FIRST AMENDMENT—Commercial Speech—FDA Cannot Prohibit Unsubstantiated Health Claims From The Labels Of Dietary Supplements When A Disclaimer About The Lack Of Approval May Render Claim Truthful—*Pearson v. Shalala,* 164 F.3d 650 (D.C. Cir. 1999).

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You, the average educated consumer, walk into a health food store and wander into the vast array of dietary supplements. Attempting to select a 'natural' remedy for what you perceive is a slight ill, you pick up a vial with a wonderfully strange word sprawled across the front. As you start rotating the bottle, to see if this is indeed a cure for your ill, you find that this product claims to reduce the risk of your particular ill. Excellent, you'll buy it.

But then you notice, much to your amazement, there is a long paragraph that follows this claim. 'The Food and Drug Administration does not approve this claim. The evidence is inconclusive because existing studies have been performed with foods containing this substance, and the effect of those foods on reducing the risk of your ill may result from other components in those foods.'

But, you thought the job of the Food and Drug Administration was ensuring the validity of claims on the tablets that Americans consume? And, if the scientific experts at the FDA do not seem able to decide whether this supplement will reduce the risk or not, then how can you make that decision as the average, educated consumer?

I. INTRODUCTION

When government regulates speech, it must have a good reason. In the context of commercial speech, if the statement is deemed to be inherently misleading to a consumer it is afforded no protection by the First Amendment.[1] However, if the commercial speech is deemed not to be inherently misleading, the speech has some protection under the First Amendment and any regulation of that speech must pass the *Central Hudson* test.[2]

The pertinent issue in *Pearson v. Shalala* is whether the Food and Drug Ad-

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[1] Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999).

[2] *Id.* Central Hudson provides a multi-step approach in determining whether regulation of commercial speech is violative of First Amendment protections. *See generally* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557 (1980).

ministration ("FDA") can, through apparent authorization from Congress, preclude a manufacturer of dietary supplements from making a health claim[3] on the label of its product if it has not met a standard of validity. If a manufacturer has not met the standard of validity, does that in turn mean that the proposed health claim would be considered misleading when placed on the label of a product marketed to the consumer? The government's interests in advancing the public health and protecting against consumer fraud must be balanced against the manufacturer's right to commercial free speech. Additionally, if a health claim does not meet the specified standard of validity, could a disclaimer to that effect be added to the claim in order for that claim to become non-misleading?

II. STATEMENT OF THE CASE

The plaintiffs in this case are two manufacturers of dietary supplements[4] who wanted to include certain health claims on the labels of their products.[5] There are four specific health claims plaintiffs sought to use on their products,[6] each of which the Food and Drug Administration rejected through its informal rulemaking process.[7] Throughout the process, the plaintiffs alleged their First Amend-

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[3] A health claim "expressly or by implication. . .characterizes the relationship of any substance to a disease or health-related condition." 21 C.F.R. § 101.14(a)(1) (1991).

[4] A dietary supplement is a "product (other than tobacco) intended to supplement the diet" that contains one or more of certain dietary ingredients, including a vitamin, a mineral, an herb or other botanical, or an amino acid. 21 U.S.C. § 321(ff)(1)(A)-(D) (1992).

[5] Pearson v. Shalala, 14 F. Supp. 2d 10, 14 (D.D.C. 1998).

[6] The specific health claims were:

(1) Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers; (2) Consumption of dietary fiber may reduce the risk of colorectal cancer; (3) Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease; (4) The U.S. Public Health Service has estimated that fifty percent of neural tube defects may be averted annually if all women maintained an adequate intake of folate during childbearing years; and (5) .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. *Id.* at 14 (citations omitted). On April 19, 1996, Plaintiffs' claim against the FDA for the prohibition of health claim (4) became moot when the FDA issued a Final Rule which adopted the view of the Public Health Service on this issue and specifically allowed this type of health claim on the label of dietary supplements, as long as it is accompanied by some disclaimer-like statements. *Id.*; *See also* 21 C.F.R. § 101.79(c)(3)(iv) (1996).

[7] *Pearson*, 164 F.3d at 651. The informal rulemaking process involves notice to the public that a certain issue will be resolved, a comment period for the public's input on the matter, and the agency (here, the Food and Drug Administration) issuing a final determination

ment right of free speech was violated by the FDA's prohibition of the health claims on their product labels.[8] A review of the statutory and administrative framework that regulates the area of dietary supplements is necessary to understand the facts of this case.

LEGISLATIVE HISTORY OF HEALTH CLAIM REGULATION

Prior to the Congressional enactment of the Nutrition Labeling and Education Act of 1990 ("NLEA"),[9] dietary supplements were regulated as foods, unless their labels contained a disease-specific health claim.[10] If such a claim was included in the product label, the supplement was regulated as a drug, subject to a demanding pre-market approval process[11] and extensive labeling requirements.[12] In response to companies making health claims on food labels without FDA pre-market approval and the fear that the FDA lacked legal authority to permit such claims, Congress enacted the NLEA as an amendment to the Federal Food, Drug, and Cosmetic Act.[13]

As the district court noted, Congress wished to accomplish two main goals in enacting the NLEA: "(1) to help consumers maintain healthy dietary practices by requiring food labeling to contain clear, consistent nutrition information, including information about the relationship of diet to disease; and (2) to protect consumers from fraud and misinformation by ensuring that claims made for food

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on the issue. The determination takes the form of a Final Rule, which must include justification for its decisions, including its decisions not to include certain viewpoints. *See* KENNETH C. DAVIS & ROBERT J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE §§ 7.1-7.12 (3d ed. 1994).

[8] *See Pearson*, 14 F. Supp. 2d at 10.

[9] The NLEA amended various portions of the Federal Food, Drug, and Cosmetic Act. *See* The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301-97; H.R. REP. NO. 101-538 (1990) (detailing the specific sections affected). The NLEA may be better known to the average consumer as the legislation that mandated the "Nutrition Facts" section on the label of food products. *See id.*

[10] *Pearson*, 14 F. Supp. 2d at 14.

[11] *See* 21 U.S.C. §321(g)(1)(B) (1992). Drugs require pre-market approval by the FDA before they can be introduced to the market for sale, in addition to pre-market approval for any and all claims. *See* THE NEW DRUG DEVELOPMENT PROCESS: STEPS FROM TEST TUBE TO NEW DRUG APPLICATION REVIEW, *at* http://www.fda.gov/cder/handbook/develop.htm.

[12] H.R. REP. NO. 101-538 (1990).

[13] *Id.*

are understandable, consistent, and scientifically valid."[14] To that end, the NLEA allowed claims to be "made in the label or labeling of the food which expressly or by implication . . . characterizes the relationship of any nutrient . . . to a disease or a health-related condition."[15] However, food or dietary supplement health claims must fulfill certain statutory requirements[16] if the health claim will be exempted from the rigorous drug regulatory scheme,[17] and protected from potential liability as a misbranded food.[18]

Congress specifically set forth the procedure and criteria the FDA should apply in authorizing health claims for foods:

only if the Secretary 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.[19]

For a food to include a health claim on its label, the FDA must apply the above criteria, also known as the "significant scientific agreement" standard, to the application for the claim through its informal rulemaking process.[20] If the claim is authorized, the FDA must issue a regulation to that effect.[21]

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[14] *Pearson*, 14 F. Supp. 2d at 13 (citing H.R. REP. NO. 101-538).

[15] 21 U.S.C. § 343(r)(1)(B) (1994).

[16] *See* 21 U.S.C. § 343(r)(3) (1994) for statutory requirements pertaining to food health claims, and 21 U.S.C. § 343(r)(5)(D) (1994) concerning dietary supplement health claims.

[17] 21 U.S.C. § 321(g)(1) (1992). The drug approval process includes countless steps, such as animal testing for short- and long- term safety, three phases of human clinical trials, multiple application processes, a review of the product label, and inspection of the manufacturing sites, among others. For a detailed outline of the process, *See* THE NEW DRUG DEVELOPMENT PROCESS: STEPS FROM TEST TUBE TO NEW DRUG APPLICATION REVIEW, *at* http://www.fda.gov/cder/handbook/develop.htm.

[18] Because of the placement of Section 343 within the Federal Food, Drug, and Cosmetic Act, if a food or dietary supplement is sold without adhering to the specified mandates, it would be considered a misbranded food and open to liability as such. *See generally* 21 U.S.C. § 343 (1994).

[19] 21 U.S.C. § 343(r)(3)(B)(i).

[20] *Pearson*, 164 F.3d at 652.

[21] 21 U.S.C. § 343(r)(3)(B)(i) (1994).

For dietary supplements, Congress delegated the power to the FDA to develop a procedure and standard to apply when determining a health claim approval.[22] Specifically, Congress mandated, "[a] claim made with respect to a dietary supplement . . . shall not be subject to [the above cited food criteria] but shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary."[23] Additionally, Congress directed the FDA to use its informal rulemaking process to establish the procedure and standard to be applied to dietary supplements, and to determine if four specific dietary supplement health claims would meet such established standards.[24]

Administrative History of Health Claim Regulation

The FDA responded to Congressional instruction by issuing a proposed rule in the Federal Register on June 18, 1993 which, if finalized, would adopt the same standard for evaluating health claims of dietary supplements as that which Congress had already adopted for foods, the "significant scientific agreement" standard.[25] Plaintiffs submitted comments that argued dietary supplements should not be evaluated using the same procedure and standard as foods, or if they are, that the "significant scientific agreement" standard should be defined with more specificity.[26] Additionally, Plaintiffs sought the ability to use disclaimers, in conjunction with the health claims, on the product labels when the claims did not meet the significant scientific agreement standard.[27] Plaintiffs alleged that if the FDA refused to consider the use of disclaimers, this would infringe upon their First Amendment right to provide true statements in the labels

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[22] 21 U.S.C. § 343(r)(5)(D) (1994).

[23] *Id.* Congress designated the "Secretary" with this authority to indicate that the FDA has the power to determine the proper standard and procedure.

[24] *See* 21 U.S.C. § 343(r)(3)(B)(i). The four nutrient-disease claims were the ones that Plaintiffs sought to use on their product labels. *Pearson*, 14 F. Supp. 2d at 14 (citations omitted).

Congress also charged the FDA with determining whether six different health claims on foods should be authorized using the significant scientific agreement standard mandated by § 343(r)(3). *Pearson*, 14 F. Supp. 2d at 14.

[25] *See Pearson*, 14 F. Supp. 2d at 13-14. *See supra* text accompanying notes 19-21 for a definition of the significant scientific agreement standard.

[26] *See Pearson*, 14 F. Supp. 2d at 14.

[27] *Id.* What this would mean is that the label would include a health claim that the FDA declined to approve, with a statement that the FDA did not approve it. *See id.*

of their products.[28]

Following extensive comment and hearing proceedings, the FDA issued a Final Rule similar to the proposed rule that Plaintiffs had argued against.[29] The Rule adopted a case-by-case application of the significant scientific agreement standard for dietary supplement health claims.[30] In supporting its decision not to specifically define the standard, the FDA noted that:

each situation may differ with the nature of the claimed substance/disease relationship. The agency believes that in deciding whether significant scientific agreement about the validity of a claim exists, it is necessary to consider both the extent of the agreement and the nature of the disagreement on a case-by-case basis.[31]

The Rule also specifically rejected Plaintiffs' approach of using disclaimers to accompany health claims that did not meet the significant scientific agreement standard.[32] This Final Rule is at issue in *Pearson v. Shalala*.[33]

The FDA then applied this case-by-case standard to each of the four health claims specified by Congress,[34] and determined through its informal rulemaking process that each claim did not meet the significant scientific agreement standard.[35] Accordingly, the FDA issued four Final Rules, each of which prohibited the use of the corresponding health claim on dietary supplement labels.[36]

In response to the Final Rules, Plaintiffs filed "Emergency Petitions for Stay of Actions" with the FDA and submitted additional comments with supporting scientific evidence in opposition to the prohibition of their health claims.[37] The

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[28] *Id.*

[29] *See id.*

[30] Food Labeling; General Requirements For Health Claims For Dietary Supplements, 59 Fed. Reg. 395, 416 (Jan. 4, 1994).

[31] *Id.*

[32] *Pearson*, 14 F. Supp. 2d at 14.

[33] *See id.*

[34] *See supra* text accompanying note 24.

[35] Pearson v. Shalala, 164 F.3d 650, 653 (D.C. Cir. 1999).

[36] *Pearson*, 14 F. Supp. 2d at 14.

[37] *Id.*

stay request was denied, the Final Rules became effective, and the plaintiffs filed suit in the United States District Court for the District of Columbia.[38]

District Court Holding and Analysis of *Pearson v. Shalala*

The district court held that the prohibition of the health claims by the FDA did not violate the First Amendment.[39] Because the health claims had not met the significant scientific agreement standard, the district court found that the health claims would be inherently misleading to consumers.[40] The court discussed that "a health claim is inherently misleading when the public lacks the necessary knowledge to evaluate it,[41] and when it is not subject to reliable verification through a consumer's personal experience."[42] Hence, if the FDA determines through its intensive rulemaking process that a health claim is not substantiated by significant scientific agreement as to its validity, then the health claim is inherently misleading to a consumer reading the same claim on a product.[43] As such, the claims are not protectable speech under First Amendment principles and the FDA can permissibly prohibit their use.[44]

Although the district court found the four health claims at issue were inherently misleading, it additionally held that the use of the significant scientific agreement standard by the FDA satisfied the test from *Central Hudson*,[45] and thus was a permissible restriction on commercial speech.[46] The *Central Hudson* three-part test as outlined by the district court[47] was: (1) the asserted governmental interest must be substantial; (2) the regulation must directly advance the

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[38] *Id.*

[39] *Id.* at 17.

[40] *Id.* at 18.

[41] *Id.* (citing *In re* R.M.J., 455 U.S. 191, 202 (1982)).

[42] *Pearson*, 14 F. Supp. 2d at 18 (citing Am. Home Prod. v. FTC, 695 F.2d 681, 698 (3d Cir. 1982)).

[43] *See Pearson*, 14 F. Supp. 2d at 19.

[44] *See id.*

[45] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557 (1980).

[46] *Pearson*, 14 F. Supp. 2d at 19.

[47] *See infra* note 76 for discussion of how many steps are involved in the *Central Hudson* analysis.

asserted governmental interest; and (3) the regulation must not be more extensive than necessary to achieve the governmental interest.[48] The court discussed that the governmental interest in ensuring that dietary supplement labels are "truthful and non-misleading to protect the health and safety of consumers"[49] was substantial.[50] Second, the court found that the regulation required health claims to be supported by significant scientific agreement, which directly advanced the interest in inhibiting consumer fraud in the context of misleading health claims.[51] Finally, the court decided that the regulation was not more extensive than necessary since only the label on the product was affected and the health claims could be disseminated through other non-commercial sources, such as scientific journals and popular media.[52]

The plaintiffs appealed this decision to the United States Court of Appeals for the District of Columbia, which reversed the decision of the district court.[53] In applying the same *Central Hudson* test, the court of appeals determined that the regulation violated each element of the test, and therefore infringed the right of the plaintiffs to use truthful information on their labels.[54] In particular, the court found that since the FDA had not explored the possibility of authorizing disclaimers in conjunction with the health claims to make the claims non-misleading, the regulation violated the First Amendment.[55]

III. PRIOR CASE HISTORY

Considered the landmark decision in commercial speech doctrine is the case of *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council.*[56] The case centered on a regulation that in effect precluded advertisement of pre-

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[48] *Pearson*, 14 F. Supp. 2d at 17.

[49] *Id.* at 19.

[50] *Id.*

[51] *Id.* at 20.

[52] *Id.* at 20-21.

[53] Pearson v. Shalala, 164 F.3d 650, 651 (D.C. Cir. 1999).

[54] *See id.*

[55] *Id.* at 654.

[56] 425 U.S. 748 (1976).

scription drug prices to consumers.[57] Plaintiffs in the case were consumers and consumer organizations who wanted the ban lifted to benefit from the access to drug pricing.[58] The issue before the Court was, "whether speech which does no more than propose a commercial transaction is so removed from any exposition of ideas and from truth, science, morality, and arts in general, in its diffusion of liberal sentiments on the administration of Government that it lacks all [First Amendment] protection."[59]

Although the prior case law seemed to support the proposition that commercial speech would not be afforded protection by the First Amendment,[60] the Court took great efforts to grant such protection.[61] For example, the Court focused on the importance of economic information to the individual consumer and society as a whole.[62] Additionally, when evaluating the arguments against sharing the information, the Court concluded that the arguments mainly encompassed maintaining the professionalism of Pharmacists.[63] The Court concluded that enough of a regulatory scheme was separately in place to ensure that the professional standards of the Pharmacist would remain intact[64]. More importantly, the Court also determined that this type of concern by the government was paternalistic in nature, the information itself was not dangerous, and that the consumer would be the ultimate decision-maker if he were allowed the opportunity.[65]

The case of *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*[66] is considered the current leading case in the area of commer-

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[57] Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, 425 U.S. 748, 752 (1976).

[58] *Id.* at 753.

[59] *Id.* at 762 (citations omitted).

[60] *Id.* at 758-59.

[61] *Id.* at 762-66.

[62] *Id.*

[63] *Va. State Bd. of Pharmacy*, at 766.

[64] *Id.* at 768-69. If the professional standards of a particular Pharmacist were to be compromised, the state's licensure laws would prevent him or her from practicing. *Id.*

[65] *Id.* at 770.

[66] 447 U.S. 557 (1980).

cial free speech. The regulation at issue in this case prohibited electric utilities in New York State from all advertising that promoted the use of electricity.[67] The Plaintiff electric utility challenged the order on the grounds that it restrained commercial speech in violation of First Amendment principles.[68] The order was upheld throughout the New York State court system, the Supreme Court granted certification, and ultimately held that the order was violative of the commercial speech doctrine.[69]

Because of the history surrounding the commercial speech doctrine,[70] the Court initially set the foundation for its holding by citing cases[71] where it established that commercial speech is worthy of some First Amendment protection.[72] However, the Court was clear that a distinction between commercial and other varieties of speech would remain, and that commercial speech would accord lesser protection than other protected speech.[73] Additionally, the Court stated that because the First Amendment's safeguard for commercial speech was in the informational aspects of advertising, that deceptive commercial speech could be prohibited without violating free speech doctrine.[74] Therefore, whenever commercial speech was not deceptive, an analysis must be undertaken to determine if

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[67] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 558-59 (1980).

[68] *Id.* at 560-61.

The plaintiff also argued the regulation violated the Fourteenth Amendment because a state commission was the government actor in this situation. *See id.* at 561.

[69] *Id.* at 560-61.

[70] *See supra* note 59.

[71] Bates v. State Bar of Ariz., 433 U.S. 350 (1977) (blanket restrictions on attorney advertising violated First Amendment rights); Linmark Assoc., Inc. v. Willingboro, 431 U.S. 85 (1977) (prohibition on real estate advertising signs was content-based, and as such impermissible because of the First Amendment); Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, 425 U.S. 748 (1976) (prohibition of prescription drug price advertising violative of First Amendment rights).

[72] *Central Hudson*, at 561-62.

[73] *Id.* at 562. The Court states, "[t]he protection available for particular commercial expression turns on the nature both of the expression and of the governmental interests served by its regulation." *Id.* at 563.

[74] *Id.* at 563.

the governmental regulation exceeded the right to speak.[75]

Accordingly, the Court set forth a four-step analysis[76] to be used when judging whether a regulation, which inhibits a form of commercial speech, violated First Amendment principles.[77] First, the commercial speech must be non-deceptive.[78] Then, the government must assert a substantial interest that it wished to achieve in enacting the regulation.[79] Next, the regulation must directly advance the stated governmental interest.[80] Finally, the regulation must not be excessive to achieve the goal.[81]

In applying the four-prong test, the Court determined that the order was violative of Plaintiff's rights under the First Amendment.[82] While the Court found that the government had asserted two substantial interests,[83] only one of those

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[75] *Id.* at 564.

[76] Both *Pearson* courts refer to the *Central Hudson* test as three-prong, while *Central Hudson* itself refers to a four-prong test. (*See Central Hudson*, at 566.) The *Central Hudson* Court numbers the determination that the speech is non-deceptive as its first prong, while *Pearson* presupposed that determination before applying the *Central Hudson* test. *Pearson*, 14 F. Supp. 2d at 14. The reasoning from *Pearson* appears to be, that if the speech was deceptive, then no balancing test would be required since the speech would be non-protectable under First Amendment doctrine. *See id.*

While the district court found that the health claims were misleading based on the fact that they did not meet the significant scientific agreement standard (the claim could not be truthful if it was not scientifically valid), the court still applied the *Central Hudson* test and determined that the regulation would withstand First Amendment analysis anyway. *See id.*

[77] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 564 (1980).

[78] *Id.*

[79] *Id.*

[80] *Id.*

[81] *Id.* Although the text from *Central Hudson* provided, "if the governmental interest could be served as well by a more limited restriction on commercial speech, the excessive restrictions cannot survive," this standard was clarified by Bd. of Tr. of the State Univ. of N.Y. v. Fox, 492 U.S. 469, 480. *See infra* text accompanying notes 85-100 for a detailed discussion of this distinction.

[82] *Central Hudson*, at 573. All of the litigants at trial agreed that the advertisements were purely truthful, which satisfied the first prong of the test. *Id.*

[83] *Id.* at 568-69. The substantial interests were (1) fair and efficient rates for electricity and (2) energy conservation. *See id.*

interests was directly advanced by the advertising ban.[84] Moreover, the complete suppression of advertising was deemed excessive to fulfill that interest.[85] Therefore, the Court held that the ban on promotional advertising did not withstand First Amendment scrutiny.[86]

The Court continued to refine the analysis required in the last step of the applicable commercial speech doctrine in *Board of Trustees of the State University of New York v. Fox*.[87] The litigation in this case centered on a regulation of a state university which prohibited "private commercial enterprises to operate on . . . campuses or in facilities furnished by the University."[88] Plaintiffs were students of the university, who lived in dormitories on-campus.[89] Because the trial court focused on whether the dormitory was a public forum[90] in the context of commercial speech restriction, and did not apply the *Central Hudson* standard, the record was incomplete for the appellate courts to apply *Central Hudson*.[91] However, the Supreme Court granted certification in order to clarify the standard to be applied in the last prong of the *Central Hudson* test.[92]

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[84] *Id.* at 569. While energy conservation was found to be directly advanced by the advertising ban, the link between rates and a ban on advertising was deemed "at most, tenuous." *Id.*

[85] *Id.* at 571. The order had prohibited all promotional advertising, including that which would lead to a decrease in the consumption of electricity. *Id.* Additionally, the commission had not shown that its interest in energy conservation could not be accomplished through less speech-restrictive means. *Id.*

[86] *Id.*

[87] 492 U.S. 469 (1989).

[88] Bd. of Tr. of the State Univ. of N.Y. v. Fox, 492 U.S. 469, 471-72 (1989).

[89] *Id.* at 472. Plaintiffs filed suit in response to an incident involving the removal of a company's representative from the plaintiff's dormitory room by campus police pursuant to the regulation at issue in the case. *Id.* The representative had been invited to the room by a student, as part of a marketing technique where household products are demonstrated and offered for sale to groups of ten or more people who are also invited by the host. *Id.* The company had originally joined the suit as a plaintiff, but by the time of appeal it had left the suit as a party. *Id.*

[90] The public forum doctrine does not apply to commercial speech cases. *See generally Fox*, 492 U.S. 469.

[91] *Id.* at 475-76.

[92] *Id.* at 476.

Because of well-established principles throughout First Amendment doctrine, the Court held that the third step of the *Central Hudson* test should be the "'no more extensive than reasonably necessary to further substantial interests'" standard.[93] Until this decision was published, some courts[94] had instead been applying a "least restrictive means" analysis for the third prong.[95]

As a basis for its decision, the Court pointed to three supporting factors.[96] First, in previous case law the Court had articulated that the *Central Hudson* test for validity of prohibitions on commercial speech was "substantially similar"[97] to the test for validity of time, place, and manner restrictions; that test did not require least restrictive means application.[98] Next, since the doctrine of commercial speech had always embodied the notion that it was afforded less protection than other protected forms of speech, the state must have had more ability to regulate in this area than in other speech.[99] Therefore, the state must have a lower burden in regulating commercial speech than it does in regulating other speech, which is protected by the least-restrictive means analysis.[100] Finally, in reviewing the cases the Court had decided based on the *Central Hudson* test, almost all of the regulations which were disallowed had been substantially excessive; the decisions upholding regulations could not be squared with the least-restrictive means analysis, but could with the reasonable fit standard.[101] Therefore, the Court concluded that the standard that it had been applying and that it should continue to apply was the reasonable fit standard.[102]

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[93] *Id.* at 477 (quoting *In re* R.M.J., 455 U.S. 191, 207 (1982)).

[94] This case was taken on certification precisely because the Second Circuit had applied the disfavored standard. *Fox*, at 476.

[95] *Fox*, 492 U.S. at 476.

[96] *Id.* at 477.

[97] *Id.* (quoting Clark v. Cmty. for Creative Non-Violence, 468 U.S. 288 (1984)).

[98] *Fox*, at 477.

[99] *Id.*

[100] *Id.*

[101] *Id.* at 479.

[102] *Id.* at 480.

IV. OPINION

Although the district court held that health claims which do not survive the significant scientific agreement standard are inherently misleading,[103] the United States Court of Appeals for the District of Columbia plainly rejected this argument.[104] The court of appeals decided that this approach to regulation of consumer information is paternalistic and mocked the idea that a consumer could not make his own decision when presented with this type of information on a product label.[105] Therefore, the court of appeals proceeded to the *Central Hudson* test to determine if the regulation withstood First Amendment scrutiny.[106]

In applying the *Central Hudson* three-part test[107] to determine if FDA's prohibition on the health claims violated the commercial free speech doctrine as applied to potentially misleading speech, the court held that the regulation does not survive scrutiny.[108]

The court discussed that the first prong of the test was whether the asserted governmental interest is substantial.[109] In this case, the FDA asserted two interests in advancing the regulation, namely the protection of public health and the prevention of consumer fraud.[110] Because the Supreme Court had held each interest substantial in other cases,[111] the court of appeals upheld the substantiality of each interest.[112]

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[103] *See* Pearson v. Shalala, 14 F. Supp. 2d 10, 19 (D.D.C. 1998).

[104] Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999).

[105] *See id.*

[106] *Id.*

[107] *See supra* note 76 for discussion of how many steps are involved in the *Central Hudson* analysis.

[108] *Id.* at 655, 59.

[109] *Id.* at 655.

[110] *Id.* at 655-56.

[111] *See* Rubin v. Coors Brewing Co., 514 U.S. 476, 485 (1995) (case holds government has a substantial interest in "promoting the health, safety, and welfare of its citizens"); Edenfield v. Fane, 507 U.S. 761, 769 (1993) ("there is no question that [the government's] interest in ensuring the accuracy of commercial information in the marketplace is substantial").

[112] *Pearson*, 164 F.3d at 656.

The court then discussed that the second prong from *Central Hudson* was "whether the regulation directly advances the governmental interest asserted."[113] The court first analyzed whether the public health interest was directly advanced by the regulation.[114] Because the FDA did not allege that dietary supplements themselves were dangerous to public health, the court of appeals determined that the FDA must be alleging, "that consumers have a limited amount of either attention or dollars that could be devoted to pursuing health through nutrition, and therefore products that are not indisputably health enhancing should be discouraged as threatening to crowd out more worthy expenditures."[115] Refusing to uphold perceived paternalistic notions behind the public health interest, the court held that the prohibition of health claims did not directly advance the governmental interest in public health.[116]

Surprisingly, the court of appeals found that the regulation directly advanced the FDA's interest in protecting against consumer fraud.[117] The court further explained, in a seemingly sarcastic tone, that requiring FDA pre-market approval of claims and setting the standard for approval extremely high will "surely prevent any confusion among consumers".[118] However, the court was willing to recognize that the government's interest in preventing consumer fraud and confusion in the context of a product that can affect the public's health may take on added importance.[119]

Then the court discussed that the last prong of the *Central Hudson* test was whether the fit between the government's ends and the means chosen to accomplish those ends "is not necessarily perfect, but reasonable."[120] Although the

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[113] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 566 (1980).

[114] *Pearson*, 164 F.3d at 656.

[115] *Id.*

[116] *Id.* In its discussion, the court quotes Bates v. State Bar of Ariz., 433 U.S. 350, 375 (1977), "[w]e view as dubious any justification that is based on the benefits of public ignorance." Interestingly, the court stated its presumption that the potential harm from a drug is much greater than that from a dietary supplement.

[117] *Pearson*, 164 F.3d at 656.

[118] *Id.* With this statement, the court implied that if the standard were so high that no health claim would be approved, then no consumers would ever be confused by a health claim. *See id.*

[119] *Id.*

[120] Bd. of Tr. of the State Univ. of N.Y. v. Fox, 492 U.S. 469, 480 (1989) (discussing

FDA argued that "commercial free speech doctrine does not embody a preference of disclosure over outright suppression",[121] the court held the opposite.[122] In support of its argument, the FDA cited *Friedman v. Rogers*[123] where the Court upheld a ban on the use of trade names by optometrists.[124] The Supreme Court stated, "[t]here 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."[125] However, the court of appeals stated this principle should be limited only to trade names, and not advertising in general.[126] In holding that the commercial speech doctrine encompassed a preference for disclosure with disclaimers rather than withholding information in an effort to protect the public, the court of appeals cited Supreme Court cases that held for disclosure.[127]

Unsuccessfully, the FDA additionally argued to the court of appeals that the Supreme Court[128] mandated a more deferential review of governmental regulations on potentially misleading speech than the court of appeals was implement-

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Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 564-66 (1980)).

[121] *Pearson*, 164 F.3d at 657.

[122] *See id.*

[123] 440 U.S. 1 (1979).

[124] *Pearson*, 164 F.3d at 657 (citing Friedman v. Rogers, 440 U.S. 1 (1979)).

[125] *Friedman*, 440 U.S. at 12 n.1.

[126] *Pearson*, 164 F.3d at 657.

[127] *See* Bates v. State Bar of Ariz., 433 U.S. 350 (1977) (attorneys challenged price advertising prohibitions, Supreme Court reasoned that public was better with correct but incomplete information rather than no information.), Peel v. Attorney Registration and Disciplinary Comm'n of Ill., 496 U.S. 91, 110 (1990) (attorney letterhead which stated that he was certified as a civil trial specialist deemed informative rather than deceptive); *In re* R.M.J., 455 U.S. 191, 206 n.20 (1982) (attorney may have to specify that direct mail is an advertisement, rather than State banning practice of direct mail advertising); Shapero v. Ky. Bar Assoc., 486 U.S. 466, 478 (1988) (attorney direct mail advertising may require disclosure of more information, but it cannot be purely banned).

[128] Assoc. of Nat'l Advertisers v. Lungren, 44 F.3d 726, 736 (9th Cir. 1994) (interpreting the Supreme Court decision in Bd. of Tr. of the State Univ. of N.Y. v. Fox, 492 U.S. 469 (1989)).

ing.[129] However, the court reasoned that since there was no showing by the FDA that a disclaimer would not overcome the misleading nature of the claims, the FDA had chosen a policy of suppression over disclosure, and therefore the FDA disregarded a "far less restrictive" means of regulation.[130] Additionally the court cited *44 Liquormart v. Rhode Island,*[131] which expressly overturned a portion of a previous Supreme Court ruling[132] which stood for the proposition that a court should not second guess a legislative decision to restrict speech rather than to require more speech.[133]

Relying upon the reasoning in *Florida Bar v. Went For It, Inc.,*[134] the FDA had also argued to the court of appeals that the existence of sufficient alternative channels of communication for the proposed health claims would count in its favor at this final step of the *Central Hudson* test.[135] Although the court of appeals agreed with FDA's statement of the doctrine, it held that the doctrine does not apply here because product labels are so much more effective in delivering information to the consumer than articles and books published separately.[136] Therefore, the existence of these alternative channels of communication had little influence (it was merely acknowledged in a footnote in the opinion) over the court of appeals' decision of whether the regulation was reasonably fit to the interest of protecting the consumer from fraud.[137]

In the end, the court of appeals held that the regulation violated the manufacturers' rights because it did not consider whether addition of disclaimers to the proposed health claims would correct for their potential-deceptiveness.[138] Upon reviewing each of the four proposed health claims at issue, the court stated

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[129] *Pearson*, 164 F.3d at 657-58.

[130] *Id.* at 658.

[131] 517 U.S. 484, 509-10 (1996).

[132] Posadas de P.R. v. Tourism Co. of P.R., 478 U.S. 328, 344 (1986).

[133] *Pearson*, 164 F.3d at 658.

[134] 515 U.S. 618, 633-34 (1995).

[135] *Pearson*, 164 F.3d at 658.

[136] *Id.*

[137] *Id.* at 658 n.7.

[138] *Id.* at 658.

disclaimers that it believed would alleviate the FDA-alleged deceptive nature of each claim.[139] However, the court acknowledged that the possibility existed that the deceptiveness of certain claims could not be overcome by the use of disclaimers;[140] only in those situations the FDA could prohibit the use of the health claim on the label of the product.[141] Additionally, the FDA could show through empirical evidence that disclaimers would not overcome the deceptiveness, but the court was "skeptical" that this could be demonstrated.[142]

V. CONCLUSION

In *Pearson*, the United States Court of Appeals for the District of Columbia has eroded the power that the FDA has to protect consumers from false claims on health products. In writing such a harsh opinion, it is hard to imagine that this court could ever take empirical studies about the consumer confusion surrounding use of disclaimers accompanying health claims seriously if presented by the FDA.

That the court was willing to strike down an effort by the FDA to ensure public health using the doctrine of commercial speech is unnerving, especially in light of the fact that commercial speech does not enjoy the same level of protection as most other forms of speech. Additionally, the court takes great lengths to seemingly circumvent established case law. It is also evident from the well-crafted district court analysis that the facts in this case could just as easily fit within the permissible framework of *Central Hudson*. With that said, it seems as if the FDA will be forced to wait for another tragedy like Thalidomide or Tylenol in order to get the funds and statutory empowerment to control this industry.

The United States Court of Appeals for the District of Columbia strongly believes that it should protect the public from the paternalistic stronghold of the FDA. Who, then, will protect the public from unsubstantiated claims on the products we buy to maintain our health?

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[139] *Id.* at 658-59.

[140] *Id.* at 659.

[141] *Pearson*, 164 F.3d at 659.

[142] *Id.* at 659-60.