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Health Claims Regulation: Balancing Commercial Free Speech and Consumer Protection

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INTRODUCTION

The manufacturer of a dietary supplement claims that its product reduces the risk of Alzheimer's disease. Assuming the Food and Drug Administration (FDA) regulates such claims, a consumer relies on the claim and purchases the product, forsaking a trip to the doctor. Unbeknownst to the consumer, only one-third of the existing research supports the manufacturer's claim and only to a minimal extent. The FDA attempted to use its statutory authority to force the manufacturer to adjust the wording of its claim to more adequately reflect the strength of the evidence, but a court struck down such an attempt as a violation of the manufacturer's commercial free speech rights. In the end, the consumer wasted money on a product and failed to seek medical attention in reliance on an unfounded health claim because he believed the FDA regulated the truth of such claims.

This example highlights the tension between the FDA's regulation of health claims on food products and dietary supplements, manufacturers' commercial free speech rights to make such claims, and the resulting impact on consumers. Congress has tasked the FDA with the regulation and prevention of misbranded food.[1] The Nutrition Labeling and Education Act (NLEA) amended the Federal Food, Drug, and Cosmetic Act (FDCA), permitting the FDA to regulate health claims on food products and dietary supplements.[2] The FDA

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[1] See 21 USC § 343.

[2] Nutrition Labeling and Education Act, Pub L No 101-535, 104 Stat 2353 (1990),

permits manufacturers to make health claims—such as "green tea reduces risk of breast cancer"—if the agency has found significant scientific agreement supporting the claim.[3] If, however, the FDA concludes the claim is not supported by sufficient evidence and is potentially misleading, the agency requires the manufacturer to add a disclaimer to accurately convey the limitations of the scientific support.[4] Lastly, if the evidence is so one-sided as to make the claim inherently misleading, the FDA may ban the claim in its entirety.[5]

Manufacturers challenge the regulation of health claims under the Administrative Procedure Act (APA) and under the First Amendment. First, when the FDA completely suppresses the claim, manufacturers urge the court to review and overturn the FDA's evaluation of the scientific evidence under the APA's arbitrary and capricious standard of review.[6] While courts invoke the deferential arbitrary and capricious standard in name, some actually apply a heightened standard and replace the FDA's technical expertise with their own judgment of the scientific evidence. This Comment argues that in applying an inappropriately heightened review, courts interfere with the statutory scheme and inhibit the FDA from fulfilling its mission of providing accurate information to consumers. Second, when the FDA permits the health claim but requires an accompanying disclaimer, manufacturers challenge the language of the disclaimer under the First Amendment: manufacturers claim the disclaimer infringes on their First Amendment commercial free speech rights, while the FDA reiterates its statutory mandate to prevent consumer fraud and protect the public health via regulation of these claims.[7]

The DC Circuit is the only court of appeals to have examined the regulation of health claims.[8] In *Pearson v Shalala*

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codified at 21 USC § 301, 321, 337, 343, 343-1, 345, 371.

[3] See 21 CFR § 101.14(c).

[4] See Food and Drug Administration, Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements; Availability, 67 Fed Reg 78002, 78003 (2002).

[5] See *Pearson v Shalala*, 164 F3d 650, 655 (1999) ("*Pearson I*").

[6] See, for example, *Whitaker v Thompson*, 248 F Supp 2d 1, 2 (DDC 2002).

[7] See Nutrition Labeling and Education Act, HR 3562, 101st Cong, 2d Sess, in 136 Cong Rec 33426 (Oct 24, 1990) (discussing the FDA's role in protecting consumers).

[8] See *Pearson I*, 164 F3d 650.

("*Pearson I*")[9], a dietary supplement manufacturer challenged the FDA's rejection of its proposed health claims.[10] The court held that although disclosure is preferred over suppression, the FDA may ban health claims where it determines that the evidence against the claim outweighs the evidence supporting the claim.[11] Further, the FDA's conclusions regarding the strength of the scientific evidence are reviewed under an arbitrary and capricious standard.[12] The district courts that have since applied *Pearson I* have drawn narrower and sometimes conflicting conclusions. Some have applied a heightened review to the APA claims, which frustrates the FDA's ability to ban claims it deems unsupported by credible evidence. Other district courts find more claims to be potentially rather than inherently misleading, however, the courts have yet to approve a qualifying disclaimer that the FDA has proposed.

Since *Pearson I*, the FDA has clarified its Guidelines for evaluating scientific evidence[13] and has proposed modified disclaimers of varying specificity and detail.[14] Nonetheless, courts continue to overturn the FDA's scientific conclusions and reject the modified disclaimers, restricting the FDA's ability to fulfill its mandate.[15] Consumers are the ultimate losers in this battle. When the courts prevent the FDA from exercising its technical expertise to evaluate the strength of the scientific evidence and its authority to require informative disclaimers, this leaves the FDA without the capacity to prevent misleading health claims and inform consumers.

This Comment proposes an interpretation of *Pearson I* that respects manufacturers' commercial free speech rights to make health claims while permitting the FDA to fulfill its mandate of protecting the public health and preventing consumer fraud via disclaimers on those claims. Part I details the FDA's statutory authority to regulate health claims, the legislative purpose in granting the FDA this enforcement authority, and the

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[9] 164 F3d 650 (DC Cir 1999).

[10] See id at 651–52.

[11] See id at 659 n 10.

[12] See id at 660.

[13] See 67 Fed Reg at 78003 (cited in note 4).

[14] See, for example, *Alliance for Natural Health US v Sebelius*, 714 F Supp 2d 48, 70–72 (DDC 2010) ("*Alliance I*").

[15] See id.

commercial free speech doctrine. Part II highlights the development of health claims regulation in the courts, beginning in the DC Circuit Court of Appeals and then in subsequent district courts.[16] Part III discusses the problems resulting from the inconsistent interpretations of the district courts. Part IV.A analyzes the heightened review some district courts apply to overturn the FDA's conclusions about the weight of the scientific evidence. This Part proposes that courts should apply the deferential arbitrary and capricious review and not conflate the APA and constitutional claims. Part IV.B suggests that, for potentially misleading claims, by first permitting the manufacturer to make a concise and specific claim and then incorporating language the DC Circuit suggested into its disclaimers, the FDA can preserve its enforcement power over health claims without infringing upon commercial free speech.

I. BACKGROUND

A. Statutory Framework

In 1990, Congress passed the NLEA, amending the FDCA to permit the FDA to regulate health claims on food labels.[17] A health claim is defined as:

> any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition.[18]

Prior to enactment of the NLEA, foods bearing a health claim were subject to the strenuous new drug application (NDA) process.[19] The NLEA created a "safe harbor" from this lengthy

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[16] See, for example, *Fleminger, Inc v United States Department of Health and Human Services*, 854 F Supp 2d 192 (D Conn 2012); *Pearson I*, 164 F 3d at 650.

[17] Nutrition Labeling and Education Act, Pub L No 101-535, 104 Stat 2353 (1990), codified at 21 USC § 301, 321, 337, 343, 343-1, 345, 371.

[18] 21 CFR § 101.14.

[19] See 21 USC § 355. The NDA process requires manufacturers to submit information to the FDA regarding the proposed drug's safety and efficacy, proposed labeling, methods of manufacturing and quality control, results of clinical and animal

drug certification process for dietary supplements and food products advertising health benefits.[20] A product escapes the NDA process if the FDA approves its health claim under 21 USC § 343(r), which specifies what qualities make a food "misbranded" and details the limitations on health claims.[21] A manufacturer must present evidence supporting its health claim to the FDA for review before the claim may be used in labeling.[22]

The drafters of the NLEA advocated two goals in enacting these amendments—consumer protection and public health.[23] Prior to 1984, health claims were regulated as new drugs under the NDA process.[24] However, relaxed enforcement during the Reagan administration led to a rise in unregulated claims on food products in the 1980s. As a result, companies began making claims that had not been approved under the NDA process, yet the FDA brought very few enforcement actions.[25] Senator Henry Waxman, one of the authors of the bill, cited this lack of enforcement as the basis for proposing the NLEA: "[W]hen the FDA relaxed enforcement of regulations during the early years of the Reagan administration, it lost control of the marketplace . . . This bill will recognize the marketplace so that only truthful claims may be made on foods."[26] When debating the bill, House Floor Managers noted the "great potential for

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tests, and a myriad of other documentation. See Food and Drug Administration, *New Drug Application* (NDA), (May 18, 2012), online at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm (visited Sept 15, 2012).

[20] See *Pearson I*, 164 F3d at 652.

[21] See 21 USC § 343(r)(3)(B)(iii), which establishes:

> A regulation . . . shall require such claim to be stated in a manner so that the claim is an accurate representation . . . and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

[22] See 21 CFR §§ 101.14(d)–(e), 101.70.

[23] Nutrition Labeling and Education Act, HR 3562, 101st Cong, 2d Sess, in 136 Cong Rec 33426 (Oct 24, 1990). See also Food and Drug Administration, Food Labeling; General Requirements for Health Claims for Dietary Supplements, 58 Fed Reg 33700, 33701 (1993) ("Congress enacted the health claims provisions of the 1990 amendments to help U.S. consumers maintain healthy dietary practices and to protect these consumers from unfounded health claims.").

[24] See 58 Fed Reg at 33702 (cited in note 23).

[25] See id.

[26] See id, citing Nutrition Labeling and Education Act of 1990, HR 3562, 101st Cong, 2d Sess (Oct 31, 1989), in 136 Cong Rec H 12951-02, 12953 (Oct 20, 1990).

defrauding consumers if food is sold that contains inaccurate or unsupportable health claims."[27]

Congressional debate on the 1990 amendments to the FDCA also focused on the "goal of improvement of the public health through use of valid and understandable claims in food labeling."[28] Congressman Edward Madigan, one of the authors of the bill, highlighted recent scientific evidence linking good health to dietary habits, which reinforced the importance of providing consumers with accurate information about the food they consume.[29] He also noted that the amendments "[strike] the right balance in providing consumers with information, without being overly burdensome on industry."[30] This statement shows congressional awareness of the potential burden on manufacturers and intent to balance that burden with the goal of consumer protection under the NLEA.

Lastly, Congressman Waxman noted the importance of scientifically valid information to achieving the goals of consumer protection and improved public health.[31] The FDA evaluates the strength and credibility of scientific evidence supporting health claims.[32] The agency authorizes claims in their entirety as an unqualified health claim 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.[33]

Initially, the FDA did not specify what met the qualifications of significant scientific agreement (SSA).[34] After

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[27] See 58 Fed Reg at 33702 (cited in note 23).

[28] Id.

[29] See Nutrition Labeling and Education Act, HR 3562, 101st Cong, 2d Sess, in 136 Cong Rec 20421 (July 30, 1990).

[30] See id.

[31] See 58 Fed Reg at 33702 (cited in note 23).

[32] See 21 CFR § 101.14(c).

[33] 21 CFR § 101.14(c) (emphasis added).

[34] See 58 Fed Reg at 2478–2501, 2506 (cited in note 23) ("FDA is not now

the DC Circuit required clarification of SSA in *Pearson I*,[35] the FDA released Guidelines explaining significant scientific agreement.[36] A finding of SSA requires "the agency's best judgment as to whether qualified experts would likely agree that the scientific evidence supports the substance/disease relationship that is the subject of a proposed health claim."[37] The Guidelines note that SSA is "intended to be a strong standard that provides a high level of confidence in the validity of the substance/disease relationship" and equates it closest to "consensus" on the spectrum of scientific evidence.[38]

The FDA considers claims that do not meet the SSA standard as potential qualified health claims.[39] The agency evaluates the evidence supporting the claim to determine if it is inherently misleading and thus banned under 21 USC § 343(r) or, alternatively, if "a credible body of scientific data support[s] the claim."[40] The test for qualified claims is less stringent than the level of SSA for unqualified claims, instead asking whether the weight of scientific evidence supports the claim—"whether

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prescribing a specific set, type, or number of studies as being necessary to support a health claim. The agency will consider all relevant data on a topic, including clinical studies, epidemiological data, and animal studies.").

[35] *Pearson I*, 164 F3d at 653–54.

[36] See Food and Drug Administration, *Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims-Final* § I (Jan 2009), online at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm073332.htm (visited Sept 15, 2013) ("Guidelines"). The Guidelines state:

> The specific topics addressed in this guidance document are: (1) identifying studies that evaluate the substance/disease relationship, (2) identifying surrogate endpoints for disease risk, (3) evaluating the human studies to determine whether scientific conclusions can be drawn from them about the substance/disease relationship, (4) assessing the methodological quality of each human study from which scientific conclusions about the substance/disease relationship can be drawn, (5) evaluating the totality of scientific evidence, (6) assessing significant scientific agreement, (7) specificity of claim language for qualified health claims, and (8) reevaluation of existing SSA or qualified health claims.

Id.

[37] Id at § III.G.

[38] Id.

[39] See generally Food and Drug Administration, Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements; Availability, 67 Fed Reg 78002-01 (2002). The FDA divided regulation of health claims into qualified and unqualified claims after *Whitaker v Thompson*, 248 F Supp 2d 1 (DDC 2002).

[40] 67 Fed Reg at 78003 (cited in note 39).

the pertinent data and information presented in those studies is sufficiently scientifically persuasive."[41] For claims meeting this test, the FDA permits the claim so long as it uses appropriate qualifying language reflecting the strength of the scientific evidence and remaining degree of uncertainty.[42]

B. Commercial Free Speech Doctrine

Courts evaluate FDA regulation of health claims under the commercial free speech doctrine.[43] While commercial speech is protected under the First Amendment, it is given less protection and is subject to greater regulatory infringement than other modes of noncommercial speech.[44] *Central Hudson Gas & Electric Corp v Public Service Commission of New York*[45] established the framework for evaluating potential infringement of commercial free speech.[46] The multi-step test begins with a determination of whether the commercial speech is unlawful or misleading, and if so, it is not protected under the First Amendment.[47] If the speech "is lawful and not misleading or is only potentially misleading, the [c]ourt must ask whether the asserted governmental interest in regulating the speech is substantial."[48] If the interest is not substantial, the government

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[41] Id.

[42] See id.

[43] See *Pearson I*, 164 F3d at 655, citing *Bolger v Youngs Drug Products Corp*, 463 US 60, 67–68 (1983) (noting that the combination of the manufacturer's economic motivation, the reference to a specific product, and the purpose of advertising made the statements commercial speech).

[44] See *Ohralik v Ohio State Bar Association*, 436 US 447, 455–56 (1978), stating: Expression

> concerning purely commercial transactions has come within the ambit of the [First] Amendment's protection only recently.... [W]e [] have afforded commercial speech a limited measure of protection, commensurate with its subordinate position in the scale of First Amendment values, while allowing modes of regulation that might be impermissible in the realm of noncommercial expression.

Id. For more information on the level of scrutiny applied to commercial speech, see generally Samantha Rauer, *When the First Amendment and Public Health Collide: The Court's Increasingly Strict Constitutional Scrutiny of Health Regulations that Restrict Commercial Speech*, 38 Am J L and Med 690 (2012).

[45] 447 US 557 (1980).

[46] See id at 566.

[47] *Thompson v Western States Medical Center*, 535 US 357, 367 (2002).

[48] *Fleminger, Inc v United States Department of Health and Human Services*, 854 F Supp 2d 192, 195 (D Conn 2012), quoting *Western States*, 535 US at 367 (internal

cannot infringe the speech. If the interest is substantial, the court next considers "whether the regulation directly advances the governmental interest asserted."[49] Lastly, the court asks "whether [the regulation] is not more extensive than necessary to serve that interest."[50]

The last step has an additional evaluation of whether there is a reasonable fit between the means chosen to accomplish the end and the end itself.[51] At the time of *Pearson I*, the Supreme Court did not define "reasonable fit" to mean the *least restrictive* option but merely required that the "regulation not burden substantially more speech than is necessary to further the government's legitimate interests."[52] The Supreme Court has since clarified that "[i]f the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so."[53] The government has the burden of demonstrating that the restrictions "that it seeks to impose are not more extensive than is necessary to serve the interests it attempts to advance."[54]

Members of Congress had this framework in mind when they helped enact the NLEA; after a notice and comment period, the FDA responded to comments on the proposed statute, citing the *Central Hudson* framework.[55] Congress also acknowledged that "regulation of food labeling would be impossible if the Government could not restrict speech"[56] and that "[f]reedom of [s]peech does not include the freedom to violate the labeling provisions of the Federal Food, Drug, and Cosmetic Act."[57]

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quotations omitted).

[49] *Western States*, 535 US at 367, quoting *Central Hudson*, 447 US at 566.

[50] *Western States*, 535 US at 367, quoting *Central Hudson*, 447 US at 566.

[51] *Pearson I*, 164 F3d at 656.

[52] *Board of Trustees of the State University of New York v Fox*, 492 US 469, 478 (1989), quoting *Ward v Rock Against Racism*, 491 US 781, 799 (1989) (quotation marks omitted).

[53] *Western States*, 535 US at 371.

[54] *Alliance for Natural Health US v Sebelius*, 786 F Supp 2d 1 (DDC 2011) ("*Alliance II*"), quoting *Western States*, 535 US at 371 (quotation marks omitted).

[55] See 58 Fed Reg at 2524 (cited in note 23) (responding to comments arguing that the regulations both do and do not violate manufacturers' First Amendment rights).

[56] Id at 2525, citing *SEC v Wall Street Publishing Institute*, 851 F2d 365, 373 (DC Cir 1988).

[57] 58 Fed Reg at 2525 (cited in note 23), citing *United States v Articles of Food. . .Clover Club Potato Chips*, 67 FRD 419, 424 (D Idaho 1975).

II. DEVELOPMENT OF CASE LAW

This Part explores how courts have tackled the constitutional and regulatory problems presented by manufacturers' health claims. Challenges to qualified health claims fall under the First Amendment as well as under the Administrative Procedure Act's arbitrary and capricious review. In addressing the First Amendment challenges, courts apply the *Central Hudson* test. The DC Circuit is the only court of appeals to have addressed this issue in the seminal case, *Pearson I*.[58] In subsequent cases, district courts have failed to uniformly apply *Pearson I*. The DC Circuit held that disclosure is preferred over suppression and required disclaimers to rectify potentially misleading claims.[59] However, the court also left open the possibility of complete suppression of inherently misleading claims where the FDA determines the evidence supporting the claim is qualitatively weaker than evidence against the claim.[60] District courts have expanded the holding in favor of increased commercial free speech at the expense of consumer protection by applying a heightened standard of review to overturn the FDA's evaluation of the claim's scientific support and misleadingness. Although the FDA has responded to judicial interpretation of the NLEA by issuing SSA Guidelines and implementing disclaimers on health claims,[61] courts continue to substitute their judgment of the scientific evidence and reject FDA attempts to exercise regulatory authority via disclaimers.

A. *Pearson I*

In *Pearson I*, dietary supplement marketers contested the FDA's rejection of four health claims printed on their supplements:

> (1) Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers.

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[58] See *Pearson I*, 164 F3d at 654 n 4 (noting the Tenth Circuit and Second Circuit had been presented with general challenges to 21 CFR § 101.14 but failed to rule on the issue).

[59] See id at 657–59.

[60] Id at 659 n 10.

[61] See generally Food and Drug Administration, Guidelines (cited in note 36). See, for example, *Alliance for Natural Health v Sebelius*, 714 F Supp 2d 48 (DDC 2010).

> (2) Consumption of fiber may reduce the risk of colorectal cancer.
>
> (3) Consumption of omega-3 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.[62]

The FDA rejected the claims, saying the evidence was "inconclusive" and did not "give rise to significant scientific agreement."[63] The FDA also rejected the manufacturer's suggestion of a corrective disclaimer, noting that disclaimers would be "ineffective because there would be a question as to whether consumers would be able to ascertain which claims were preliminary [and accompanied by a disclaimer] and which were not."[64] The government made two arguments supporting its rejection of disclaimers: (1) that the lack of significant scientific agreement rendered the claims inherently misleading and, thus, not protected under the First Amendment; and (2) that even claims that are only potentially misleading do not merit a disclaimer if they lack significant scientific agreement.[65] In response, plaintiffs challenged the rejected claims under the APA and the First Amendment.[66]

The DC Circuit conceded that the FDA could ban the claims if they were inherently misleading.[67] However, the court rejected the government's first argument that any and all claims lacking significant scientific agreement would inherently mislead consumers, calling this a paternalistic assumption because consumers could still exercise judgment in purchasing

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[62] *Pearson I*, 164 F3d at 651–52. (quotation marks omitted).

[63] Id at 653 (quotation marks omitted).

[64] Id at 653–54, quoting Food and Drug Administration, Food Labeling; General Requirements for Health Claims for Dietary Supplements, 59 Fed Reg 395-01, 405 (1994).

[65] See id at 654.

[66] *Pearson I*, 164 F3d at 655.

[67] See id at 655, quoting *In re RMJ*, 455 US 191, 203 (1982) ("[W]hen the particular content or method of the advertising suggests that it is inherently misleading or when experience has proved that in fact such advertising is subject to abuse, the States may impose appropriate restrictions. Misleading advertising may be prohibited entirely.").

supplements.[68] The court evaluated the government's second argument under *Central Hudson*.[69] For the first prong—whether the government interest was substantial—the court held that the government interest in "ensuring the accuracy of commercial information in the marketplace"[70] and "promoting the health, safety, and welfare of its citizens . . . [was] undeniable."[71] However, the court rejected the argument under the next prong—whether the regulation directly advanced the substantial interest and was a reasonable means of doing so.[72] The court respected the FDA's evaluation of the scientific evidence, noting the logical determination that studies linking foods with certain dietary components to reduction of a disease did not necessarily transfer to a dietary supplement with that component.[73] Nonetheless, the court reiterated that "disclaimers [were] constitutionally preferable to outright suppression"[74] and required that the FDA consider disclaimers to rectify the ambiguity or deceptiveness in any potentially misleading claims.[75]

The FDA also expressed general concern to the court that consumers might assume health claims on labels were approved by the government, due to the extensive regulation of the sale of food and drugs.[76] The court responded with an "obvious answer: . . . requir[ing] the label to state 'The FDA does not

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[68] *Pearson I*, 164 F3d at 655.

[69] Id at 656–57.

[70] Id at 656, quoting *Edenfield v Fane*, 507 US 761, 769 (1993) (quotation marks omitted).

[71] *Pearson I*, 164 F3d at 656, quoting *Rubin v Coors Brewing Co*, 514 US 476, 485 (1995) (internal quotations omitted).

[72] *Pearson I*, 164 F3d at 656 ("[I]t surely cannot be said that this notion—which the government does not even dare openly to set forth—is a *direct* pursuit of consumer health; it would seem a rather indirect route, to say the least.").

[73] Id at 658.

[74] Id at 657, citing *Peel v Attorney Registration and Disciplinary Commission of Illinois*, 496 US 91, 110 (1990).

[75] *Pearson I*, 164 F3d at 658–59 (proposing disclaimer language: (1) "The evidence is inconclusive because existing studies have been performed with *foods* containing antioxidant vitamins, and the effect of those foods on reducing the risk of cancer may result from other components in those foods;" and (2) "The evidence in support of this claim is inconclusive.").

[76] Id at 659.

approve this claim.'"[77] The court remanded the case for the FDA to reconsider the proposed health claims.[78]

In sum, *Pearson I* established the groundwork for evaluating a First Amendment challenge to the FDA's regulation of qualified health claims. The DC Circuit was skeptical that the proposed claims were inherently misleading in this instance but left the door open to the complete ban of a claim "where evidence in support of a claim is outweighed by evidence against a claim" or "where evidence in support of the claim is *qualitatively* weaker than evidence against the claim—for example, where the claim rests on only one or two old studies."[79] The court focused on the reasonable fit between the manner of restriction and the government's interest by mandating that the FDA consider corrective disclaimers rather than outright suppression of potentially misleading claims.[80] While the court required clarification of the standards the FDA applied in evaluating the scientific evidence, it deferred to the agency's evaluation of the scientific studies for three of the four proposed claims.[81]

B. Applications of *Pearson I* in the District Courts

This Part describes the six cases interpreting *Pearson I*. Each case steps further from the original *Pearson I* holding, giving less deference to the FDA's conclusions of the scientific evidence and eventually straying from the APA's arbitrary and capricious review to an unfounded "independent" review. The most recent court interpreting *Pearson I*, the District Court for the District of Connecticut, finally struck a balance between deferring to the FDA's scientific conclusions and permitting disclaimer language that accurately reflected the strength of the scientific evidence.[82]

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[77] Id.

[78] Id at 661.

[79] *Pearson I*, 164 F3d at 659 & n 10.

[80] Id at 657.

[81] See id at 658–59 (agreeing with the FDA's conclusion regarding the studies for the first three claims but disagreeing that a credible study supported the fourth claim).

[82] See *Fleminger, Inc v United States Department of Health and Human Services*, 854 F Supp 2d 192, 211, 216–17 (D Conn 2012).

1. *Pearson II.*

In response to *Pearson I*, the FDA requested submissions of scientific data regarding the *Pearson I* plaintiffs' proposed health claims.[83] The FDA also followed the DC Circuit's order to define SSA and released a draft of industry Guidelines explaining the FDA's evaluation process for scientific evidence.[84] Eighteen months after *Pearson I*, the FDA again refused to authorize plaintiffs' four proposed claims, deeming them "inherently misleading." This time, however, the FDA proposed alternative claims it would be willing to accept, such as:

> Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect. The scientific evidence that 400 mcg folic acid daily reduces the risk of such defects is stronger than the evidence for the effectiveness of lower amounts. This is because most such tests have not looked at amounts less than 400 mcg folic acid daily.[85]

Plaintiffs rejected the alternative claims and filed suit for First Amendment and APA violations.[86]

In *Pearson v Shalala* ("*Pearson II*"),[87] the district court followed *Pearson I*'s application of the *Central Hudson* framework by concluding that the government had a substantial interest in protecting the public health and preventing fraud and that FDA regulation of health claims was directly related to that interest.[88] The court focused on the third prong—whether

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[83] *Pearson v Shalala*, 130 F Supp 2d 105, 110 (DDC 2001) ("*Pearson II*"). See also Food and Drug Administration, Food Labeling; Health Claims and Label Statements; Request for Scientific Data and Information, 64 Fed Reg 48841-02 (1999).

[84] See Food and Drug Administration, Draft Guidance for Industry on Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research, Beginning on January 1, 2000; Availability, 64 Fed Reg 71794-02 (1999).

[85] *Pearson II*, 130 F Supp 2d at 111 n 12 (providing additional examples of qualifying language in the disclaimers: "It is not known whether the same level of protection can be achieved by using only food that is naturally rich in folate. Neither is it known whether lower intakes would be protective or whether there is a threshold below which no protection occurs" and "It is not known whether the same level of protection can be achieved by using lower amounts [of folate]").

[86] Id at 112.

[87] 130 F Supp 2d 105 (DDC 2001).

[88] Id at 113.

the regulation was more extensive than necessary to serve the government interest—and the DC Circuit's principle that "more disclosure rather than less is the preferred approach, so long as advertising is not inherently misleading."[89] In reaching its conclusion this second time, the FDA altered its basis for prohibiting the claims to recognize the *Pearson I* standard—"the weight of the scientific evidence [wa]s *against* . . . the proposed claim"—but continued to reject any use of disclaimers.[90] The court took issue with the FDA's failure to "demonstrate with *empirical evidence* that disclaimers similar to the ones suggested by the Court of Appeals would bewilder consumers and fail to correct for deceptiveness."[91]

The district court interpreted *Pearson I* to require an inquiry into "whether there is *any* credible evidence" in support of the claim, and if so, that it "may not be absolutely prohibited."[92] The court acknowledged that it is "not [the role of] the judicial branch to undertake comparative evaluations of conflicting scientific evidence,"[93] but then proceeded to review the FDA's evaluation of the evidence.[94] While the court agreed that the claims were potentially misleading, it disagreed that the weight of the evidence was against the claims and, thus, held that they could not be completely suppressed.[95] Narrowing the *Pearson I* standard, it concluded that "[t]he mere absence of significant affirmative evidence in support of a particular

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[89] Id at 113.

[90] Id at 114–15.

[91] *Pearson II*, 130 F Supp 2d at 118, quoting *Pearson I*, 164 F3d at 659–60 (internal quotations omitted) (emphasis added).

[92] *Pearson II*, 130 F Supp 2d at 114, 118, quoting *Pearson I*, 164 F3d at 658 (quotation marks omitted) (emphasis added).

[93] *Pearson II*, 130 F Supp 2d at 115, quoting *Natural Resources Defense Council v Environmental Protection Agency*, 824 F2d 1211, 1216 (DC Cir 1987).

[94] *Pearson II*, 130 F Supp 2d at 114. The *Pearson II* court stated that:

> [T]he FDA divided Plaintiffs' proposed claim . . . into essentially two sub-claims . . . . Then, the FDA analyzed each sub-claim separately. . . . Taking these two sub-claims together, the FDA concluded that, "based on the totality of the scientific evidence, there is not significant scientific agreement among qualified experts" . . . The FDA further concluded, without elaboration, that "the weight of the evidence is *against* both aspects of the proposed claim," and that the claim is "inherently misleading and cannot be made non-misleading with a disclaimer or other qualifying language."

Id.

[95] Id at 115.

claim . . . does not translate into negative evidence 'against' it" and that "the FDA may not ban . . . [a c]laim simply because the scientific literature is inconclusive."[96]

As a result of its review of the scientific data, the court held that, as a matter of law, the claims were not inherently misleading and that the FDA's decision to ban the claims without considering disclaimers was arbitrary and capricious in violation of the APA.[97] Reiterating the value of disclaimers in correcting any potential misleadingness, the court granted the plaintiffs' request for a preliminary injunction and ordered the FDA to draft disclaimers to rectify the claims.[98] While noting that "it is the FDA's, rather than the Court's, institutional role to draft accurate, adequate, and succinct health claim disclaimers," the court suggested that the FDA reconsider the DC Circuit's proposed disclaimers.[99]

2. *Pearson III.*

The FDA moved for reconsideration of *Pearson II*, arguing that the District Court of the District of Columbia committed clear error by "assign[ing] undue weight to a particular clinical study and failing to consider the relevant scientific evidence in totality" and by creating a standard inconsistent with the holding in *Pearson I*.[100] The court denied the motion on both accounts, agreed with *Pearson II* that the FDA failed to comply with *Pearson I*, and continued to hold the FDA to *Pearson II*'s standard for declaring a claim inherently misleading—the requirement of empirical evidence to reject disclaimers.[101] It

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[96] Id at 115, 118.

[97] Id at 114–15.

[98] *Pearson II*, 130 F Supp 2d at 120. The court required the FDA to draft disclaimers to modify the plaintiffs' proposed claims, rather than considering the alternative claims the FDA proposed. See id.

[99] Id at 120, stating that:

> The Court strongly suggests the agency consider the two disclaimers suggested by the *Pearson* Court ("The evidence in support of this claim is inconclusive" and "The FDA does not approve this claim"), as well as the disclaimer put forth by Plaintiffs ("Foods fortified with similar amounts of folic acid may be as effective as dietary supplements in reducing the risk of neural tube defects").

Id.

[100] *Pearson v Thompson*, 141 F Supp 2d 105, 108 (DDC 2001) ("*Pearson III*") (quotation marks omitted).

[101] Id.

denied that *Pearson II* "implied that the FDA *must* authorize a [health] claim whenever any credible evidence supports the claim."[102] Rather, the court offered a clarification of *Pearson II* in conjunction with *Pearson I*, reiterating:

> [T]he FDA [may] impos[e] an outright ban on a claim where evidence in support of the claim is *qualitatively* weaker than evidence against the claim—for example, where the claim rests on only one or two old studies or where evidence in support of a claim is outweighed by evidence against the claim.[103]

The court then stated that *Pearson II* clarified the meaning of "against" when it held that "[t]he mere absence of significant affirmative evidence in support of a particular claim . . . does not translate into negative evidence 'against' it."[104]

3. *Whitaker.*

The District Court of the District of Columbia refused to defer to the FDA's conclusions regarding the scientific evidence in *Whitaker v Thompson*.[105] The *Pearson I* plaintiffs filed another suit regarding the antioxidant claim on their dietary supplements: "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers."[106] The plaintiffs filed suit after the FDA found a lack of significant scientific agreement and found the claim inherently misleading because "the weight of the scientific evidence against the relationship was greater than the weight of evidence in favor of the relationship."[107]

The court granted plaintiffs' preliminary injunction, concluding that the FDA failed to demonstrate that complete suppression was "the *least restrictive* means of protecting consumers against the potential of being mislead [sic] by the [c]laim."[108] The district court took the *Pearson I* holding a step further from merely requiring a "reasonable fit" to now requiring

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[102] Id at 110 (internal quotation omitted) (emphasis added).

[103] Id at 112, citing *Pearson I*, 164 F3d at 659 n 10, 660 (quotation marks omitted).

[104] *Pearson III*, 141 F Supp 2d at 112, citing *Pearson II*, 130 F Supp 2d at 115.

[105] 248 F Supp 2d 1 (DDC 2002).

[106] Id at 2.

[107] Id at 7.

[108] Id at 8 (emphasis added).

the "least restrictive" means.[109] The court stated that *Pearson I* stood for two conclusions: (1) it did not eliminate the possibility that a disclaimer could correct an inherently misleading claim; and (2) total suppression of a claim was restricted to two scenarios—when no evidence supported a claim or when evidence supporting the claim was "qualitatively weaker than evidence against the claim."[110] It further required in both scenarios that the FDA demonstrate with empirical evidence that a disclaimer would not correct the claim's misleadingness.[111]

Like in *Pearson II*, the court thoroughly reviewed the FDA's analysis of the scientific evidence, citing the FDA's failure to authorize disclaimers in light of *Pearson I* as authorization.[112] It elaborated that deference to the agency's expertise "does not negate the duty of [the] court to ensure that an agency . . . conduct a process of *reasoned* decisionmaking."[113] Of the 150 studies the FDA considered, the court concluded that one-third supported the health claim.[114] The FDA discounted the evidentiary value of many of those studies, however, for "study errors or design limitations."[115] Nonetheless, the court concluded that the FDA was unreasonable in its analysis of the scientific data.[116] Because it construed *Pearson I* as permitting complete bans only when there was qualitatively weak evidence in *one or two old studies* and because the FDA failed to provide empirical

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[109] See *Pearson I*, 164 F3d at 656. See note 108.

[110] *Whitaker*, 248 F Supp 2d at 10–11.

[111] Id.

[112] See id at 10–14. The court wrote that:

> Given the FDA's continual refusal to authorize the disclaimers suggested by the Court of Appeals, or any other disclaimers, as well as the FDA's resistance to the teachings of Pearson I, it is essential to carefully review the analysis it relied upon to ban Plaintiffs' Antioxidant Vitamin Claim in the context of the *Pearson I* opinion.

Id.

[113] Id at 11, quoting *K N Energy, Inc v Federal Energy Regulatory Commission*, 968 F2d 1295, 1303 (DC Cir 1992) (quotation marks omitted).

[114] *Whitaker*, 248 F Supp 2d at 11.

[115] Id at 11 n 12.

[116] Id at 13. The court also noted that, under the Guidelines, certain types of studies should get more weight than others and stated that the FDA did not follow its own guidelines in this respect. See id at 12 ("Th[e] Report states that intervention studies should be weighed more heavily than observational studies. Thus, the FDA simply failed to follow its own Report and give appropriate weight to the approximately one-third of the intervention studies that supported the Plaintiffs' Claim.").

evidence of the disclaimer's ineffectiveness, the court held that suppression of the claim was unconstitutional.[117] It remanded the case to the FDA to draft "accurate, adequate, and succinct" disclaimers and suggested that the FDA consider the proposed disclaimers from *Pearson I*—"The evidence in support of this claim is inconclusive" and "The FDA does not approve this claim."[118]

Following *Whitaker*, the FDA separated the evaluation of health claims into qualified and unqualified claims.[119] For claims supported by SSA, the FDA considered the claim "unqualified" and approved it without a disclaimer.[120] If the FDA determined that the proposed claim lacked support of SSA but that the "weight of the evidence" supported the claim, the FDA considered the claim "qualified" and proposed a disclaimer to reflect the appropriate value of scientific support.[121] In drafting a disclaimer, the FDA focused on clarifying the degree of scientific certainty for consumers.[122] Additionally, the FDA used a "reasonable consumer standard" in evaluating the language of health claims, meaning the information must be appropriate for a consumer taking an active role in his or her health choices, rather than the "ignorant, the unthinking, and the credulous" consumer.[123]

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[117] See id at 13–14 (emphasis added). The court reasoned that:

> The FDA has banned the Plaintiffs' claim by concluding that the evidence in support of it was weaker than evidence against it, but it is clear that *more than 60 recent studies* reviewed by the FDA supported the claim. This hardly constitutes the "one or two old studies" that the Court of Appeals contemplated might support a total ban.

Id.

[118] *Whitaker*, 248 F Supp 2d at 17.

[119] *Fleminger, Inc v United States Department of Health and Human Services*, 854 F Supp 2d 192, 200 (D Conn 2012). See also 67 Fed Reg at 78003–04 (cited in note 39).

[120] *Fleminger*, 854 F Supp 2d at 200.

[121] See id; 67 Fed Reg at 78003 (cited in note 39) ("The test is not whether the claim is supported numerically (i.e., whether more studies support the proposed claim than not), but rather whether the pertinent data and information presented in those studies is sufficiently scientifically persuasive.").

[122] See 67 Fed Reg at 78003 (cited in note 39).

[123] Id at 78004.

4. *Alliance I.*

The District Court first verbalized its use of an "independent" review in *Alliance for Natural Health US v Sebelius* ("*Alliance I*").[124] The FDA rejected seven of ten of a dietary supplement manufacturer's proposed health claims as inherently misleading—such as "Selenium may reduce the risk of certain cancers. Scientific evidence supporting this claim is convincing but not yet conclusive."[125] The FDA exercised enforcement discretion as to the remaining three, drafting lengthy and detailed claims:

> 1) One study suggests that selenium intake may reduce the risk of bladder cancer in women. However, one smaller study showed no reduction in risk. Based on these studies, FDA concludes that it [sic] highly uncertain that selenium supplements reduce the risk of bladder cancer in women;
>
> 2) Two weak studies suggest that selenium intake may reduce the risk of prostate cancer. However, four stronger studies and three weak studies showed no reduction in risk. Based on these studies, FDA concludes that it is highly unlikely that selenium supplements reduce the risk of prostate cancer; and
>
> 3) One weak, small study suggests that selenium intake may reduce the risk of thyroid cancer. Based on this study, FDA concludes that it is highly uncertain that selenium supplements reduce the risk of thyroid cancer.[126]

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[124] 714 F Supp 2d 48 (DDC 2010).

[125] See id at 57–58 & n 16. The remaining claims referred to specific types of cancers and were all qualified with the language "convincing but not yet conclusive." Id at 57 n 16.

[126] See id at 57–58 & n 19. The original language of the claims read:

> 1) Selenium may reduce the risk of bladder and urinary tract cancers. Scientific evidence supporting this claim is convincing but not yet conclusive.
>
> 2) Selenium may reduce the risk of prostate cancer. Scientific evidence supporting this claim is convincing but not yet conclusive.
>
> 3) Selenium may reduce the risk of thyroid cancer. Scientific evidence supporting this claim is convincing but not yet conclusive.

Plaintiffs claimed the seven claims were rejected in violation of *Pearson I* and that the modification of the remaining three claims was "unreasonably long and burdensome," in violation of the First Amendment.[127]

The parties disagreed as to the standard of review the court should apply in reviewing the FDA's conclusions under the APA.[128] The plaintiffs urged the court to adopt a heightened review because they raised a constitutional issue, while the FDA contended that "particularized findings concerning the scientific evidence" merited an arbitrary and capricious review.[129] The court concluded that it would conduct an "independent review" of agency decisions on constitutional issues,[130] but noted that it would be inappropriate to review the scientific evidence without some deference.[131] Nevertheless, the court determined that an "independent review," more thorough than an arbitrary and capricious review, was appropriate.[132] The court stated that this was consistent with *Pearson I*:

> By instructing the FDA to employ less restrictive means of regulating speech and to provide greater empirical support for its regulatory decisions, the DC Circuit did not purport to tell the Agency how to assess scientific data. Rather, it provided the Agency with guidelines for developing regulations once it had evaluated the evidence before it.[133]

The *Alliance I* court noted that *Whitaker* went further than *Pearson I* in requiring practically no qualitative evidence supporting the claim *and* requiring empirical evidence of public

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See id at 57 n 16.

[127] Id at 58.

[128] See *Alliance I*, 714 F Supp at 59.

[129] Id.

[130] Id at 59–60, citing *JJ Cassone Bakery, Inc v NLRB*, 554 F3d 1041, 1044 (DC Cir 2009) ("The Court concludes that it is obligated to conduct an independent review of the record and must do so without reliance on the Agency's determinations as to constitutional questions.").

[131] Id at 60, quoting *Ethyl Corp v Environmental Protection Agency*, 541 F2d 1, 36 (DC Cir 1976) ("[T]he enforced education into the intricacies of the problem before the agency is not designed to enable the court to become a superagency that can supplant the agency's expert decision-maker.").

[132] *Alliance I*, 714 F Supp 2d at 59–60, citing *JJ Cassone Bakery*, 554 F3d at 1044.

[133] *Alliance I*, 714 F Supp 2d at 60.

deceit for a complete ban of a claim.[134] The court then employed this heightened standard, however, to conclude that the FDA "fail[ed] under *Pearson I*."[135] The court reviewed each study the FDA discounted in rejecting plaintiffs' claims, agreeing with the FDA in almost every case.[136] However, the court disagreed with the FDA's conclusion on the value of one or two studies per claim and, thus, concluded a complete ban was unreasonable and a disclaimer could rectify the potential misleadingness.[137]

The court also declined the FDA's use of enforcement discretion to rewrite plaintiffs' prostate claim.[138] The FDA did not refuse this claim in its entirety because it concluded the scientific literature supported the claim. However, the FDA rejected plaintiffs' proposed wording because "it found the characterization of the evidence in support of the claim as 'convincing but not yet conclusive' to be false and misleading."[139] The court, in turn, rejected the FDA's reworded claim as "inconsistent with the spirit, if not the letter, of *Pearson I*," because it "contradict[ed] the claim and defeat[ed] the purpose of making [it] in the first place."[140] The court remanded to the FDA to draft "short, succinct, and accurate disclaimers" instead of completely rejecting or rewriting plaintiffs' proposed claims.[141]

5. *Alliance II.*

The District Court continued to use the "independent" review, rather than the APA's arbitrary and capricious review,

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[134] See id at 62, quoting *Whitaker*, 248 F Supp 2d at 11.

[135] *Alliance I*, 714 F Supp 2d at 63 ("The Agency has not provided any empirical evidence, such as 'studies' or 'anecdotal evidence,' that consumers would be misled by either of plaintiffs' claims were they accompanied by qualifications.").

[136] See id at 65–70.

[137] See id (disagreeing with the exclusion of one study for plaintiffs' lung and respiratory tract claims and with the exclusion of two studies for plaintiffs' colon and digestive tract claims).

[138] The FDA rewrote plaintiffs' original claim—"Selenium may reduce the risk of prostate cancer. Scientific evidence supporting this claim is convincing but not yet conclusive."—as "Two weak studies suggest that selenium intake may reduce the risk of prostate cancer. However, four stronger studies and three weak studies showed no reduction in risk. Based on these studies, FDA concludes that it is highly unlikely that selenium supplements reduce the risk of prostate cancer." Id at 57 n 16, 58 n 19.

[139] *Alliance I*, 714 F Supp 2d at 71.

[140] Id at 71–72.

[141] Id at 72.

in *Alliance for Natural Health US v Sebelius* ("*Alliance II*").[142] The same dietary supplement manufacturers from *Alliance I* filed suit for a similar set of facts, with the FDA entirely denying thirteen proposed claims and modifying the language of four others.[143] Plaintiffs objected that the ruling on six of the claims—four of the rejected claims and two modified claims—violated the First Amendment.[144] The rejected claims used language similar to those rejected in *Alliance I*—"Vitamin C may reduce the risk of lung cancer. The scientific evidence supporting this claim is convincing, but not conclusive."[145] The modified claims had similar language—"Vitamin C may reduce the risk of gastric cancer. The scientific evidence supporting this claim is persuasive, but not conclusive."—and the FDA rewrote them as, "One weak study and one study with inconsistent results suggest that vitamin C supplements may reduce the risk of gastric cancer. Based on these studies, FDA concludes that it is highly uncertain that vitamin C supplements reduce the risk of gastric cancer."[146]

The court cited *Alliance I*'s use of an "independent assessment" when reviewing the FDA's conclusions impacting a constitutional issue, while simultaneously stating it must defer to the agency's technical expertise.[147] After reviewing the FDA's application of its Guidelines to the studies, the court determined the complete ban of the four claims was not arbitrary and capricious.[148] Conversely, it rejected the rewording of the two modified claims.[149] Following the reasoning in *Alliance I*, the court determined the modifications completely replaced the plaintiffs' claims and effectively negated the relationship between the dietary supplement and the health benefit.[150] The

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[142] 786 F Supp 2d 1 (DDC 2011).

[143] Id at 10.

[144] Id at 10–11.

[145] Id at 11.

[146] *Alliance II*, 786 F Supp 2d at 11.

[147] Id at 12 ("While the Court is obligated to conduct an independent review of the record and must do so without reliance on the [FDA's] determinations as to constitutional questions, it must also give deference to an agency's assessment of scientific or technical data within its area of expertise.") (quotation marks omitted).

[148] See id at 18–23 (finding that the FDA provided reasoned explanations for why it excluded certain studies).

[149] See id at 23–24.

[150] *Alliance II*, 786 F Supp 2d at 24.

court concluded that "[w]here the evidence supporting a claim is inconclusive, the First Amendment permits the claim to be made; the FDA cannot require a disclaimer that simply swallows the claim."[151] It remanded to the FDA to draft precise disclaimers focusing on the "strength or nature of the evidentiary support for that substance-disease relationship."[152]

The court also reviewed the FDA's 2009 Guidance Document[153] in light of plaintiffs' argument that the Guidelines instituted the *Pearson I* standard in theory but that "the FDA ha[d] simply shifted the focus to the question of what constitute[d] 'credible' evidence and ha[d] adopted an overly restrictive standard of credibility."[154] The court rejected the plaintiffs' argument, finding the FDA's application of the Guidance Document in assessing the credibility of the scientific evidence to be reasonable.[155] The court reviewed the FDA's evaluation of each of the plaintiffs' scientific studies and, in each instance, found the FDA's conclusion in excluding the study, or rejecting its credibility, reasonable and not arbitrary and capricious.[156]

In dicta, the court noted that it did not interpret *Pearson I* as requiring the FDA to present empirical evidence on a disclaimer's efficacy before banning a claim, but rather, "unsupported or very weakly supported claims may simply be banned outright" because they would be unprotected commercial speech under the first step of *Central Hudson*.[157] However, the court reiterated that for claims that are only potentially misleading, the FDA would have to present empirical evidence showing the inefficacy of a disclaimer if it attempted to ban the claim outright.[158]

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[151] Id at 24.

[152] Id at 24 n 22.

[153] See text accompanying note 36.

[154] *Alliance II*, 786 F Supp 2d at 17. See Food and Drug Administration, Guidelines at § II (cited in note 36).

[155] See *Alliance II*, 786 F Supp 2d at 16–17 (breaking down the guideline framework for assessing the evidence supporting proposed health claims).

[156] *Alliance II*, 786 F Supp 2d at 18–23 (agreeing with the rejection of the proposed Vitamin C lung cancer claim, the Vitamin C colon cancer claim, the Vitamin E lung cancer claim, and the Vitamin E gastric cancer claim).

[157] Id at 14, citing *Pearson I*, 164 F3d at 659 n 10.

[158] *Alliance II*, 786 F Supp 2d at 15.

6. *Fleminger.*

Unlike the previous interpretations of *Pearson I*, the District Court for the District of Connecticut struck the balance of respecting the FDA's evaluation of the scientific evidence and directing the FDA to issue disclaimer language that reflected the strength of the evidence. In *Fleminger, Inc v United States Department of Health and Human Services*,[159] the District Court for the District of Connecticut encountered a challenge to the regulation of qualified health claims.[160] Because the Second Circuit had not addressed the issue, the court looked to the DC Circuit precedent for guidance.[161] Fleminger proposed a health claim for its green tea products linking consumption of green tea with a reduced risk of cancer: "Daily consumption of 40 ounces of typical green tea containing 710 g/ml of natural (-) - epigallocatechin gallate (EGCG) may reduce the risk of certain forms of cancer. There is scientific evidence supporting this health claim although the evidence is not conclusive."[162] The FDA concluded that it would exercise enforcement discretion on claims for breast and prostate cancer only because there was a lack of credible evidence supporting the claims for other types of cancer.[163] Fleminger resubmitted its claim: "Green tea may reduce the risk of cancer of the breast and the prostate. The FDA has concluded that there is credible evidence supporting this claim although the evidence is limited."[164] After some back and forth, the FDA proposed its own modified claim: "Green tea may reduce the risk of breast or prostate cancer. FDA does not agree that green tea may reduce the risk because there is very little scientific evidence for the claim."[165] Fleminger sued for

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[159] 854 F Supp 2d 192 (D Conn 2012).

[160] Id.

[161] Although the DC Circuit precedent involves health claims on dietary supplements and the health claims at issue in *Fleminger* are on food products, the court concluded that the analysis is the same. See id at 195.

[162] Id at 203.

[163] *Fleminger*, 854 F Supp 2d at 203.

[164] Id at 204–05.

[165] Id at 206. The FDA initially proposed claims similar to those rejected in *Alliance I*. Fleminger sought reconsideration, which was denied. Fleminger informally responded, received no response, and began using its resubmitted claim. The FDA reconsidered its rejection and proposed claims in light of the ruling in *Alliance I*, and then proposed the modified claim instead.

violation of its First Amendment commercial free speech rights.[166]

The FDA voiced concern that consumers would likely assume the FDA endorsed the strength of Fleminger's proposed claim, particularly because the claim invoked the FDA by name, citing empirical evidence that "35% to 57% of consumers, with or without use experience with dietary supplements, mistakenly believe that the government regulates the manufacturing and pre-approves the marketing of these products."[167] The court embraced this concern, highlighting the extensive history linking the FDA to food regulation and the substantial interest the FDA has in "preventing consumers from assuming the FDA has approved the qualified health claim."[168] The court held that without the FDA's approval, "a proposed health claim cannot include specific reference to the 'FDA' in its marketing."[169]

The court articulated that it was not its role to assess scientific data and that it would defer to both the FDA's assessment of the scientific evidence[170] and to "the FDA's determination that Fleminger's articulation of the level of scientific evidence was inaccurate and misleading."[171] Fleminger did not challenge the FDA's conclusion about the minimal strength of the evidence; it argued that the FDA did not need to replace Fleminger's claim with its own because Fleminger's claim "accurately convey[ed] the strength of scientific evidence."[172] After reviewing the FDA's rationale in concluding the claim was misleading, the court agreed with the FDA that

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[166] Id at 206.

[167] *Fleminger*, 854 F Supp 2d at 205.

[168] Id at 209–11.

[169] Id at 211.

[170] Id at 207, citing *Marsh v Oregon Natural Resources Council*, 490 US 360, 377 (1989). The court explained that:

> The Court is not in the position, nor is it the Court's role, to independently assess the highly technical scientific data to determine what amount of scientific evidence supports the proposed health claim at issue. Such a determination falls squarely within the ambit of the FDA's expertise and therefore the Court must give deference to the FDA's assessment of the strength of the scientific data at issue.

Id.

[171] *Fleminger*, 854 F Supp 2d at 211, citing *Federal Power Commission v Florida Power & Light Co*, 404 US 453, 463 (1972).

[172] *Fleminger*, 854 F Supp 2d at 211.

"credible but limited" was an inaccurate description of the evidence.[173]

The court accepted the FDA's modified claim in part and rejected it in part. According to the court, the portion stating there is "very little scientific evidence" attained a reasonable balance between permitting the claim to be made, accurately reflecting the strength of the evidence, and not burdening more speech than necessary.[174] Conversely, the court rejected the portion stating "FDA does not agree that green tea may reduce that risk."[175] Like the rejected modifications in *Alliance II*, the court found that this statement effectively negated the relationship between green tea and a reduction in the risk of cancer and found it to be unnecessary in addition to the disclaimer "very little scientific evidence."[176] The court recommended that the FDA follow *Pearson I*'s suggestion, stating, "the FDA does not approve this claim," without the effect of negating the claim.[177]

III. INCONSISTENCIES INTERPRETING *PEARSON I*

This Part explores the number of problems that emerge from the district courts' varying applications and expansions of *Pearson I*. First, *Pearson I* cited the APA's arbitrary and capricious standard in requiring the FDA to clarify "significant scientific agreement."[178] However, while the district courts mention the deferential standard of review, they frequently apply a more searching review to overturn the FDA's judgment. Second, the district courts go beyond the *Pearson I* holding that disclosure is preferable to suppression to almost eliminating the FDA's ability to ban a misleading claim. The additional restrictions the district courts impose on the FDA's ability to regulate health claims and to draft disclaimers it considers

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[173] Id at 211–12. The court drew a distinction between "credible evidence" in a regulatory framework versus a consumer context. In a regulatory framework, the term indicates there is minimal evidence supporting the claim. To consumers, "credible evidence" indicates a basis for believing the claim to be true. The court likens the use of the term in a consumer context to the SSA standard, which the FDA uses as a reflection of scientific consensus that the claim is true. See id at 213–14.

[174] Id at 216–17.

[175] Id at 217–18.

[176] *Fleminger*, 854 F Supp 2d at 217–18.

[177] Id at 218.

[178] See *Pearson I*, 164 F3d at 660–61.

accurate and informative negate the agency's mandated goal of protecting consumers and the public health.[179] Furthermore, the inconsistencies between the holdings fail to provide clear guidance for the FDA to proceed in the regulation of future health claims.

A. Complete Ban of a Claim

The first principle the DC Circuit espoused in *Pearson I* is that disclaimers are preferable to outright suppression.[180] However, the court expressly left open the possibility of a complete ban of a claim "where evidence in support of a claim is outweighed by evidence against the claim" or "where evidence in support of the claim is *qualitatively* weaker than evidence against the claim."[181] The court recognized that, in instances when the balance of evidence was against the claim, no disclaimer would rectify the potential misleadingness of the claim.[182] The court provided an illustrative example:

> [I]f the weight of the evidence were against the hypothetical claim that "Consumption of Vitamin E reduces the risk of Alzheimer's disease," the agency might reasonably determine that adding a disclaimer such as "The FDA has determined that *no* evidence supports this claim" would not suffice to mitigate the claim's misleadingness.[183]

Pearson I expressly left an opening for the FDA to exercise its judgment in evaluating the evidence and completely ban claims unsupported by science. The court did not require that the claim have absolutely no support to be banned but merely be "outweighed" or supported by evidence of a lesser quality. Furthermore, the court noted that judicial review of the FDA's

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[179] See Nutrition Labeling and Education Act, HR 3562, 101st Cong, 2d Sess, in 136 Cong Rec 33426 (Oct 24, 1990). See also Food and Drug Administration, *The Mission of the FDA* *1, online at http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM195857.pdf (visited Sept 15, 2013).

[180] See *Pearson I*, 164 F3d at 657.

[181] Id at 659 & n 10.

[182] See id at 659.

[183] Id.

conclusions of the weight of the evidence fell under the APA's arbitrary and capricious standard.[184]

In interpreting *Pearson I*, the district courts' confusion arises over how to measure the "weight" of the evidence. *Pearson II* construed the standard more strictly; although the court conceded that "there [wa]s not a scientific consensus which affirmatively support[ed] [p]laintiffs' assertion," it determined that the "mere absence of significant affirmative evidence in support of a particular claim . . . does not translate into negative evidence 'against' it."[185] This conclusion is problematic because it implies that the FDA may not ban claims that it determines are scientifically unsupported. This would leave the agency statutorily authorized to regulate health claims and prevent consumer fraud[186] no authority to prevent unsupported claims. The court does not clarify how it classifies evidence that is not affirmatively supporting the claim but that is not against the claim. The balancing of this hazy category of not-affirmative-but-not-negative evidence should fall upon the FDA, only to be reviewed by the court for arbitrariness.[187] By holding that a lack of affirmative evidence cannot shift the balance of the weight of the evidence against the claim, the court limited the range of claims the FDA can ban as scientifically unsupported.

The *Whitaker* court focused on the qualitative nature of the evidence to completely ban a claim.[188] *Pearson I* gave an example of qualitatively weak evidence—"where the claim rests on only one or two old studies"—that would shift the weight of evidence against the claim.[189] *Whitaker* focused on the quantity and age of the evidence, "one or two old studies," rather than the principle that the FDA Guidelines determine the quality of the evidence, based on factors like the type of study or the population considered.[190] If the FDA determines that the study is scientifically weak, *Pearson I* implied that the agency may disregard the study or reduce its value in determining the

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[184] See *Pearson I*, 164 F3d at 660.

[185] *Pearson II*, 130 F Supp 2d at 115.

[186] See Part I.A.

[187] See Part IV.A.

[188] *Whitaker*, 248 F Supp 2d at 13.

[189] *Pearson I*, 164 F3d at 659 n 10.

[190] See *Whitaker*, 248 F Supp 2d at 12–13. See Food and Drug Administration, Guidelines at § III (cited in note 36).

weight of the evidence.[191] In *Whitaker*, approximately sixty recent studies—only one-third of the submitted studies—supported the claim.[192] The FDA further "discounted many of the studies supporting the relationship for study errors or design limitations," which the court found arbitrary and in violation of the FDA's Guidance Report.[193] Regardless, *Whitaker* held that when only one-third of evidence supports the claim, this does not fall under *Pearson I*'s "weight of the evidence" against the claim standard to allow a complete ban.[194] Thus, *Whitaker* mischaracterizes *Pearson I*, focusing on the specifics of the example rather than the principle.

Overall, the district courts have limited the exceptions *Pearson I* provided for a complete ban of a claim. Even when there was little affirmative support for the claim or the evidence supporting the claim was of a lesser quality, the district courts prohibited a complete ban. This greatly restricts the FDA's ability to fulfill its mandate. The FDA declares its mission as follows: "The FDA is responsible for advancing the public health by helping to speed the innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get accurate, science-based information they need to use medicines and foods to *improve their health*."[195] Furthermore, Congress enacted the NLEA with the specific goals of consumer protection and public health in mind.[196] By replacing their judgment of the scientific evidence over that of the FDA, the courts interfere with the statutory scheme and inhibit the FDA from fulfilling its mission of providing accurate information to consumers.

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[191] See *Pearson I*, 164 F3d at 659 n 10.

[192] *Whitaker*, 248 F Supp 2d at 13.

[193] See id at 11 n 12, 12–13.

[194] Compare *Pearson I*, 164 F3d at 659, with *Whitaker*, 248 F Supp 2d at 13.

[195] Food and Drug Administration, *The Mission of the FDA* *1, online at http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM195857.pdf (visited Sept 15, 2013) (emphasis added).

[196] See Nutrition Labeling and Education Act, HR 3562, 101st Cong, 2d Sess, in 136 Cong Rec 33426 (Oct 24, 1990).

B. Language of Disclaimers

The DC Circuit acknowledged that it was the FDA's task to draft disclaimers and not the court's.[197] However, the court offered examples of general disclaimers that would rectify potential misleadingness without infringing on manufacturers' speech, such as, "The FDA does not approve this claim," or "The evidence in support of this claim is inconclusive."[198] Additionally, the court offered an example of a specific disclaimer detailing the strength of the scientific evidence and the rationale for that determination: "The evidence is inconclusive because existing studies have been performed with *foods* containing antioxidant vitamins, and the effect of those foods on reducing the risk of cancer may result from other components in those foods."[199] These examples provide the FDA with two alternate routes, one of general disclaimers and one of specific disclaimers explaining the rationale of the FDA's evaluation of the evidence.

Thus far, district courts have been reluctant to approve disclaimer language the FDA has proposed, on the grounds that the verbiage is too strongly worded and sometimes negates the claim. Courts are especially hostile when the FDA completely rewrites a claim, rather than permitting the manufacturer to make the claim and follow it with the FDA's supplemental disclaimer. In *Alliance I*, the FDA attempted to follow *Pearson I*'s instruction to provide precise disclaimers.[200] It seems that "precise" is not the appropriate term to describe what courts are looking for, however, because the court rejected the precise disclaimer for being too imposing on speech:

> Two weak studies suggest that selenium intake may reduce the risk of prostate cancer. However, four stronger studies and three weak studies showed no reduction in risk. Based on these studies, FDA concludes that it is highly unlikely that selenium supplements reduce the risk of prostate cancer.[201]

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[197] See *Pearson I*, 164 F3d at 659.

[198] Id.

[199] Id at 658 (emphasis in original) (modifying the claim "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers").

[200] See id at 659.

[201] See *Alliance I*, 714 F Supp 2d at 71.

The court described this modification as an example of a disclaimer that "contradict[s] the claim and defeats the purpose of making [it] in the first place."[202] Rather, the example of the specific disclaimer in *Pearson I* implied that the disclaimer would follow the manufacturer's claim, not replace it, and was specific in describing the limitations of the existing studies without negating the claim entirely.[203]

When the FDA proposed language similar to the DC Circuit and some district courts' suggestions, courts still rejected it.[204] In *Fleminger*, the court rejected the language "The FDA does not agree that green tea may reduce that risk."[205] However, it encouraged language quite similar—"The FDA does not approve this claim"—without adequately explaining the difference in its preference.[206] The court only said that the former had the effect of negating the claim, whereas the latter, which uses more absolute terms, did not.[207] If the courts force the FDA to permit health claims with which the FDA does not agree and simply state that "the FDA does not approve this claim" without further qualification, this leaves the FDA minimal to no authority to prevent claims it considers misleading. Merely informing consumers that the FDA does not agree with a claim does not fulfill the mission of protecting the public health and preventing consumer fraud because consumers are left in the dark as to how much credit to give the claim. Following this methodology, a health claim is either permitted or banned (although courts permit very few complete bans) and if it is permitted, it is offered at face value without qualification. *Pearson I* does not preempt the FDA from qualifying the strength of the evidence, and it is essential to do so to aid consumers in deciphering the value of health claims.

Courts remind the FDA that its role is to draft "short, succinct, and accurate disclaimers" reflecting the strength of the

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[202] Id.

[203] See *Pearson I*, 164 F3d at 658.

[204] See, for example, *Fleminger*, 854 F Supp 2d at 217–18.

[205] Id.

[206] See id at 218.

[207] See id ("Such a disclaimer [—'FDA does not approve this claim.'—] would not have the same effect of negating Fleminger's proposed health claim in the first instance and would therefore allow the FDA to achieve its interest in a manner that restricts less speech.").

scientific evidence.[208] The FDA was unsuccessful, until *Fleminger*, in reflecting the strength of the evidence in a meaningful way. *Fleminger* approved the portion of the disclaimer stating there is "very little scientific evidence" supporting the claim.[209] This, for the first time, suggested a compromise accurately reflecting the lack of scientific support that is short and easily understood by consumers. Thus, *Fleminger* may provide a model on how the FDA should proceed in drafting disclaimer language.

IV. SEPARATE AND DISTINCT CHALLENGES UNDER THE APA AND THE FIRST AMENDMENT: DEFERRING TO THE FDA FOR INHERENTLY MISLEADING CLAIMS AND CRAFTING DISCLAIMERS FOR POTENTIALLY MISLEADING CLAIMS

Courts face two separate and distinct challenges to FDA regulation of health claims, one under the APA and another under the First Amendment. However, courts have blurred the distinction between the two challenges by inaccurately applying a heightened standard of review to APA claims. Rather than applying the deferential arbitrary and capricious review to the FDA's conclusions regarding the evidence against an inherently misleading claim, the courts often substitute their own judgment to overturn the FDA out of concern for infringement on commercial free speech. For potentially misleading claims, courts continue to reject the FDA's proposed disclaimers. Combining a suggested disclaimer from *Pearson I* with a qualification of the strength of the evidence supporting the claim results in a disclaimer that both informs consumers and respects the First Amendment.

A. Inherently Misleading Claims: Deferring to the FDA

In reviewing the FDA's assessment of the scientific evidence surrounding a health claim, courts refer to the APA's arbitrary and capricious standard of review.[210] *Pearson I* required the

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[208] See *Pearson II*, 130 F Supp 2d at 120.

[209] See *Fleminger*, 854 F Supp 2d at 216–17.

[210] Because the FDA's regulation of health claims does not involve agency interpretation of a statute, *Chevron* deference does not apply. See generally *Chevron USA, Inc v Natural Resources Defense Council, Inc*, 467 US 837 (1984). See also *Fleminger*, 854 F Supp 2d at 206 (noting that challenging the FDA's conclusions should be analyzed "under Section 706(2) of the APA which provides that final agency action

FDA to offer clarification of the SSA standard so the court could review the agency's conclusion under the arbitrary and capricious standard. The court also held that there were certain instances where complete suppression of claims was appropriate, such as when the FDA "deem[ed] [the claim] incurable by a disclaimer."[211] Thus, the DC Circuit deferred to the FDA's judgment of whether the claim was supported by the weight of the evidence based on its technocratic expertise in evaluating the scientific studies. However, when the district courts that interpreted *Pearson I* applied the arbitrary and capricious or "independent" review, they did a thorough evaluation of the evidence—more than what is permitted under the deferential standard—and often reached their own, contrary conclusions. By applying a heightened review, the district courts are already taking into consideration the First Amendment preference for disclosure over suppression. Rather than applying the deferential APA review and then separately addressing the constitutional concerns, courts are preventing complete suppression in the instances specifically carved out by *Pearson I* by substituting their own judgment for that of the FDA.

1. Arbitrary and capricious review.

Courts are not accurately applying the arbitrary and capricious standard as required by the Administrative Procedure Act. Under 5 USC § 706, the court must "hold unlawful and set aside agency action" where those actions are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[212] There are both substantive and procedural components to the review.[213] First, the court considers whether the agency acted within the scope of its authority.[214] Next, the court evaluates the substantive validity of the action, meaning "the court must consider whether the decision was based on a consideration of the relevant factors and

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may only be set aside if arbitrary, capricious and an abuse of discretion").

[211] See *Pearson I*, 164 F3d at 659–60.

[212] Administrative Procedure Act, Pub L No 79–404, 60 Stat 237 (1946), codified at 5 USC § 706(2)(A).

[213] See *Citizens to Preserve Overton Park v Volpe*, 401 US 402, 416–17 (1971) ("*Overton Park*").

[214] See id at 416, citing *Schilling v Rogers*, 363 US 666, 676–77 (1960).

whether there has been a clear error of judgment."[215] The court may also set aside the action where there has been a procedural violation.[216] Although there are various components to the review, "the ultimate standard of review is a narrow one."[217] Even where the court may disagree with the agency's conclusion, as long as the agency followed procedure and gave a rationale for its conclusion, "[t]he court is not empowered to substitute its judgment for that of the agency."[218] Especially where the dispute involves questions of fact that "require[ ] a high level of technical expertise, [the court] must defer to the informed discretion of the responsible federal agencies."[219]

2. Arbitrary and capricious review as applied to health claims.

The DC Circuit did not focus on the appropriate level of deference accorded to an agency like the FDA. However, *Pearson I* required the FDA to define "significant scientific agreement" so the court could evaluate the FDA's scientific conclusions under the APA's arbitrary and capricious standard. The court reasoned that the lack of definition of the standard the FDA applied when evaluating the scientific evidence was the "equivalent to simply saying no without explanation."[220] However, the court qualified this request, noting that the FDA was not "obliged to issue a comprehensive definition" and was "entitled to proceed case by case."[221] Thus, the DC Circuit required, at a minimum, that the FDA explain its evaluation of the evidence for each claim.

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[215] *Overton Park*, 401 US at 416, citing Louis Leventhal Jaffe, *Judicial Control of Administrative Action* 359 (Little, Brown 1965).

[216] See 5 USC § 706(2)(D). See also *Overton Park*, 401 US at 417.

[217] *Overton Park*, 401 US at 416.

[218] Id. See also *Environmental Defense Fund, Inc v Costle*, 657 F2d 275, 283 (DC Cir 1981), stating:

> This "arbitrary and capricious" standard of review is a highly deferential one. . .which presumes the agency's action to be valid. . . . This standard is viewed as a narrow one, which forbids a court from substituting its judgment for that of the agency. . . . The standard mandates judicial affirmance if a rational basis for the agency's decision is presented . . . even though we might otherwise disagree.

[219] *Marsh v Oregon Natural Resources Council*, 490 US 360, 377 (1989), quoting *Kleppe v Sierra Club*, 427 US 390, 412 (1976) (quotation marks omitted).

[220] *Pearson I*, 164 F3d at 660.

[221] Id at 661.

The majority of the district courts pay lip service to the principle of giving deference to the agency's technical expertise.[222] However, many then do a thorough review of the scientific evidence to determine whether the court agrees with the exclusion of certain studies or with the FDA's determination of the study's strength and credibility.[223] The district courts that have overturned the FDA's judgment reasoned that the FDA did not appropriately apply its own Guidelines by excluding certain studies or giving them less weight.[224] However, for each denial of a claim, the FDA created a detailed record explaining which studies supported the claim, to what extent, and the value of that conclusion based on the strength and type of study.[225]

For example, in *Alliance I*, the FDA excluded certain studies from the evaluation of plaintiffs' colon and digestive track claims because they were retrospective, meaning they measured supplement intake after the subjects had already been diagnosed with the related disease.[226] The court determined this exclusion was unreasonable; while the court agreed with the FDA on three of the four studies it reviewed, for the last one, it noted that the measurement represented intake prior to diagnosis because the samples were "collected *mainly* before the *final* diagnosis *or* major treatment."[227] To withstand arbitrary and capricious review, the agency is only required to have made a reasoned decision supported adequately by evidence in the record. Here, the FDA gave a reasoned explanation for its exclusion of the study as retrospective because some samples were collected post-diagnosis. Thus, when the court substituted its own judgment for that of the agency technically qualified and statutorily authorized to review the scientific evidence, it exceeded the deferential standard of review. The court's heightened review resulted in the conclusion that a complete ban of the claim was unwarranted and a remand to consider disclaimers, if necessary.[228]

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[222] See, for example, *Alliance for Natural Health US v Sebelius*, 714 F Supp 2d 48, 60 (DDC 2010) ("*Alliance I*").

[223] See, for example, id at 63–70.

[224] See id at 68–71; *Whitaker*, 248 F Supp 2d at 11–13.

[225] See, for example, *Whitaker*, 248 F Supp 2d at 11 n 12 ("[T]he FDA discounted many of the studies supporting the relationship for study errors or design limitations.").

[226] See *Alliance I*, 714 F Supp 2d at 69.

[227] Id (emphasis added).

[228] Id at 70.

This is not to say that the FDA never misapplies its Guidelines or that the courts never apply the correct standard of review. For example, in *Whitaker*, the FDA emphasized studies that focused on high-risk populations to determine that the evidence did not support the claim, whereas the Guidelines discourage extrapolating such studies to the general population.[229] The court correctly determined that this misapplication of the Guidelines was unreasonable under an arbitrary and capricious review.[230] Alternatively, *Alliance II* found the FDA's decision to completely suppress four claims reasonable and not arbitrary because the FDA explained its rationale: "Since the FDA has provided a *reasoned explanation* for the exclusion of these studies and the explanation is consistent with the FDA's Guidance Document, the FDA's decision that these studies do not constitute credible evidence of the claim must be upheld."[231] While a misapplication of the Guidelines is appropriate grounds for remand, the court's mere disagreement with the FDA's conclusions is not.

3. Rationale for the application of a heightened standard of review.

Although the courts refer to the appropriate legal standard when reviewing an APA claim, they actually apply a stricter standard that results in fewer complete bans on health claims. Courts may apply a stricter standard of review, either unconsciously or knowingly but subversively, because of concerns of the resulting First Amendment conflict if they defer to the FDA. In the health claims cases, the courts reviewed the FDA's conclusions under a heightened standard, often reached an opposing conclusion that the speech was not inherently misleading, and thus preempted the more significant

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[229] See *Whitaker*, 248 F Supp 2d at 12–13. The court reasoned that:

> The [Guidance] Report clearly states that "[a]lthough interventional studies are the most reliable category of studies for determining cause-and-effect relationships, generalizing from selected populations often presents serious problems in the interpretation of such studies." . . . Yet, that is precisely what the FDA did when it generalized from studies of high-risk populations to evaluate the Plaintiffs' health claim.

Id.

[230] See id at 13.

[231] *Alliance II*, 786 F Supp 2d at 19.

infringement on manufacturers' commercial free speech that would have resulted from a complete ban.

The *Alliance I* and *Alliance II* courts acknowledged their application of a heightened standard, the "independent review": "While the Court is obligated to conduct an independent review of the record and must do so without reliance on the [FDA's] determinations as to constitutional questions, it must also give deference to an agency's assessment of scientific or technical data within its area of expertise."[232] Neither the *Alliance I* nor the *Alliance II* courts elaborated on how they could both independently review the constitutional question of whether to suppress speech while simultaneously deferring to the FDA's determination that the evidence did not support the claims, which would result in suppressed speech under *Pearson I*. *Fleminger*, on the other hand, stated that the level of support for a claim was "squarely within the ambit of the FDA's expertise," and as such, the court would give deference not only to the FDA's assessment of the weight of the evidence but also to "the FDA's determination that Fleminger's articulation of the level of scientific evidence was inaccurate and misleading."[233] This court accurately applied *Pearson I* by deferring to the FDA's conclusions of the weight of the evidence and the resulting impact on commercial speech.[234]

The antecedent question is who gets to determine if the speech is misleading, the FDA or the court? *Pearson I* implies that the FDA has the authority, via its conclusions regarding the weight of the evidence supporting the claim, to determine whether the claim is inherently misleading:

> [W]here evidence in support of a claim is outweighed by evidence against the claim, *the FDA could deem it incurable* by a disclaimer and ban it outright. . . . [W]e see no problem with *the FDA imposing an outright ban*

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[232] *Alliance II*, 786 F Supp 2d at 12, citing *Alliance I*, 714 F Supp 2d at 60 (quotation marks omitted).

[233] *Fleminger*, 854 F Supp 2d at 211.

[234] Because the FDA determined the claim in *Fleminger* was only potentially misleading, not inherently misleading and subject to complete suppression, perhaps the court was not tempted to apply a higher standard of review.

> on a claim where evidence in support of the claim is qualitatively weaker than evidence against the claim.[235]

These statements suggest that the FDA has the authority to determine when a claim may be banned outright. However, this conflicts with the first prong of the *Central Hudson* analysis, which requires *the court* to determine "whether the commercial speech . . . is misleading."[236] Legal scholarship is beginning to explore whether courts applying the *Central Hudson* test to constitutional claims are actually invoking a stricter standard than the intermediate scrutiny the test originally articulated.[237] Permitting a court to answer this antecedent question, however, often forces the answer to the first prong of *Central Hudson*—that the claim is not inherently misleading and cannot be completely suppressed.

While courts seek to avoid a constitutional question where possible,[238] they should not do so by misapplying the legal standard. In other constitutional challenges, courts have claimed to apply a deferential standard of review to overturn a decision, only later acknowledging they actually applied a heightened review.[239] Perhaps the Supreme Court will acknowledge that this interaction of regulatory and constitutional issues also requires a heightened review of administrative agency action. However, until that time, a district court must apply the law in reviewing a challenged health claim, even if that means deferring to an FDA conclusion with which it disagrees. Such is the result of an arbitrary and capricious standard of review for conclusions resulting from an agency's area of expertise.

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[235] *Pearson I*, 164 F3d at 659 (emphasis added).

[236] *Thompson v Western States Medical Center*, 535 US 357, 367 (2002).

[237] See generally Samantha Rauer, *When the First Amendment and Public Health Collide: The Court's Increasingly Strict Constitutional Scrutiny of Health Regulations that Restrict Commercial Speech*, 38 Am J L & Med 690 (2012); David Orentlicher, *The Commercial Speech Doctrine in Health Regulation: The Clash Between the Public Interest in a Robust First Amendment and the Public Interest in Effective Protection from Harm*, 37 Am J L & Med 299 (2011).

[238] See Charles H. Koch Jr, 4 Administrative Law And Practice § 11:11[3] (West 3d 2013) ("A well-established judicial practice has been to interpret statutes so as to avoid, if possible, constitutional questions.").

[239] Compare *Craig v Boren*, 429 US 190 (1976), with *Reed v Reed*, 404 US 71 (1971). In a gender discrimination context, the Supreme Court acknowledged that, while initially overturning gender discrimination under the guise of rational basis review, it was actually applying heightened scrutiny the entire time.

B. Potentially Misleading Claims: Acceptable Disclaimers under the First Amendment

Even if courts appropriately apply the arbitrary and capricious standard of review, this only eliminates the First Amendment problem for inherently misleading claims. For potentially misleading claims, courts often agree with the FDA's evaluation of the scientific evidence but still find the language of the disclaimer too burdensome on speech.[240] Combining the example disclaimer proposed in *Pearson I* with district courts' emphasis on conciseness and the strength of the evidence results in an example disclaimer that balances the FDA's goals with the First Amendment.

For potentially misleading claims, the FDA is often more concerned with the language of the claim than with the claim, itself: "[I]t appears that the Agency's central objection to the claim concerns the nature of the qualifying language, not the underlying relationship claim."[241] The various interpretations of the district courts share two principles for the successful wording of a disclaimer. First, courts are more likely to approve a disclaimer that alters some wording of the claim rather than completely rewriting it. Courts rejected FDA attempts to rewrite claims in their entirety as too burdensome and more likely to negate the claim.[242] On the other hand, the FDA had success in *Fleminger* with a disclaimer merely altering the qualifying language.[243] Second, the proposed disclaimers must be "short, succinct, and accurate."[244] The FDA needs to focus on "the strength or nature of the evidentiary support for that substance-disease relationship."[245] A short, accurate statement regarding the strength of the evidence is informative for consumers and not overly burdensome on manufacturers' commercial speech.

Every court that has addressed this issue suggested the language, "FDA does not approve this claim."[246] Thus far, the FDA has resisted using this language, perhaps because allowing

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[240] See, for example, *Whitaker*, 248 F Supp 2d at 24.

[241] *Alliance I*, 714 F Supp 2d at 72.

[242] See, for example, id at 71–72.

[243] See *Fleminger*, 854 F Supp 2d at 217.

[244] *Pearson II*, 130 F Supp 2d at 120.

[245] See *Alliance II*, 786 F Supp 2d at 24 n 22.

[246] See, for example, *Pearson I*, 164 F3d at 659.

a manufacturer to make a claim and merely noting that the FDA does not approve does not seem the most effective way to prevent consumer fraud. However, if the FDA combines this disclaimer with other approved language that informs consumers of the strength of the evidence—such as "very little scientific evidence," as in *Fleminger*[247]—courts would be more likely to uphold it.

The following example permits the claim followed by a short, informative disclaimer: "[Food product or dietary supplement] may reduce the risk of [specific disease]. The FDA does not approve this claim because there is very little scientific evidence for the claim." Here, the first portion permits the manufacturer to exercise its commercial free speech rights in making the claim. The second portion incorporates the court-suggested language with a short, succinct, and accurate disclaimer evaluating the strength of the evidence. The FDA could substitute "very little" with different but similarly worded descriptors reflecting its conclusion about the strength of the supporting evidence. While manufacturers and the FDA may continue to disagree over those qualifying words, a strong record of the FDA's application of the Guidelines and a court that truly applies the deferential arbitrary and capricious review should minimize the disagreements and begin to establish a stable body of case law on which the FDA can rely going forward.

V. CONCLUSION

The FDA's regulation of health claims juxtaposes two conflicting objectives, preserving commercial free speech and ensuring consumer protection. Every court that has addressed the regulation of health claims agrees that the FDA has a substantial interest in protecting public health and preventing consumer confusion.[248] The courts further agree that the "FDCA[ ] and NLEA[ ] express[ly] grant [ ] authority to the FDA to ensure that only truthful and accurate health claims supported by reliable scientific evidence are permitted in the marketplace."[249] If courts utilize the appropriately deferential arbitrary and capricious review, they not only comply with the

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[247] *Fleminger*, 854 F Supp 2d at 217.

[248] See, for example, *Pearson I*, 164 F3d at 655–56.

[249] See, for example, *Fleminger*, 854 F Supp 2d at 209.

APA but also permit the FDA to exercise its statutory and regulatory authority to protect consumers from inherently misleading claims. *Pearson I* and the district courts' varying interpretations, when synthesized, provide a path the FDA can follow in drafting disclaimers for potentially misleading claims. If the FDA respects manufacturers' commercial free speech rights by permitting them to make claims and then adds a short disclaimer noting why it does not endorse the claim, the FDA can successfully inform consumers of the value of the health claims on food products and dietary supplements while still respecting the First Amendment.