regulate the product includes the lesser power to regulate speech about that product, may not

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131. *See* Gina Kolata, *The Unwholesome Tale of the Herb Market*, N.Y. TIMES, April 21, 1996, at 1.

132. *Id.*

133. *See* McNamara, *supra* note 13, at 341-38.

134. Bruce A. Silverglade, *The Vitamin Wars—Marketing, Lobbying, and the Consumer*, 13 J. PUB. POL'Y & MARKETING 152–54; Anthony Young & I. Scott Bass, *The Dietary Supplement Health and Education Act*, 50 FOOD & DRUG L.J. 285–92 (1995).

be as inapplicable to this case as it may seem on first glance. If the FDA can keep the product off the shelf because it is unsafe, they should do so and avoid the First Amendment debate over health claims. If the FDA, however, has the power to keep the supplement off the market based on objective evaluations of safety and yet considers the product sufficiently safe to remain in the market, the idea of allowing uncertain health claims on products should not be alarming, especially considering the court's allowance of disclaimers in such instances. This solution gives the FDA the ability to protect health and safety by keeping unsafe products off the market while allowing the responsible consumer access to possibly truthful information about products that pass that safety test and may provide valuable health benefits. If a product is determined to be safe by the FDA, a false statement about its possible health benefits is not particularly dangerous and will at most cause harm to the consumer's pocketbook if it is allowed to remain on a label until the FDA proves it false. There seems to be no reason beyond government patronism to deny the consumer access to possibly beneficial health information about a product that has been declared safe.

Congress should revise its stance on dietary supplement regulation and allow the FDA to require that dietary supplements be pre-approved for sale solely based on a clearly defined safety analysis. Then, if the manufacturer cannot prove under the courts' reasonableness standard that the product is safe for use at levels advocated by the manufacturer or generally practiced by the general public, the product should not be allowed to enter the market, or should be removed from the market if it is already present. However, once the safety-approved product is placed on the market, the manufacturers should be able to place health claims on the products that have not been pre-approved by the FDA. After the label is in the market, if the FDA can conclusively prove in court that the health claims are not true under a "reasonableness" standard, the court should enjoin the manufacturer from using the label. If, however, the product is safe and the FDA merely does not feel comfortable with the health claim because it has not been affirmed by scientific consensus, First Amendment principles dictate that the manufacturer should be allowed to attach the claim, albeit with a disclaimer stating that the FDA does not support the claim. By allowing the FDA to pre-approve the supplement based on safety requirements and yet prohibiting the agency from imposing prior restraints on health claims, Congress would be permitting the agency to further its purpose of protecting health and safety while respecting the First Amendment rights of the manufacturer and the consumer.

VII. CONCLUSION

The debate over the FDA NLEA regulation of health claims on dietary supplements at issue in *Pearson* concerns basic principles of American government. The questions involved in this inquiry pierce to the center of free speech jurisprudence and the value of the free flow of information in the individual's search for the best health solutions. *Pearson* focuses the debate on whether the individual or the agency should determine what is in the public's best interest. While the medical industry and the government have a valid interest in keeping false and misleading health claims out of the public discourse and the marketplace, the FDA and Congress should not interfere with patronistic motives to impose prior restraints on labeling and to sift health information to protect the consumer's best interest. If a health claim lies in the gray area of science where connections between health and particular nutrients are unclear, legislation and regulation should favor the policy that the healthcare consumer should be provided with more rather than less information whenever possible, based on the theory that the individual is the appropriate determiner of his or her own best interest. This theory is consistent with the model of communication in traditional medicine, fully inform the patient of all possible benefits, risks and uncertainties and then leave the final choice to him whenever possible. If Congress grants the FDA the authority to require the safety of dietary supplements before they enter the market, the possibility that some false health claims will enter the marketplace may be threatening to the consumer's pocketbook but not to her health.

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