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## Is the FDA's Nose Growing? The FDA Does Not "Exaggerate Its Overall Place in the Universe" When Regulating Speech Incident to "Off-Label" Prescription Drug Labeling and Advertising

Nicole Endejann

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IS THE FDA'S NOSE GROWING?: THE FDA DOES NOT "EXAGGERATE[] ITS OVERALL PLACE IN THE UNIVERSE"<sup>1</sup> WHEN REGULATING SPEECH INCIDENT TO "OFF-LABEL" PRESCRIPTION DRUG LABELING AND ADVERTISING

In 1999, over two billion retail prescriptions were written and dispensed to patients.<sup>2</sup> Chances are, if you are not currently using a prescription drug, eventually you will come to rely on one to increase the quality or quantity of your life. How do you know if the drug will actually work as your physician says? Or if the drug is safe? Every year, over 125,000 patients die as a direct result of using a prescription drug.<sup>3</sup> Prescription drugs are legally classified as unavoidably unsafe products.<sup>4</sup> For over 60 years, the Food and Drug Administration (FDA) has been ensuring that the prescription drugs you use are safe and effective through the FDA approval process.<sup>5</sup> The FDA's objective has become

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1. *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 67 (D.D.C. 1998). District Judge Lamberth made this statement while reprimanding the FDA for promulgating regulations limiting the distribution of materials by prescription drug manufacturers. *See id.* at 67.

2. Fred Gebhart, *Rx Scoreboard*, 144 DRUG TOPICS, Apr. 3, 2000, at 31 (2000). The number of people using prescription drugs increased from 60 percent in 1996 to 66 percent in 1999 in a sample of 1.4 million insured. Tom Graham, *Study: People Using More Prescriptions*, SUN-SENTINEL (Ft. Lauderdale), June 4, 2000, available at 2000 WL 22177447. The largest growth was seen in patients between the ages of forty-five to sixty-five. *Id.* Eight out of ten senior citizens rely on a prescription drug for health maintenance. Pat Thibaudeau & Alex Deccio, *Making Prescription Drugs Affordable*, SEATTLE TIMES, Feb. 25, 2000, available at 2000 WL 5522664.

3. Amy D. White, Note, *The Mass Marketing of Prescription Drugs and Its Effect on the Learned Intermediary Doctrine*, 25 OKLA. CITY U. L. REV. 745, 761 (2000).

4. *See* RESTATEMENT (SECOND) OF TORTS § 402A (1965). The Restatement further explains: [T]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs . . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many . . . drugs . . . many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician.

RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

5. The Food, Drug and Cosmetic Act was passed in 1938. Patricia I. Carter, *Federal Regulation of Pharmaceuticals in the United States and Canada*, 21 Loy. L.A. Int'l & Comp. L.J. 215, 218 (1999). The Act created the FDA and required all new drugs to be adequately tested, ensuring the drug's safety. *Id.* at 224. In 1962, the Kefauver-Harris Amendments were passed, which required all new drugs to be proven both safe and effective. *Id.* at 220.

even more critical as the use of prescription drugs increases and the amount of information available to consumers increases through Direct-to-Consumer (DTC) advertising.<sup>6</sup> In an effort to accomplish its purpose, the FDA promulgates regulations directed towards labeling and advertising by drug manufacturers, which incidentally affects speech related to the sale of prescription drugs.

## I. INTRODUCTION

This Comment will begin by reviewing the development of the commercial speech doctrine,<sup>7</sup> followed by an introduction into compelled speech.<sup>8</sup> Next, this Comment will outline the Food and Drug Administration (FDA) regulations, as found in the Food, Drug and Cosmetic Act (FDCA), regarding prescription drug approval, labeling and advertising, including the Food and Drug Administration Modernization Act (FDAMA).<sup>9</sup> Next, this Comment will focus on two recent cases, which held that various FDA regulations violated the drug manufacturer's First Amendment right to engage in commercial speech, examining the analysis and reasoning of the courts.<sup>10</sup> Finally, this Comment will raise possible implications of these recent decisions, by applying the constitutional analysis and examining the possible consequences for the FDA's regulatory powers over prescription drugs<sup>11</sup> and drug manufacturer liability.<sup>12</sup>

## II. THE COMMERCIAL SPEECH DOCTRINE

The First Amendment provides in part that "Congress shall make no law . . . abridging the freedom of speech."<sup>13</sup> It is a simple command, which the courts have not strictly enforced.<sup>14</sup> Throughout U.S. jurispru-

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6. See *infra* notes 73-75 and accompanying text (discussing the effects of DTC advertising by drug manufacturers).

7. See *infra* Section II.

8. See *infra* Section III.

9. See *infra* Section IV.

10. See *infra* Section V.

11. See *infra* Section VI.A.

12. See *infra* Section VI.B.

13. U.S. CONST. amend. I.

14. See Jo-Jo Baldwin, Note, *Constitutional Law-Freedom of Speech. No Longer That Crazy Aunt in the Basement, Commercial Speech Joins the Family*. 44 *Liquormart, Inc. v. Rhode Island*, 116 S. Ct. 1495 (1996), 20 U. ARK. LITTLE ROCK L.J. 163, 167 (1997). The lack of uniformity in speech protection may be attributed to the lack of understanding of the framer's intent, different categories of speech, and potential effects resulting from government restrictions. *Id.* at 167-68.

dence, the courts have created multiple categories of speech,<sup>15</sup> each with a different applicable legal analysis.<sup>16</sup> Commercial speech is one of the categories the courts have not provided with full First Amendment protection.<sup>17</sup>

The origins of commercial speech may be traced back to *Valentine v. Chrestensen*.<sup>18</sup> Ironically, the Court never actually discussed the First Amendment, nor its relation to commercial speech,<sup>19</sup> but did remark that “the Constitution imposes no such restraint on government as respects purely commercial advertising.”<sup>20</sup>

The concept of commercial speech was not fully revisited by the Supreme Court until 1976 in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*<sup>21</sup> In this groundbreaking decision,

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15. *Id.* at 168. Categories of speech include fighting words, pornography, false statements, non-commercial and commercial speech. *Id.* at 168 n. 40.

16. Baldwin, *supra* note 14, at 168 n. 39. Courts generally apply strict scrutiny in content-based restrictions. *Id.* However, a lower scrutiny applies to “low-value” speech, in which there is a balancing of interests. *Id.* There are a range of tests for content-neutral based restrictions. *Id.*

17. *Id.* at 168. Possible reasons for the lack of full protection include failure to use the First Amendment as a defense in early case law, inapplicability of the First Amendment to the states until 1931 and viewing commercial advertising as an occupation rather than a form of expression. *Id.* at 169-70. In addition, the purposes of the First Amendment do not include aspects of commercial speech, such as the political process, self-expression, marketplace of ideas, or promotion of social stability. See Charles Gardner Geyh, *The Regulation of Speech Incident to the Sale or Promotion of Goods and Services: A Multifactor Approach*, 52 U. PITT. L. REV. 1, 10 (1990). Overall, commercial speech falls in a gray area between the valid regulation of goods and services and the presumptively invalid regulation of speech. *Id.* at 18. For a more in-depth analysis of the development of the commercial speech doctrine see P. Cameron DeVore, *Advertising and Commercial Speech*, in COMM. LAW 2000, at 31 (PLI Pat., Copyrights, Trademarks & Literary Prop. Course, Handbook Series No. G0-00BB, 2000).

18. *Valentine v. Chrestensen*, 316 U.S. 52 (1942). The New York City Sanitary Code prohibited distribution of commercial and business advertising in the streets. *Id.* at 53. The plaintiff distributed double-sided handbills, with an advertisement on one side and a protest against the city on the other side. *Id.*

19. *Valentine*, 316 U.S. at 52-55. The court focused on the power of government to regulate commerce. See *id.* at 54-55. The extent to which a person may promote an occupation is a matter of legislative judgment. *Id.* at 54.

20. *Id.* at 54. The court was illustrating the principle that the government may not “unduly burden” the freedom of communicating information, whereas the power to regulate commercial advertising bears no such restriction. See *id.* Later courts relied on Justice Robert’s statement in *Valentine* to distinguish between protection of commercial and non-commercial speech. See, e.g., *Pittsburgh Press Co. v. Pittsburgh Comm’n on Human Relations*, 413 U.S. 376, 388 (1973) (“Insisting that the exchange of information is as important in the commercial realm as in any other, the newspaper here would have us abrogate the distinction between commercial and other speech . . . it is [an] unpersuasive [argument].”); *Bigelow v. Virginia*, 421 U.S. 809, 821 (1975) (“[T]he advertisements would have received *some* degree of First Amendment protection . . . . Advertising is not thereby stripped of all First Amendment protection.”) (emphasis added).

21. *Virginia St. Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976).

the Court held that a state statute prohibiting pharmacists from advertising prescription drug prices violated the First Amendment.<sup>22</sup> Flying in the face of precedent,<sup>23</sup> Justice Blackmun cited four principles justifying the protection of purely commercial speech: a speaker's profit motivation does not remove speech from First Amendment protection,<sup>24</sup> the public need for commercial information was as important, if not more important, than political information,<sup>25</sup> free dissemination and availability of commercial information is required to sustain a free economy and democracy,<sup>26</sup> and the First Amendment prohibits the government from preventing the free flow of commercial information for the purpose of affecting public decisions.<sup>27</sup> Ultimately, the Court concluded that "[i]t is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us,"<sup>28</sup> and abruptly struck down the statute. Unfortunately, the Court left the door open for later encroachment by stating that the differentiating characteristics of commercial speech "suggest that a different degree of protection is necessary . . . ."<sup>29</sup>

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22. *Id.* at 773.

23. *See, e.g.,* *Bigelow v. Virginia*, 421 U.S. 809 (1975) (unconstitutional prohibition of advertisement by abortion referral agency); *Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations*, 413 U.S. 376 (1973) (municipal ordinance prohibiting "help-wanted" advertisements in gender-designated columns was constitutional); *Valentine v. Chrestensen*, 316 U.S. 52 (1942).

24. *Virginia St. Bd. of Pharmacy*, 425 U.S. at 762. Justice Blackmun relied on a long line of Supreme Court decisions, where labor disputes involving significant economic interests of employers and employees, retained First Amendment protection for their speech. *See id.*

25. *Id.* at 763. Because many users depend upon prescription drugs to extend the quantity of life or improve the quality of life, consumers are extremely interested in receiving price information. *Id.* at 736-64. The lack of information resulting from the statutory prohibition will most affect the elderly and low-income families. *Id.* at 763. On a more general level, prescription drug prices are of general public interest. *Id.* at 764.

26. *Virginia St. Bd. of Pharmacy*, 425 U.S. at 765. "The allocation of our resources. . . will be made through numerous private economic decisions" which must be "intelligent and well-informed." *Id.*

27. *Id.* at 770. "[P]eople will perceive their own best interests if only they are well enough informed, and. . . the best means to that end is to open the channels of communication rather than to close them." *Id.* The Court criticized the Virginia State Board of Pharmacy's "highly paternalistic approach" to protecting the public health. *Id.*

28. *Id.* at 770. The Supreme Court did not follow its own balancing test as set forth in *Bigelow v. Virginia*, 421 U.S. 809 (1975). In *Bigelow*, the Supreme Court overturned a conviction of a newspaper editor for publishing an abortion referral service advertisement on First Amendment grounds. *Bigelow*, 421 U.S. at 829. The court balanced the First Amendment interest against the public interest served by the regulation. *Id.* at 826-29.

29. *Virginia St. Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 n.24 (1976). The Court supported its conclusion based upon the "commonsense differences" between commercial speech and other forms of speech. *Id.* These differences include the greater objectivity and hardness of commercial speech. *Id.* Commercial speech is more objective because it may be more easily verifiable by the disseminator and more hardy or durable because its is less

Relying on its own open door and retreating from its blazon stance in *Virginia Board of Pharmacy*, the Supreme Court went back to the balancing test used in its pre-*Virginia* cases<sup>30</sup> where commercial speech had a “limited measure of protection, commensurate with its subordinate position in the scale of First Amendment values.”<sup>31</sup> The Court explained its reproach was a consequence of potential “dilution, simply by a leveling process of the force of the [First] Amendment guarantee with respect to non-commercial speech.”<sup>32</sup>

Finally, in 1980 the Supreme Court developed a four-part test for commercial speech protection in *Central Hudson Gas & Electric Corp. v. Public Service Commission*.<sup>33</sup> The Court instructed:

We must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than necessary to serve that interest.<sup>34</sup>

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likely to be chilled by regulation since it is a means for producing profits. *Id.*

30. *See, e.g., Bigelow*, 421 U.S. at 809; *Valentine v. Chrestensen*, 316 U.S. 52 (1942).

31. *Ohralik v. Ohio St. Bar Ass'n*, 436 U.S. 447, 456 (1978). *See, e.g., Ohralik*, 436 U.S. at 447 (state's restriction of personal solicitation by attorney constitutional); *Bates v. St. Bar of Ariz.*, 433 U.S. 350 (1977) (blanket restriction of attorney advertising unconstitutional). In both cases, the court balanced the value of the commercial speech at hand with the state's interest in regulation. *See, e.g., Ohralik*, 436 U.S. at 455-68; *Bates*, 433 U.S. at 365-85.

32. *Ohralik*, 436 U.S. at 456. The courts have given commercial speech limited protection of the First Amendment, enabling some regulation that would otherwise be unconstitutional in the realm of non-commercial speech. *Id.*

33. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980) (prohibition of promotional advertising by electric utility company unconstitutional).

34. *Id.* at 566. Before applying the four-part test, the court must first determine whether the speech involves a legal activity and is truthful because speech, which is inaccurate or relates to illegal conduct, may be constitutionally suppressed. *Id.* at 563-64 (citing *Friedman v. Rogers*, 440 U.S. 1, 13 (1979)); *Pittsburgh Press Co. v. Human Relations Comm'n*, 413 U.S. 376, 388 (1973)). Inaccurate information includes “communication more likely to deceive the public than to inform it.” *Central Hudson*, 447 U.S. at 563. In applying this test to the case, the prohibited speech was considered commercial in nature, even though the utility company held a monopoly, and did not involve illegal activity or misleading information. *Central Hudson*, 447 U.S. at 566-67. The government asserted two substantial interests of conserving energy and ensuring fair rates. *Id.* at 568-69. The government's interest in equitable rates was only tenuously connected to promotional advertising. *Id.* at 569. However, the interest in energy conservation was directly linked to advertising. *Id.* However, the regulation prohibiting advertising by electric utilities did not justify the suppression of electric utility information to the public because it prohibiting all advertising, regardless of its effect on energy consumption. *Id.* at 570. Therefore, the regulation was an invalid violation of the First Amendment. *Id.*

After developing the *Central Hudson* test,<sup>35</sup> the Supreme Court then grappled with the issue of what constitutes commercial speech. Commercial speech was defined as speech that does “no more than propose a commercial transaction.”<sup>36</sup> However, in *Bolger v. Youngs Drug Products Corp.*, the Court supplemented that definition with factors to help indicate forms of commercial speech: an intent for the speech to function as an advertisement, the speech refers to a specific product, and the speech is economically motivated.<sup>37</sup>

Next, in a surprising decision, the Supreme Court upheld a blanket prohibition of casino gambling advertisements directed towards residents of Puerto Rico in *Posadas de Puerto Rico Association v. Tourism Co. of Puerto Rico*.<sup>38</sup> Relying solely on the legislative findings,<sup>39</sup> the Court concluded that the “greater power to completely ban casino gambling necessarily includes the lesser power to ban advertising of casino gambling” by the legislature.<sup>40</sup> An alternate option of requiring “counterspeech” was also discounted based on the legislature’s failure to pass regulations aimed at mandating counterspeech.<sup>41</sup>

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35. See *supra* note 34 and accompanying text (discussing the *Central Hudson* test).

36. *Pittsburgh Press Co.*, 413 U.S. at 385. This definition has been modified, discarded and returned to, as a final definition seemingly eludes the judiciary. See Glenn C. Smith, *Avoiding Awkward Alchemy-In the Off-Label Drug Context and Beyond: Fully-Protected Independent Research Should Not Transmogrify Into Mere Commercial Speech Just Because Product Manufacturers Distribute It*, 34 WAKE FOREST L. REV. 963, 989-1004 (1999). The Supreme Court has used various approaches to define commercial speech including: common sense distinctions, proposing commercial transactions, serving economic interests of the speaker and audience and various descriptive factors. *Id.* See also *infra* note 37 and accompanying text (discussing the *Bolger* factors).

37. *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 66-67 (1983). The court relied on the combination of characteristics to find informational pamphlets on the use and availability of the manufacturer’s product were commercial speech. *Id.* at 67. The pamphlets were acknowledged to be advertisements, referred to a specific product and economically motivated, thereby encouraging the classification of commercial speech. *Id.* at 66-67. The informational pamphlets were considered commercial in nature, even though they contained information about important public issues. *Id.* at 67-68. The Court reasoned that a company has many other non-commercial avenues to inform the public of important issues, which would be fully protected. *Id.* at 68.

38. *Posadas de Puerto Rico Ass’n v. Tourism Co. of Puerto Rico*, 478 U.S. 328 (1986). The Puerto Rico legislature legalized certain forms of gambling, but prohibited any advertisements to the people of Puerto Rico, whereas advertisements to tourists were allowed. *Id.* at 331-32.

39. *Id.* at 341-45. The court found that the legislature’s belief that “excessive casino gambling among local residents. . . would produce serious harmful effects on the health, safety and welfare of the Puerto Rico citizens” was reasonable, and therefore a substantial interest restricting no more speech than necessary. *Id.* at 341-43 (quoting Appellee’s Brief at 37, *Posadas de Puerto Rico Ass’n v. Tourism Co. of Puerto Rico*, 478 U.S. 328 (1986) (No. 84-1903)).

40. *Posadas*, 478 U.S. at 345-46. The court reasoned that advertising regulations were permissible because they were less intrusive than completely prohibiting the underlying act altogether. *Id.* at 346.

41. *Id.* at 344. “We think it is up to the legislature to decide whether or not such a ‘counterspeech’ policy would be as effective in reducing the demand for casino gambling as restriction on

In *44 Liquormart, Inc. v. Rhode Island*, the Supreme Court did not extend such deference to the legislature when it struck down a complete statutory ban on alcohol pricing information, and held that its analysis in *Posadas* was erroneous.<sup>42</sup> Recognizing that some room for legislative judgment is appropriate, the Court went back to the *Central Hudson* test requirement that the government must show the regulation would advance its interest to a “material degree.”<sup>43</sup> In striking down the statute, the Court also relied heavily on the availability of less restrictive forms of regulation to attain the same goal.<sup>44</sup>

### III. COMPELLED SPEECH

The First Amendment includes both the right to speak freely and the right to refrain from speaking at all.<sup>45</sup> Although the Supreme Court has developed a compelled speech doctrine in the context of non-commercial speech,<sup>46</sup> it has not offered any guidance in the area of commercial speech.<sup>47</sup> However, it seems government mandated warning

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advertising.” *Id.*

42. *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 508-13 (1996). “*Posadas* clearly erred in concluding it was ‘up to the legislature’ to choose suppression over a less speech-restrictive policy.” *Id.* at 509. In this case, Rhode Island prohibited the advertisement of alcohol price information. *Id.* at 489. The court held that the ban violated the First Amendment under the *Central Hudson* analysis. *Id.*

43. *44 Liquormart*, 517 U.S. at 505-09 (quoting *Edenfield v. Fane*, 507 U.S. 761, 771 (1993)). The government must show a stronger effectual relationship between the regulation and its interest because it has chosen the drastic means of restricting speech to achieve its goal. *Id.* at 505. Although the court noted that logic teaches that a lack of advertising will decrease competition, thereby increasing prices, in this case, the government failed to provide any actual evidence to show the prohibition of alcohol pricing advertisements would significantly decrease market demand. *See id.* at 506.

44. *Id.* at 507-08. The court pointed to tax increases and educational programs as less speech-restrictive means to attain the government’s objective. *Id.* at 507.

45. *Wooley v. Maynard*, 430 U.S. 705, 714 (1977) (citing *West Virginia St. Bd. of Educ. v. Barnette*, 319 U.S. 624, 645 (1943) (Murphy, J. concurring)).

46. *See, e.g., Talley v. California*, 362 U.S. 60 (1960) (compulsory disclosure of a publisher’s name and address is an unconstitutional requirement discouraging publication and dissemination of work); *West Virginia St. Bd. of Educ. v. Barnette*, 319 U.S. 624 (1943) (compulsory flag salute is an unconstitutional requirement to affirm an ideology in which one does not believe). The courts have created two theories of protection for compelled, non-commercial speech: ensuring the “freedom of belief” and preventing deterrence of a speaker’s protected activity. Kathryn Murphy, Note, *Can the Budweiser Frogs Be Forced to Sing a New Tune?: Compelled Commercial Counter-Speech and the First Amendment*, 84 VA. L. REV. 1195, 1204-05 (1998).

47. Murphy, *supra* note 46, at 1211. Compelled speech within the commercial arena does not seem to implicate the constitutional issues raised in the non-commercial arena. *Id.* at 1211. Because one of the underlying purposes of commercial speech protection is to ensure the “stream of commercial speech flows cleanly, as well as freely,” compelling disclosure of truthful information does not interrupt the stream. *Id.* (quoting *Virginia St. Bd. of Pharmacy v. Virginia Citizens Con-*

labels, which could be considered compelled speech, are not regarded as suspect as other forms of compelled speech.<sup>48</sup>

The Second Circuit has touched upon this issue within the food industry, which is analogous to the FDA's power in the drug industry.<sup>49</sup> In *International Dairy Foods Ass'n v. Amestoy*, a state statute required milk labels to disclose any use of synthetic growth hormone in milk production.<sup>50</sup> However, because the FDA found that milk treated with the growth hormone was indistinguishable from untreated milk, the FDA did not require any such labeling.<sup>51</sup>

The Court found the state requirement compelling manufacturers to disclose use of hormones violated the First Amendment.<sup>52</sup> The Court noted that even though the statute required disclosure of truthful information to the public, it must still pass the *Central Hudson* test to avoid constitutional issues.<sup>53</sup> Under the test, the "strong consumer interest and the public's 'right to know'" asserted by the state government were not

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sumer Council, Inc., 425 U.S. 748, 772 (1976)). *But see* *Glickman v. Wileman Bros. & Elliott Inc.*, 521 U.S. 457 (1997) (mandatory funding of generic advertising by state fruit producers not a violation of the First Amendment). In *Glickman*, the court had a perfect opportunity to develop an analysis of compelled, commercial speech, but instead the court treated the compelled funding of commercial expression as the regulation of economics, not commercial speech. Murphy, *supra* note 46, at 1211-13.

48. Jack B. Harrison & Mina J. Jefferson, "Some Accurate Information is Better Than No Information At All": Arguments Against an Exception to the Learned Intermediary Doctrine Based on Direct-To-Consumer Advertising, 78 OR. L. REV. 605, 635 (1999). The government may compel the disclosure of factual information in labeling for the benefit of health information. Murphy, *supra* note 46, at 1221. Possibly because factual disclosures do not keep consumers in the dark, but rather keep consumers better informed, thereby avoiding any paternalistic government purposes. *Id.* at 1211.

49. See 21 U.S.C. §§ 16-250b (1994 & Supp. 1998) (regulating food within the FDCA).

50. *International Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 69 (2d Cir. 1996). The State of Vermont gave manufacturers four labeling options under the statute, which informed the consumer that rBST (a synthetic growth hormone) may have been used in the milk's production. *Id.* at 70.

51. *Id.* at 69.

52. *Id.* at 72. "Because compelled speech 'contravenes core First Amendment values' appellants have 'satisfied the initial requirement for securing injunctive relief.'" *Id.* (quoting *Paulsen v. County of Nassau*, 925 F.2d 65, 68 (2d Cir. 1991)). The milk producers were entitled to a preliminary injunction due to irreparable harm to their First Amendment rights. *Id.* at 71. Preliminary injunctions are granted when the plaintiff shows "(a) irreparable harm and (b) either (1) likelihood of success on the merits or (2) sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly toward the party requesting the preliminary relief." *International Dairy Foods Ass'n*, 92 F.3d at 70. Looking at a number of cases, the court noted that loss of any First Amendment rights, even for an insubstantial amount of time, will constitute irreparable harm. *Id.* at 71.

53. *Id.* at 71. The court did not determine whether or not the compelled speech was purely commercial because even if it was not, the government could not meet its burden under the less rigorous *Central Hudson* test. *Id.* at 72-73.

substantial enough to justify the restrictions on commercial speech.<sup>54</sup>

#### IV. FDA PRESCRIPTION DRUG REGULATIONS

##### A. FDA Prescription Drug Approval Process

The FDA was established by the Food, Drug and Cosmetic Act (FDCA)<sup>55</sup> to regulate the importation, manufacture, distribution and sale of drugs in the United States.<sup>56</sup> The FDA must approve all new drugs entering the U.S. to ensure both safety and efficacy.<sup>57</sup> A manufacturer must submit a New Drug Application (NDA) to the FDA, which provides detailed safety and efficacy data and analysis.<sup>58</sup> The NDA must also include proposed labeling for the new drug, which is adequate for the intended use.<sup>59</sup> The FDA will approve a new drug if the manufacturer provides “substantial evidence” of its safety and efficacy.<sup>60</sup> The

54. *Id.* at 73. The state never asserted an interest in protection of public health and safety, since the FDA position clearly showed a lack of health impact. *Id.*

55. Pub. L. No. 52-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-397 (1994 & 1998 Supp.)).

56. Carter, *supra* note 5, at 224 (discussing the complete history of the development of the current FDCA). The FDCA was promulgated under Congress’s power to regulate interstate commerce. *Id.* at 223. The FDCA prohibits the movement of adulterated or misbranded food, drugs, devices or cosmetics in interstate commerce. 21 U.S.C. § 331 (1994 & Supp. 1998). The FDA is an independent agency within the department of Health and Human Services (DHHS). Carter, *supra* note 5, at 225 (1994). The FDA’s enforcement authority is derived from Congress’s delegation of power to regulate food and drugs to the Secretary of the DHHS, who in turn, delegated the authority to the Commissioner of the FDA. *Id.*

57. See 21 U.S.C. § 355(a), (d) (1994 & Supp. 1998). A new drug is defined as a “drug not generally recognized among experts. . .as safe and effective under the conditions prescribed, recommended or suggested in the labeling thereof.” 21 U.S.C. § 321(p) (1994).

58. See 21 U.S.C. § 355(b) (1994 & Supp. 1998). Manufacturers may also submit an abbreviated new drug application (ANDA) for approval of a bioequivalent drug (also known as a “me too” drug). See 21 U.S.C. § 355(j) (1994 & Supp. 1998). However, an ANDA is not applicable for approval of a drug with an intended new use; manufacturers must submit an NDA for each intended new use of a drug which has been approved for a different use. See 21 C.F.R. § 314.54 (2000). For a discussion of the sequential phases of clinical studies required for NDA see Carter, *supra* note 5, at 230-35.

59. See 21 U.S.C. § 355(b)(1)(F) (1994 & Supp. 1998) (proposed labeling required); 21 U.S.C. § 355(d) (1994 & Supp. 1998) (denial of approval if labeling inadequate).

60. See 21 U.S.C. § 355(b). Substantial evidence is defined as:  
evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.  
21 U.S.C. § 355(d).

label will indicate only approved uses, or uses in which there is substantial evidence of their safety and efficacy.<sup>61</sup> The label must also reveal all medically relevant information regarding the appropriate use of the drug, such as dosage, directions for administration, known precautions, warnings, and contraindications.<sup>62</sup> Once the new drug has been approved, the manufacturer may introduce the drug into interstate commerce, however, the FDA still has broad powers to control multiple aspects of the drug's journey.<sup>63</sup>

### *B. FDA Prescription Drug Labeling Regulations*

Labeling is defined in the FDCA as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.”<sup>64</sup> The Supreme Court construed the term “accompanying” as matter that supplements or explains the product.<sup>65</sup> A label is “misbranded” if the label contains false or misleading information,<sup>66</sup> which is determined by not only what is stated on the label, but also what information is not included on the label.<sup>67</sup> A label is also deemed false or misleading if the label does not contain ade-

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61. 21 U.S.C. § 355(d). A manufacturer must show the drug is “safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof.” 21 U.S.C. § 355(d).

62. 21 C.F.R. § 201.56(d)(1) (2000).

63. *See* 21 U.S.C. §§ 301-379 (1994 & Supp. 1998) (regulating the manufacture, packaging, distribution, shipment and inspection of prescription drugs). The FDA has promulgated many regulations on communications emanating directly or indirectly from drug manufacturers because of the intent to influence the market and decisions of prescribers and/or consumers. David G. Adams, *FDA Regulation of Communications on Pharmaceutical Products*, 24 SETON HALL L. REV. 1399, 1400 (1994). The regulations are comprehensive and aggressive due to the FDA's jurisdiction over a vast array of products, multiple avenues of communication and the variety of audiences consuming the information. *Id.* at 1400-01.

64. 21 U.S.C. § 321(m) (1994). The FDA has further defined labeling as including “brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, . . . reprints . . . and references published . . .” 21 C.F.R. § 202.1(1)(2) (2000).

65. *Kordel v. United States*, 335 U.S. 345, 350 (1948). The court further explained that physical attachment is not required for an article to accompany another, only a textual relationship. *Id.* at 349-50.

66. 21 U.S.C. § 352(a) (1994 & Supp. 1998) (applies to both drugs and devices). Food and cosmetics are also subject to the same requirements. *See* 21 U.S.C. § 343(a)(1) (1994) (food); 21 U.S.C. § 362(a) (1994) (cosmetics).

67. *See* 21 U.S.C. § 321(n) (1994). Any failure to reveal material facts will be deemed a false or misleading label. 21 U.S.C. § 321(n). The FDA may take into account “representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations . . .” 21 U.S.C. § 321(n).

quate directions for every use of the drug.<sup>68</sup>

### C. FDA Prescription Drug Advertising Regulations

Advertising is not defined in the FDCA;<sup>69</sup> however, the FDA states that it includes “advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.”<sup>70</sup> The FDCA does not directly prohibit false or misleading advertising of prescription drugs, however the FDA accomplishes this by mandating requirements for advertising.<sup>71</sup> If the advertisement fails to reveal all material facts, or a fair balance of the information, it is considered “misbranded.”<sup>72</sup>

Over the past three decades, the FDA has increasingly relaxed advertising regulations, finally permitting manufacturers to advertise directly to the public, in the form of direct-to-consumer (DTC) advertising.<sup>73</sup> The effects of DTC advertising have been mixed. Proponents

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68. 21 U.S.C. § 352(f) (1994). A drug’s label must include every purpose for which a drug is intended to be used, along with adequate information for use. *See e.g.*, *United States v. Device Labeled “Cameron Spittler, Etc.”* 261 F. Supp. 243, 245 (D. Neb. 1966); 21 C.F.R. § 20.100 (2000). Therefore, if an intended use is not listed, or if adequate information for every intended use is not provided in the label, the drug is misbranded. *See* 21 U.S.C. § 352(a). Therefore, if a drug is used “off-label,” the label is considered “false and misleading” because the new use or information has not been approved by the FDA and included within the labeling. 21 U.S.C. § 352(a). *See also* David A. Kessler, *Regulating the Prescribing of Human Drugs for Nonapproved Uses Under the Food, Drug and Cosmetic Act*, 15 HARV. J. ON LEGIS. 693, 745-46 (1978) (discussing the dilemma between labeling, intended uses and off-label uses by physicians).

69. *See* 21 U.S.C. § 352(n) (1994) (advertising does not include labeling). Although there is no definition of advertising in the FDCA, the FDA distinguishes between advertisements and labels based upon the form of communication. *See Adams, supra* note 63, at 1408. If the communication is written, printed or graphic it is considered a label; otherwise the communication is considered an advertisement. *Id.*

70. 21 C.F.R. § 202.1(1)(1) (2000).

71. 21 C.F.R. § 202.1 (2000). The advertisement must include a brief summary of side effects, contraindications, warnings, precautions and effectiveness. 21 C.F.R. § 202.1(e) (2000). If there is not a brief summary, adequate provisions must be made to provide the information in the approved labeling. 21 C.F.R. § 202.1(e). The statement must give a fair balance and not be false, misleading or fail to reveal any material facts. 21 C.F.R. § 202.1(e)(5) (2000).

72. 21 U.S.C. § 352(n) (1994). The advertisement will be misbranded unless it contains a true statement of the name and ingredients and a brief summary of side effects, contraindications and effectiveness. 21 U.S.C. § 352(n).

73. Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 147 (1997) [hereinafter Noah, *Advertising Prescription Drugs*]. Prior to the 1980’s, only drug prices were advertised, as long as there was no mention of the drugs safety or efficacy. *Id.* In 1982, the FDA placed a moratorium on advertising, while it reviewed its regulations. *Id.* In 1985, the FDA lifted the moratorium, announcing the current advertising regulations were sufficient to protect the public. *Id.* DTC advertisements are found on the

believe DTC advertising will ultimately lead to decreased drug prices, encourage patients to seek treatment for conditions that would otherwise be undiagnosed and/or treated and result in a more enlightened and involved patient increasing the likelihood of better medical outcomes.<sup>74</sup> However, critics believe DTC advertising will adversely affect the physician-patient relationship.<sup>75</sup>

*D. FDA Policy on “Off-Label” Uses of Prescription Drugs and the Food and Drug Administration Modernization Act of 1997 (FDAMA)*

Often, researchers and doctors find new uses for drugs,<sup>76</sup> which are

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Internet, in newspapers, magazines and television commercials. White, *supra* note 3, at 756. In 1993, drug manufacturers spent an estimated \$100 million, and by 1998, the amount increased to over \$1 billion. *Id.*

74. White, *supra* note 3, at 759. Manufacturer’s use DTC advertising to encourage patients to visit physicians and request prescription drugs for previously untreated conditions, to encourage the switch to newly marketed drugs faster, and to create brand loyalty. Noah, *Advertising Prescription Drugs*, *supra* note 73, at 150. DTC advertising is paying off, since the top three newly launched drugs in 1999, Celebrex, Viagra and Vioxx, were all heavily advertised to consumers. Gebhart, *supra* note 2, at 35. DTC advertising is not the only means to increase sales of prescription drugs, but it is a major contributor. *Id.*

75. White, *supra* note 3, at 757-58. The purpose of DTC advertising is to “convince consumers to visit the physicians and request specific drugs for their medical conditions, to encourage them to request new drugs more rapidly than physicians might otherwise decide, and to create brand loyalty such that the consumer resists the physician’s efforts to change prescriptions.” Harrison, *supra* note 48, at 616. In one study, three in ten patients knew which drug they wanted before going to see a physician. Milt Freudenheim, *Prescription drug sales soar with help of advertisements*, J. REC. (Okla. City), Dec. 2, 1998, available at 1998 WL 11962205. Forty percent of those patients actually received a prescription for the drug requested. *Id.* In another study conducted in New Zealand and the United States, the only countries with DTC advertising, revealed that ninety percent of physicians felt pressured to prescribe the requested medication, and eighty percent succumbed to the patient pressure, even though it was not necessarily the physician’s first choice. Yonni D. Fushman, Comment, *Perez v. Wyeth Labs., Inc.: Toward Creating a Direct-To-Consumer Advertisement Exception to the Learned Intermediary Doctrine*, 80 B.U. L. REV. 1161, 1172 (2000). One reason why physicians fall victim to patient pressure is the fear of losing patients, which is very harmful in today’s managed care system. *Id.* The physician’s fear is not exaggerated because seventy-five percent of patients said they would switch physicians in order to receive the medication requested. *Id.* Some physicians believe the resultant partially informed patient will become aggressive and distrusting. Gebhart, *supra* note 2, at 36. DTC advertising may cause “significant tension. The physician can be put in the position of having to unsell the patient on a completely inappropriate product. That’s what physicians hate about DTC.” *Id.* (quoting Michael Wilkes, M.D., associate professor of medicine at the University of California Los Angeles Medical Center).

76. Steven R. Salbu, *Off-Label Use, Prescription, And Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 FLA. L. REV. 181, 196-97 (1999). Physicians play a crucial role in the development of new drug uses because they are involved with patients on a routine basis, thereby noting trends and developing theories of treatment, the number of practicing physicians exceeds the number of research facilities, and there is a lack of formalized, rigid constraints in testing new theories for physicians in practice. *Id.* at 196-98. Also, the financial and time costs of conducting research in laboratories are much greater. *Id.*

different from those uses tested and approved by the FDA, and therefore are not provided for in the drug label.<sup>77</sup> These “off-label” uses are often “necessary for optimal patient care.”<sup>78</sup> The FDA’s policy regarding off-label uses is that “once a [drug] has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in the approved labeling.”<sup>79</sup> The FDA’s policy reflects the lack of power to limit a physician’s practice of medicine.<sup>80</sup> The permissibility of off-label uses recognizes the physician’s need to treat patients individually and the role of the medical practice in developing and researching new drug uses.<sup>81</sup> Although the FDA has no power to limit off-label prescribing habits, Congress has attempted to give the FDA the power to regulate the distribution of off-label information by drug manufacturers.

In 1997, Congress enacted the FDAMA to protect the public’s health and safety by ensuring distribution of only truthful, non-

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77. Edmund Polubinski III, Note, *Closing the Channels of Communication: A First Amendment Analysis of the FDA’s Policy on Manufacturer Promotion of “Off-Label” Use*, 83 VA. L. REV. 991, 992. See also Citizen Petition Regarding the Food and Drug Administration’s Policy on Promotion of Unapproved Uses of Approved Drugs and Devices; Request for Comments, 59 Fed. Reg. 59820, 59821 (1994) [hereinafter Citizen Petition]. Off-label use includes any deviation from the intended patient, dosage, condition or drug combination identified in the approved drug label. Salbu, *supra* note 76, at 188.

78. James M. Beck & Elizabeth D. Azari, FDA, *Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 80 (1998). Researchers estimate that 25-60% of the 1.6 billion prescriptions written per year are for “off-label” uses. *Id.* The majority of medical conditions with standard “off-label” use treatment include cancer, heart disease, AIDS, kidney disease with dialysis, osteoporosis and pediatric uses. *Id.* It is often stated that “if you didn’t use the drug in the off-label way, you’d be guilty of [medical] malpractice.” *Id.* (quoting Fran Kritz, *FDA Seeks To Add Drugs’ Uses To Labels*, WASH POST, Mar. 29, 1997, at 11).

79. Citizen Petition, *supra* note 77, at 59,821 (quoting FDA Drug Bulletin 12:4-5, 1982). The reasons behind the FDA’s hands-off policy for off-label prescribing is because the off-label use may be “appropriate and rational in certain circumstances, and may, in fact reflect approaches to drug therapy that have been extensively reported in medical literature . . . . Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations . . .” *Id.*

80. In fact, the FDCA expressly prohibits the FDA from exercising any authority within a physician’s prescribing practice. See 21 U.S.C. § 396 (1994 & Supp. 1998). “Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health-care-practitioner-patient relationship.” 21 U.S.C. § 396.

81. Margaret Gilhooley, *Constitutionalizing Food and Drug Law*, 74 TUL. L. REV. 815, 828 (2000) [hereinafter Gilhooley, *Constitutionalizing Law*]. The advantages of off-label prescribing include earlier availability of life-saving treatments, encouragement of medical innovation, and decreased drug costs resulting from bypassing the costly and timely FDA approval process. Polubinski, *supra* note 77, at 1005-09. The disadvantages include risks to public health and safety, misleading physicians, and decreasing incentives for FDA approval. *Id.*

misleading information regarding uses of prescription drugs.<sup>82</sup> The main thrust of the FDAMA is to regulate the dissemination of off-label uses to physicians by drug manufacturers in enduring materials.<sup>83</sup> The statute specifically allows a drug manufacturer to “disseminate . . . written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling of a drug” if the manufacturer complies with certain requirements.<sup>84</sup> The requirements include: (1) submission of a new drug application,<sup>85</sup> (2) the disseminated information is not

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82. See Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074, 64,079 (1997). Initially, the FDA released two guidances regulating enduring materials and manufacturer involvement in continuing medical education seminars. See Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (1997) (regulating manufacturer involvement in CME’s); Final Guidance on Advertising and Promotion, 61 Fed. Reg. 52,800 (1996) (regulating manufacturer distribution of enduring materials). Enduring materials are reprints of medical text and peer reviewed journal articles. See 21 U.S.C. § 360aaa-1 (1994 & Supp. 1998). CME’s are continuing medical education programs and symposia. See Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (1997). The FDA listed twelve factors to determine whether off-label information was independent of the manufacturer’s promotional activity in CME’s. See *id.* The twelve factors are: control of content and selection of presenters, disclosure of manufacturer involvement, program focus(es), relationship between manufacturer and provider, provider involvement in manufacturer promotion, provider reputation, number of presentations, audience selection, discussion opportunity, further dissemination, promotional activities and complaints. *Id.* at 64,092. Only the policy regarding enduring materials was codified in the FDCA. See *infra* note 83 (detailing the codified provisions of the FDAMA). Passage of the FDAMA was controversial because many felt the changes decreased public protection, while others felt the changes were inconsequential. Gilhooley, *Constitutionalizing Law*, *supra* note 81, at 831. President Clinton remarked the FDAMA was a compromise between consumer protection and medical information. *Id.*

83. See 21 U.S.C. § 360aaa (Supp. 1998). The Act also concerns pediatric drug studies, fast-track studies and approvals, clinical research, small-scale drug manufacturing, exemptions for investigational devices and pharmacy compounding among other topics. See Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-15, 111 Stat. 2296 (now codified in scattered sections throughout the FDCA at 21 U.S.C. §§ 343-3 to 397). The FDAMA also provides for the regulation of pharmacy compounding advertisements. 21 U.S.C. § 353a (Supp. 1998). Pharmacy compounding is the “process by which a pharmacist combines, mixes or alters ingredients to create a medication that serves the unique needs of specific patients.” *Western States Medical Center v. Shalala*, 69 F. Supp.2d 1288, 1291 (D. Nev. 1999). The FDAMA provision prohibiting advertisements of pharmacy compounded drugs violated the First Amendment under the *Central Hudson* framework. *Id.* at 1309. The advertisements were not inherently misleading, and the statute did not directly advance the government’s interest of ensuring low volumes of compounded drugs nor was it narrowly tailored. *Id.* at 1298-1309.

84. 21 U.S.C. § 360aaa(a) (Supp. 1998).

85. 21 U.S.C. § 360aaa(b)(1)(A) (Supp. 1998). An ANDA may be submitted in lieu of the NDA if the drug qualifies. See 21 U.S.C. § 360aaa(b)(5) (Supp. 1998) (referring to 21 U.S.C. § 360aaa-3). A manufacturer may also disseminate information even though an ANDA has not been filed and clinical studies have not been completed, if the manufacturer submits a proposed protocol and schedule for the studies to be completed within thirty-six months of the initial dissemination. 21 U.S.C. § 360aaa-3(c) (Supp. 1998). A manufacturer may be exempted if it is determined that the ANDA is economically prohibitive or the studies would be unethical. 21 U.S.C. § 360aaa-3(d)

abridged, false, misleading or poses a significant health risk,<sup>86</sup> (3) any clinical research found in the information is not conducted by another manufacturer,<sup>87</sup> (4) submitting a copy of the disseminated information to the FDA,<sup>88</sup> and (5) prominently displayed disclosures with the disseminated information.<sup>89</sup> The Act expressly prohibits dissemination of off-label use information that does not comply with the regulations.<sup>90</sup>

## V. RECENT CASES

### A. *Washington Legal Foundation v. Friedman*

The Washington Legal Foundation (WLF) sought to enjoin the FDA from enforcing policies restricting dissemination of off-label use information by drug manufacturers as expressed in the Guidance Documents, because the policies violated the First Amendment.<sup>91</sup> The threshold issue was to determine whether the policies were actually regulating conduct or speech; and if the material was deemed speech, what level of protection it must be afforded. The District Court quickly discarded the FDA's argument that the regulations involved conduct.<sup>92</sup>

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(Supp. 1998). *See also supra* note 58 (explaining NDA's and ANDA's).

86. 21 U.S.C. § 360aaa(b)(2) (Supp. 1998) (referring to 21 U.S.C. § 360aaa-1).

87. 21 U.S.C. § 360aaa(b)(3) (Supp. 1998). The manufacturer may use another manufacturer's clinical research if the researching manufacturer gives permission. 21 U.S.C. § 360aaa(b)(3).

88. 21 U.S.C. § 360aaa(b)(4) (Supp. 1998). The manufacturer must also submit any clinical trial information relating to the new use, any reports of clinical experience of the new use and a summary of this information. 21 U.S.C. § 360aaa(b)(4)(B).

89. 21 U.S.C. § 360aaa(b)(6)(A) (Supp. 1998). The statement must disclose: (1) the use has not been approved by the FDA, (2) the dissemination is at the manufacturer's expense, (3) authors' names who received compensation from the manufacturer, (4) the approved FDA labeling, (5) availability of other approved treatments, (6) name of the funding entity, and (7) a bibliography of other articles concerning the off-label use of the drug. 21 U.S.C. § 360aaa-1(b)(6)(A).

90. 21 U.S.C. § 331(z) (Supp. 1998).

91. *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 54 (D.D.C. 1998). The Guidance Documents regulate the manufacturer dissemination of copies of medical texts and peer-reviewed journal articles (enduring materials) and manufacturer promotion of continuing medical education programs (CME). *See* Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (1997); Final Guidance on Advertising and Promotion, 61 Fed. Reg. 52,800 (1996). The policies concerning enduring materials were codified, after a few changes, in the FDAMA; the policies on CME's were not subsequently codified. *See supra* notes 82-83 (discussing the codification of the FDAMA provisions).

92. *Washington Legal Foundation*, 13 F. Supp. 2d at 59. The court explained its conclusion: [T]here is little question that the relevant 'conduct' is the off-label prescription of drugs by physicians. The distribution of enduring materials and sponsorship of CME seminars addressing and encouraging that conduct is speech. . . . [T]he activities at issue in this case are only 'conduct' to the extent that moving one's lips is 'conduct'. . . ."

*Id.*

The next issue was how to classify the speech. The Court refused to adopt the FDA's assertion that the speech being regulated by the Guidance Documents falls outside the scope of First Amendment protection because of the federal government's extensive power to regulate the pharmaceutical industry under the FDCA.<sup>93</sup> Relying on the "commonsense" distinction, the District Court determined that the speech involving enduring materials and CME's<sup>94</sup> was commercial in nature, and thus entitled to limited protection.<sup>95</sup> The Court went on to analyze the restrictions under the *Central Hudson* four-prong test.<sup>96</sup> The speech was found to involve lawful acts<sup>97</sup> and was not inherently misleading.<sup>98</sup> The Court acknowledged that the government had two substantial interests: a broad interest in protecting public health and safety<sup>99</sup> and a more narrow

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93. *Id.* at 60. The court dismissed the FDA's reliance on *Posadas de Puerto Rico Assoc. v. Tourism Co. of Puerto Rico* by stating that the development of the *Central Hudson* framework, as embodied in *44 Liquormart Inc., v. Rhode Island*, clearly indicated that the Supreme Court has consistently refused to recognize such an argument. *Id.* See *supra* notes 38-44 and accompanying text (discussing the *Posadas* and *44 Liquormart* decisions). However, certain communications within highly regulated areas may be restricted without violating the First Amendment. See *Ohralik v. Ohio St. Bar Ass'n*, 436 U.S. 447, 456 (1978). Permissible regulations involve exchange of securities information, corporate proxy statements, competitor price and production information and retaliation threats during labor disputes. *Id.*

94. See *supra* note 82 (defining enduring materials and CME's).

95. *Washington Legal Foundation*, 13 F. Supp. 2d at 64.

96. See *supra* note 34 and accompanying text (discussing the *Central Hudson* test).

97. *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 69 (D.D.C. 1998). The court stated that the FDA's view that the speech involved illegal activities was "tautological." *Id.* at 66. The court reasoned that the inquiry is whether the *conduct* that the speech proscribes is illegal, not whether the speech itself is illegal. *Id.* (emphasis added). The court further supported its conclusion by characterizing the FDA's argument as a slippery slope; if the court agreed with the FDA's argument, the government could then defeat all commercial speech protection by declaring commercial speech illegal. *Id.*

98. *Id.* at 69. "In asserting that any and all scientific claims about the safety, effectiveness, contraindications, side effects, and the like regarding prescription drugs are presumptively untruthful or misleading until the FDA has had the opportunity to evaluate them, FDA exaggerates its overall place in the universe." *Id.* at 67. The court supported its finding by first explaining the government can not reduce its burden by merely showing the speech is "potentially misleading." *Id.* at 66. Rather, the government must show the speech is "inherently misleading" or "more likely to deceive the public than inform it." *Id.* (quoting *Central Hudson Gas & Elec. Corp. v. Public Service Comm'n*, 447 U.S. 557, 563 (1980)). The court noted that prior to litigation, the FDA stated that the enduring materials and CME's were "clearly potentially misleading," and not inherently misleading. *Id.* at 67 (citing Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,079 (1997)). The court also pointed to the FDA's willingness to freely allow dissemination of the same information upon a physician's own request or from any other source than the manufacturer. *Id.* at 67.

99. *Id.* at 69. Ironically, the court stated:

[T]here are few, if any, more important functions performed by any regulatory agency than the function this case concerns—ensuring that when a citizen takes a prescription drug, that individual has *absolute assurance that the product is safe and effective* for the

interest in providing manufacturers with incentives to pursue FDA approval of new uses for prescription drugs.<sup>100</sup> Focusing on the more narrow interest, the Court found that the Guidance Documents directly and materially advanced the interest of encouraging manufacturers to apply for subsequent approval of the off-label use.<sup>101</sup> However, the restrictions of speech found in the Guidance Documents were more extensive than necessary to serve the government's interest.<sup>102</sup> Since the Guidance Documents were found unconstitutional, the FDA was enjoined from enforcing any provisions.<sup>103</sup>

Subsequently, the Guidance Documents concerning enduring materials were superseded by the FDAMA, which contained essentially the same regulatory provisions found in the FDA's written policy.<sup>104</sup> During a rehearing, the District Court ruled that the commercial speech doctrine still applied even though, as the FDA asserted, the FDAMA "affirmatively permits" speech as long as the manufacturer complied with

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condition for which his physician has prescribed it.

*Id.* (emphasis added).

100. *Id.* at 70. The court seems to give deference to Congress's conclusion that approval of all drug uses is mandated by the benefit to the public. *See id.* at 71. However, the government's interest in "ensuring physicians receive accurate and unbiased information so that they may make informed prescription choices" was not a substantial interest because the judicial system has consistently struck down the paternalistic assumption that the public will use information unwisely to justify suppression of commercial speech. *Id.* at 69-70 (citing 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 497 (1996)).

101. *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 71-72 (D.D.C. 1998). The government had to meet this burden by "demonstrat[ing] that the harms it recites are real and that its restriction will in fact alleviate them to a material degree" rather than mere "speculation or conjecture." *Id.* at 72. (citing *Edenfield v. Fane*, 507 U.S. 761 (1993)). In this case, the government did not provide substantial evidence to show that the regulation would actually compel manufacturer's to seek subsequent approval of the off-label use. *Id.* However, the court relied on WLF's argument to ultimately support a finding of direct advancement. *Id.* The WLF conceded that manufacturers disseminate off-label information rather than applying for subsequent approval due to the delayed time to receive such approval. *See id.*

102. *Id.* at 74. Recognizing that the commercial speech doctrine does not require finding that the government has used the least restrictive means possible to advance a substantial interest, the means must still reasonably fit the end sought. *Id.* at 72. The court looked to the fact that the less burdensome alternative, requiring full disclosure by the manufacturer, was available to the FDA. *Id.* at 73. The court reasoned that mandating full disclosure alleviates concerns that the off-label information would be potentially misleading, encourages subsequent approval and protects the truthful information, which the manufacturers want to distribute. *Id.* at 73.

103. *Id.* at 74.

104. The injunction was issued on July 30, 1998. However, Congress enacted the FDAMA on November 20, 1997, which became effective on November 21, 1998. The FDA petitioned the court to amend the injunction to limit its application solely to the Guidance Documents, and not the FDAMA. *See Washington Legal Foundation v. Friedman*, 36 F. Supp. 2d 16, 17-18 (D.D.C. 1999). The District Court declined, and ordered the parties to submit supplemental briefs addressing the possible application of the prior injunction to the FDAMA. *See id.* at 20.

the provisions.<sup>105</sup> The Court held fast to its previous findings and declared that the FDAMA was an unconstitutional restriction of commercial speech<sup>106</sup> and again enjoined the FDA from enforcing the statute.<sup>107</sup>

105. *Washington Legal Foundation v. Henney*, 56 F. Supp. 2d 81, 85 (D.D.C. 1999). The FDA's argument was "'preposterous' . . . [because] the First Amendment is premised upon the idea that people do not need the government's permission to engage in truthful, nonmisleading speech about lawful activity." *Id.*

106. *Id.* at 87. The court admonished the FDA's "tactic" and pointed to other options such as banning off-label prescriptions, prohibiting profits from off-label uses, or pursuing more misbranding actions. *Id.* However, these measures have been criticized as too extreme and an invasion into the practice of medicine. Gilhooley, *Constitutionalizing Law*, *supra* note 81, at 833.

107. *Henney*, 56 F. Supp. 2d at 88-89. The District Court concluded:

In conclusion, the Court finds that the FDAMA unconstitutionally restricts protected commercial speech.

....

THE COURT FINDS AND DECLARES that the policies, rules and regulations of the United States Food and Drug Administration ("FDA") set forth in the Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data, 61 Fed.Reg. 52800 (Oct. 8, 1996) (the "Reprint Guidance"), Guidance for Industry Funded Dissemination of Reference Texts, 61 Fed. Reg. 52800 (Oct. 8, 1996) (the "Textbook Guidance"), and Final Guidance on Industry Supported Scientific and Educational Activities, 62 Fed.Reg. 64074 (Dec. 3, 1997) (the "Final CME Guidance"), are contrary to rights secured by the United States Constitution. . . .

THE COURT FURTHER FINDS AND DECLARES that the policies, rules and regulations of the United States Food and Drug Administration ("FDA") set forth in the Food and Drug Administration Modernization Act, 21 U.S.C. §§ 360aaa through 360aaa-6, and in the FDA's Final Rule on the Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices, 21 C.F.R. Part 99, are contrary to rights secured by the United States Constitution. . . .

THE COURT HEREBY ENJOINS Defendants. . . from application or enforcement of any regulation, guidance, policy, order or other official action, as follows:

1. Defendants SHALL NOT in any way prohibit, restrict, sanction or otherwise seek to limit any pharmaceutical or medical device manufacturer or any other person:

a) from disseminating or redistributing to physicians or other medical professionals any article concerning prescription drugs or medical devices previously published in a bona fide peer-reviewed professional journal, regardless of whether such article includes a significant or exclusive focus on unapproved uses for drugs or medical devices that are approved by FDA for other uses and regardless of whether such article reports the original study on which FDA approval of the drug or device in question was based;

b) from disseminating or redistributing to physicians or other medical professionals any reference textbook including any medical textbook or compendium) or any portion thereof published by a bona fide independent publisher and otherwise generally available for sale in bookstores or other distribution channels where similar books are normally available, regardless of whether such reference textbook or portion thereof includes a significant or exclusive focus on unapproved uses for drugs or medical devices that are approved by FDA for other uses;

c) from suggesting content or speakers to an independent program provider in connection with a continuing medical education seminar program or other symposium regardless of whether unapproved uses for drugs or medical devices that are approved by FDA for other uses are to be discussed.

....

The FDA subsequently appealed.<sup>108</sup> The Court of Appeals dismissed the appeal and vacated the District Court's decision, which declared the FDAMA and Guidance Documents unconstitutional.<sup>109</sup> The Court expressed the intention that the ruling at hand did not review the holdings of the lower court.<sup>110</sup> The District Court's decision was vacated due to a lack of constitutional controversy since the FDA asserted that the FDAMA and Guidance Documents did not "independently authorize the FDA to prohibit or sanction speech."<sup>111</sup> However, the Court conceded that the FDA still had the power to use the "promotional conduct" as evidence of misbranding if the conduct fell outside of the proscribed regulations.<sup>112</sup> Nevertheless, the Court indicated that a misbranding action under these circumstances might still violate the First Amendment.<sup>113</sup>

### B. Analyzing the WLF Decision

So exactly where does that leave drug manufacturers with respect to dissemination of off-label uses? If a manufacturer follows the regulations as found in the FDAMA "safe harbor," dissemination of information cannot be prohibited.<sup>114</sup> If a manufacturer does not follow the

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5. Nothing herein shall be construed to limit Defendants' application or enforcement of any rules, regulations, guidances, statutes or other provisions of law that sanction the dissemination or redistribution of any material that is false or misleading. In addition, Defendants may require any pharmaceutical or medical device manufacturer that sponsors or provides financial support for the dissemination or redistribution of articles or reference textbooks or for seminars that include references to unapproved uses for drugs or medical devices that are approved by FDA for other uses to disclose (i) its interest in such drugs or devices, and (ii) the fact that the use discussed has not been approved by FDA.

*Id.*

108. Washington Legal Foundation v. Henney, 202 F.3d 331 (D.C. Cir. 2000).

109. *Id.* at 337.

110. *Id.* at 337 n.7. "In disposing of the case in this manner, we certainly do not criticize the reasoning or conclusions of the district court. As we have made clear, we do not reach the merits of the district court's First Amendment holdings and part of its injunction still stands." *Id.*

111. *Id.* at 335. Rather, the FDA asserted at oral argument that the regulations merely established a "safe harbor" for dissemination of information falling within the regulations, ensuring certain conduct would not be used as evidence of misbranding by the FDA. *Id.* And 21 U.S.C. § 331(z), which prohibits dissemination in violation of the FDAMA, merely provides that a manufacturer who does not follow the "safe harbor" provisions, may be liable. *Id.*

112. *Id.* at 336.

113. *Id.* at 336 n.6. The FDA still has the ability to use any promotional conduct outside of the safe harbor as evidence in a misbranding enforcement action, however the manufacturer may still argue such an action violates the First Amendment. *Id.*

114. Richard M. Cooper, *The WLF Case Thus Far: Not with a Bang, But a Whimper*, 55 FOOD & DRUG L.J. 477, 486 (2000). By statute, manufacturers are prohibited only from disseminating

FDAMA regulations, the situation becomes questionable.<sup>115</sup> Scholars are unsure what the Court of Appeals meant when it “vacated the . . . decisions and injunctions” of the lower court.<sup>116</sup> Most likely, the battle has only begun, since the Court acknowledged the FDA’s ability to institute misbranding actions against manufacturers and the potential for First Amendment violations within this context.<sup>117</sup>

Assuming the analysis of the First Amendment issues by the District Court is still valid, the findings can be criticized on various grounds.<sup>118</sup> The FDA unsuccessfully argued that the manufacturer’s

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information in violation of 21 U.S.C. § 360aaa. See 21 U.S.C. § 331(z) (Supp. 1998). Section 360aaa only provides certain conditions for disseminations affirmatively permitted by the FDA. Cooper, *supra*, at 481. Therefore, section 360aaa is correctly construed as creating a “safe harbor.” *Id.*

115. See Cooper, *supra* note 114, at 487. See also Linda S. Svitak & Peter J. Goss, *Drug and Device Litigation in the 21st Century*, 27 WM. MITCHELL L. REV. 271, 289-90 (2000).

116. Cooper, *supra* note 114, at 487. Cooper suggests multiple options in construing the Court of Appeals decree regarding dissemination of information outside of the regulations:

[T]he situation is unclear and depends on the status of the district court’s final order. That order is divided into two sections, one that “finds and declares,” and another that “enjoins.” The court of appeals vacated “the district court’s decisions and injunctions insofar as they declare the FDAMA and the CME Guidance unconstitutional.” It is not absolutely clear what the court of appeals meant by “decisions and injunctions.” Presumably, the term “decisions” encompasses opinions and orders. In this context, the term “injunctions” is odd and ambiguous. It is odd because it is plural: although the district court issued more than one order in the case, it issued only one amended final order, which was the order from which the appeal was taken. The term “injunctions” is also ambiguous because it is not clear whether it applies to the amended final order in its entirety or only to the injunctive section of the amended final order, i.e., the second section. If the D.C. Circuit’s statement about vacating was intended to refer to the district court’s amended final order in its entirety, then it would be natural to treat the first, declaratory section of the order as vacated and the second, injunctive section as surviving. The second section, which includes the three operative prohibitions applicable to FDA enforcement actions, does not declare anything unconstitutional, and so, arguably, survives. If, however, the vacation order vacated the declaratory section as part of the district court’s “decisions” and was intended to refer specifically to the injunctive section of the district court’s order in order to address that specific section, then, apparently, part of that injunctive section has been vacated and part survives. In that scenario, it is not easy to tell which part has been vacated and which survives. In light of the colloquy during oral argument, however, it may be doubted whether the court of appeals really intended to leave the entire injunctive section intact without reviewing it on the merits. In sum, the court of appeals has created a mess. . . .”

*Id.*

117. See *supra* notes 66-68, 71-72 and accompanying text (discussing the misbranding provisions of the FDCA). See also *infra* Section VI.A. (analyzing the constitutionality of the FDA’s authority to regulate manufacturer labeling and advertising under the *Central Hudson* test).

118. The WLF also attempted to argue that the speech was not commercial in nature, therefore worthy of full First Amendment protection. See *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 62-63 (D.D.C. 1998). Many scholars agree, reasoning that scientific research is often not verifiable, has the potential to be “chilled.” *E.g.*, Smith, *supra* note 36, at 1022-25; John Kamp

conduct was illegal because it was considered misbranding under the FDCA.<sup>119</sup> In doing so, the Court failed to focus on the fact that before Congress's enactment of the FDAMA, the FDA considered any such conduct by a manufacturer as evidence of misbranding, therefore the FDAMA actually enabled manufacturers to act in a manner that was entirely prohibited previously.<sup>120</sup> Ironically, the Court also stated that the lawfulness of physician off-label prescribing does not enable manufacturers to circumvent the FDA's required new drug approval process.<sup>121</sup> However, the Court later noted that the government's interest in ensuring ample incentives to approve off-label uses is "one of the few mechanisms available to the FDA to compel manufacturer behavior is to constrain their marketing options."<sup>122</sup> The Court also erred by finding the regulations were more extensive than necessary, because the FDAMA only prohibits manufacturers from distributing the information, while other entities are still free to disseminate the same information.<sup>123</sup>

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et al., *FDA Marketing v. First Amendment: Washington Legal Foundation Legal Challenges to Off-Label Policies May Force Unprecedented Changes at FDA*, 54 FOOD & DRUG L.J. 555, 563-63 (1999) (arguing the materials do not exemplify any commercial speech traits). Another compelling reason is the lack of rationale for transforming non-commercial speech into commercial speech when distributed by a manufacturer: "when considered outside of the context of manufacturer promotion. . . CME seminars, peer-reviewed medical journal articles, and commercially-available medical textbooks merit the highest degree of constitutional protection." *Washington Legal Foundation*, 13 F. Supp. 2d at 62. See also Smith, *supra* note 36, at 1017-19.

119. See U.S.C. § 352(a), (f) (1994 & Supp. 1998). The FDA's argument has also been criticized because the government could bypass the First Amendment by passing a law to prohibit such speech; even so, courts must still determine whether the law unduly burdens free speech. *E.g.*, Polubinski, *supra* note 77, at 1024; Kamp, *supra* note 118, at 559.

120. Cooper, *supra* note 114, at 480. See U.S.C. § 352(f) (1994 & Supp. 1998) (completely prohibiting dissemination of off-label information). Previously the FDA's actions were not considered a violation of the First Amendment. See Adams, *supra* note 63, at 1414 & n.61. The FDA also has "told" manufacturers what information to include or exclude in package inserts, without raising First Amendment issues. Polubinski, *supra* note 77, at 1012. The FDA's ability to regulate prescription drug advertising has yet to be questioned, although the issue is now questionable after *Pearson v. Shalala*. See *infra* Sections V.C. & V.D. (discussing and analyzing *Pearson v. Shalala*).

121. *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 71 n.4 (D.D.C. 1999). "There is no support for the contention that this approval process is discretionary. . . ." *Id.* However, the court's final ruling, in effect, allows manufacturer discretion in determining whether to pursue FDA approval of the off-label use.

122. *Id.* at 72.

123. See Adams, *supra* note 63, at 1409-14. Information regarding off-label uses is not subject to regulation by the FDA, receiving full First Amendment protection, if research is independent and original or the physician requests the information from the manufacturer. *Id.*

C. *Pearson v. Shalala*

The FDA was also involved in a very similar case dealing with dietary supplements in *Pearson v. Shalala*.<sup>124</sup> The FDA declined to authorize four health claims<sup>125</sup> for a dietary supplement label, because the manufacturer had failed to show that there was significant scientific agreement among experts that the evidence available supported such health claims.<sup>126</sup> Subsequently, the supplement marketers brought an action alleging a violation of the First Amendment.

In applying the *Central Hudson* test, the District Court found that the health claims were inherently misleading because they did not meet the threshold requirement of significant scientific agreement, and therefore were not scientifically proven.<sup>127</sup> Also, the average consumer lacked the necessary ability to evaluate health claims on dietary supplements, which further supported the Court's finding that the labeled health claims were inherently misleading.<sup>128</sup> The FDA also asserted

124. *Pearson v. Shalala*, 14 F. Supp. 2d 10 (D.D.C. 1998). A dietary supplement is a: product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient [described above];

21 U.S.C. § 321(ff)(1) (1994 & Supp. 1998). Dietary supplements are not subject to the same regulations as drugs, however health claims may be made if the FDA approves the claims prior to marketing. *See* 21 U.S.C. § 343(r)(5)(D) (1994 & Supp. 1998).

125. A health claim is "any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication . . . , characterizes the relationship of any substance to a disease or health-related condition." 21 C.F.R. § 101.14(a)(1) (2000). In this case, the marketer wanted to use four claims on the label: (1) antioxidant vitamins decrease cancer, (2) fiber decreases colorectal cancer, (3) fatty acids decrease heart disease and (4) folate decreases neural tube defects during pregnancy. *Pearson*, 14 F. Supp. 2d at 14.

126. *Id.* *See also* 21 C.F.R. § 101.14(c) (2000) (FDA's health claim safe harbor for dietary supplements is authorized by 21 U.S.C. § 343(r)(5)(D)). The FDA requires proof of significant scientific agreement because of testing difficulties for health claims:

Many of the diet-disease associations of potential relevance for health claims relate to chronic disease processes for which diet is one of many possible causes and which, for both ethical and practical reasons, are often not subject to direct experimentation. Thus, different types of evidence are usually considered in attempting to establish that a causal association actually exists and that dietary change would have preventative value. Where human experimentation is not appropriate, other approaches are useful. . . . [Testing for disease prevention] is more expensive and difficult than determination of an effect in a population with a disease [which is performed for new drugs in clinical trials.]

Gilhooley, *Constitutionalizing Law*, *supra* note 81, at 849 (quoting Commission on Dietary Supplement Labels, Report of the Commission on Dietary Supplements Labels 30, 31, 70 (1997)).

127. *Pearson*, 14 F. Supp. 2d at 18. The FDA showed that health claims based upon preliminary studies and hypothetical associations create an "'ill-defined association' in the mind of consumers that is not based on solid, reliable, scientific data." *Id.*

128. *Id.* Relying on *In re R.M.J.*, the court noted that speech is inherently misleading when the

substantial government interests in protecting the public and preventing consumer fraud.<sup>129</sup> In addition, the District Court found that the scientific standard directly advanced the government's interest and was no more extensive than necessary, and subsequently upheld the FDA's health claim regulation.<sup>130</sup>

The Court of Appeals reversed.<sup>131</sup> The Appeals Court agreed that the FDA met the burden of establishing a substantial government interest by asserting concerns of protecting public health and safety and preventing consumer fraud.<sup>132</sup> However, the Court disagreed with the FDA's argument that health claims were inherently misleading.<sup>133</sup> The Appeals Court held that the regulation did not directly advance the government's interest in protecting the public's health and safety, because the FDA never claimed that dietary supplements were harmful.<sup>134</sup> Rather, the Court believed the FDA had an underlying premise, that due to consumer limitations, only products with unquestionable health benefit claims should be available, which the court regarded as suspect.<sup>135</sup> The Court

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audience does not possess the requisite knowledge to evaluate it. *See In re R.M.J.*, 455 U.S. 191 (1982) (topic and audience restrictions on lawyer advertising violated the First Amendment). In this case, the Court distinguished the in-person solicitation by an attorney in *Bates v. State Bar of Arizona* from the mailings used in the present case. *In re R.M.J.*, 455 U.S. at 200-04. The Court remarked that advertising is misleading when the public lacks the requisite knowledge or sophistication to understand the information. *Id.* at 200-02. However, the method of advertising employed in the present case did not pose a risk of consumer deception. *Id.* at 206-07.

129. *Pearson v. Shalala*, 14 F. Supp. 2d 10, 19-20 (D.D.C. 1998). The legislative history suggested that the purpose of the regulation was to protect public health and safety, prevent unsubstantiated health claims and ensure the use of reliable scientific data. *Id.*

130. *Id.* at 20. The regulation directly advanced the government interest because it only permitted claims with significant scientific agreement. *Id.* Consumers are not capable of researching and independently verifying the claims based upon personal experience. *Id.* Since the regulation is only required to be reasonable, not perfect, the regulation was not more extensive than necessary because the regulation only applied to health claims on labels. *Id.* (citing *Board of Trustees of the St. Univ. of N.Y. v. Fox*, 492 U.S. 469 (1989)). The regulation did not apply to health claims made in scientific research journals or magazines. *Pearson*, 14 F. Supp. 2d at 20.

131. *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

132. *Id.* at 655-56.

133. *Id.* at 655. The court felt that the health claims would only be inherently misleading if they would have "an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment at the point of sale. . . as if. . . buy[ing] something while hypnotized, and therefore they are bound to be misled." *Id.* The court rejected this presumption. *Id.*

134. *Pearson*, 164 F.3d at 656. The court expressed its opinion that "drugs, on the other hand, appear to be in an entirely different category-the potential for harm is much greater" than dietary supplements. *Id.* at 656 n.6.

135. *Id.* at 656. Since the court did not find any assertion of direct harm to the consumer's health, the only other harm possible would be a "crowd[ing] out" of known beneficial products by not-so-known beneficial products, which may be indirectly accomplished by the regulation. *Id.* However, the government interest in the prevention of fraud was directly advanced by the regulation. *Id.*

did agree that some health claims would mislead consumers, therefore pre-approval requirements would prevent any misleading labels.<sup>136</sup> However, the regulation still failed because it was more extensive than necessary, since a less restrictive regulation requiring disclaimers was available.<sup>137</sup>

#### D. Analyzing the Pearson Decision

The Court made several errors in applying the *Central Hudson* test to the regulated health claims. The legislature was not afforded any deference in its decision to regulated dietary supplement health claims.<sup>138</sup> Usually, the government is given some latitude when the regulation incidentally restricts truthful information.<sup>139</sup> The Court simply rejected the FDA's assertion that the claims were harmful to the public, and substituted its own judgment in a highly specialized, technical field.<sup>140</sup> The Court also misconstrued the final prong by requiring the FDA to regulate with "surgical precision" in order to ensure only false or misleading speech was prohibited.<sup>141</sup> However, the test only requires the government to make regulations that are not more extensive than necessary; it does not require the government to use the least restrictive regulations.<sup>142</sup> Therefore, the Court's reliance on the FDA's failure to use dis-

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136. *Pearson v. Shalala*, 164 F.2d 650, 656 (D.C. Cir. 1999).

137. *Id.* at 657-59. The court ultimately placed the burden of drafting sufficient disclaimers for the health claims on the FDA. *Id.* at 659.

138. *See Posadas de Puerto Rico Ass'n v. Tourism Co. of Puerto Rico*, 478 U.S. 328 (1986); *See also supra* notes 38-41 and accompanying text. Courts owe the legislature considerable deference to the policy judgments made, especially in commercial speech. David C. Vladeck, *Truth and consequences: The perils of half-truths and unsubstantiated health claims for dietary supplements*, J. PUB. POL'Y & MKT, Apr. 1, 2000, available at 2000 WL 23815812. Previously, Congress refused to repeal or amend the regulations at issue because it felt the high evidentiary standards required by the FDA were appropriate measures to protect the public.

139. *See Ohralik v. Ohio St. Bar Ass'n*, 436 U.S. 447 (1978). Overinclusiveness is allowed if there is a history of abuse, no other effective regulatory options are available and the damage to the consumers is difficult or impossible to repair. Vladeck, *supra* note 138.

140. The court distinguished between dietary supplements and prescription drugs on the basis that dietary supplements are not harmful since the FDA has declined to promulgate regulations similar to those for prescription drugs. *Pearson v. Shalala*, 164 F.3d 650, 656 & n.6 (D.C. Cir. 1999). However, dietary supplements may be harmful. Howard M. Rubin, *Courts, Congress Re-examine Nondrug Products; Makers of Dietary Supplements Now Can Tout Health Benefits with less FDA Interference*, NAT'L L.J., July 5, 1999, at B8. The trend is to allow consumers to determine the need and effectiveness of a drug without FDA involvement or protection. *Id.* However, there is no regulation prohibiting marketing of a drug where the doses are ineffective for the claim being promoted. *Id.*

141. Vladeck, *supra* note 138.

142. *See Board of Trustees of the St. Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989). The primary issue before the Court in *Fox* was the interpretation of the fourth prong of the *Central Hud-*

claimers is unwarranted.

## VI. IMPLICATIONS OF THE RECENT DECISIONS FOR FDA REGULATIONS

### A. Are FDA Labeling and Advertising Regulations Prohibiting Off-Label Use Information Unconstitutional under *Central Hudson*?

Although these two decisions are prone to criticism, the analysis and reasoning could arguably affect the FDA's authority over prescription drug regulation. After *WLF*, the FDA may not prohibit the dissemination of off-label information to health care professionals.<sup>143</sup> After *Pearson*, the FDA may not prohibit health claims on dietary supplement labels.<sup>144</sup> The ultimate concern is that the reasoning of these two decisions will align to prevent the FDA from prohibiting off-label use claims on prescription drug labels and in advertisements to the public.

The FDA's ability to prohibit the inclusion of off-label use information on labels and advertisements is found within its authority to misbrand prescription drugs.<sup>145</sup> To determine if such an alignment is possible, it is necessary to visit the *Central Hudson* test<sup>146</sup> once again to determine if the FDA may prohibit manufacturers from placing off-label use claims in labeling and advertisements to the public by declaring the drug misbranded without violating the manufacturer's First Amendment rights.

#### 1. Are Labels and Advertisements Commercial Speech?

Before embarking upon the *Central Hudson* test, the threshold issue, which must be addressed, is whether off-label use claims on labels or in advertisements are commercial speech. The act of labeling and advertising off-label uses can be classified as conduct, not just speech.<sup>147</sup> The difficulty between such a distinction is prevalent in highly regulated

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*son* test, where restrictions may not be "more extensive than is necessary." *Id.* at 476. The Court concluded that the term "necessary" requires something "short of a least-restrictive-means standard," even though prior Supreme Court cases may have conflicted with this interpretation. *Id.* at 477.

143. See *supra* notes 91-113 and accompanying text (discussing the *WLF* decision).

144. See *supra* notes 124-37 and accompanying text (discussing the *Pearson* decision).

145. See *supra* notes 66-68 & 71-72 and accompanying text (discussing the misbranding provisions of the FDCA).

146. See *supra* note 34 and accompanying text (discussing the *Central Hudson* test).

147. Gilhooley, *Constitutionalizing Law*, *supra* note 81, at 834. The legality must only relate to the underlying conduct to avoid any circular reasoning. See *supra* note 97 and accompanying text (discussing the FDA's argument in *WLF*).

areas, such as prescription drugs.<sup>148</sup> When pre-market approval of a new drug is required, the FDA is regulating a product, not speech.<sup>149</sup> However, once the product is on the market, any similar regulation is seen as regulating the manufacturer's speech.<sup>150</sup>

If labeling and advertising are not considered conduct, but rather speech, then advertisements may quickly be discarded as commercial speech because inherent in an advertisement is a proposal for a commercial transaction.<sup>151</sup> However, drug labels are not so easily classified as commercial speech because they do not necessarily propose a commercial transaction.<sup>152</sup> The information on the prescription drug label is not made available to either the consumer or the physician to influence the decision to purchase or prescribe, a central function of commercial speech.<sup>153</sup> However, the Supreme Court remarked in *U.S. v. Kordel*, that "[e]very labeling is in a sense an advertisement."<sup>154</sup> Many courts have also considered information on labels to be commercial speech.<sup>155</sup> Most likely advertisements, as well as labels, will be considered commercial speech in light of previous decisions including *Pearson* and *WLF*.<sup>156</sup>

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148. Gilhooley, *Constitutionalizing Law*, *supra* note 81, at 876-77.

149. *Id.* at 876-77.

150. *Id.* at 877. But pre-market approval of a new drug and approval of an off-label use are treated the same under FDA regulations; without approval in either instance, the drug is misbranded. See 21 U.S.C §§ 331(a), (d) (1994 & Supp. 1998) (prohibiting introduction of misbranded drugs into interstate commerce); 21 U.S.C § 352(a) (1994 & Supp. 1998) (false or misleading labeling is misbranding); 21 U.S.C. § 355 (1994 & Supp. 1998) (prohibits introduction of new drugs into interstate commerce without FDA approval).

151. See *supra* note 36 and accompanying text (defining commercial speech).

152. Geyh, *supra* note 17, at 51. Information on labels aren't necessarily commercial speech because of the product's characteristics: drugs are only available to consumer's through a physician's prescription, prescription drugs are stored in pharmacies, therefore the labels are not viewable by physicians when prescribing or consumers, and when the drug is dispensed to a consumer, the labeled bottle has been discarded or covered by the pharmacy's label. See *generally id.*

153. See *supra* notes 36-37 and accompanying text (discussing the various commercial speech definitions).

154. *Kordel v. United States*, 335 U.S. 345, 351 (1948).

155. Lars Noah & Barbara A. Noah, *Liberating Commercial Speech: Product Labeling Controls and the First Amendment*, 47 FLA. L. REV. 63, 90 n.143 (1995) [hereinafter Noah, *Liberating Speech*]. One difference to note is that in those cases, the products were available for consumers to view prior to purchasing. Other scholars argue the speech is actually pure scientific information, worthy of full protection. See *generally* Smith, *supra* note 36 at 965 (noting that scientific articles and books distributed by non-drug manufacturers are considered fully protected forms of "scientific and academic speech"). However, using the *Bolger* approach, labels do satisfy the three characteristics of commercial speech: an advertisement referring to a specific product which is economically motivated. Polubinski, *supra* note 77, at 1016.

156. See *supra* notes 92-95, 125-27 and accompanying text (discussing the *WLF* and *Pearson* findings).

## 2. Does the Speech Involve Legal and Truthful Activity?

If a manufacturer does not seek approval of a promoted off-label use, the drug is misbranded.<sup>157</sup> Misbranding is a form of illegal conduct by the manufacturer.<sup>158</sup> However, using the reasoning of *WLF*, both labeling and advertising of prescription drugs are legal activities even though inclusion of off-label information is prohibited by the FDCA.<sup>159</sup>

Is the off-label information on labels and advertisements truthful or inherently misleading? Essential to this analysis is determining the audience. For labels and advertisements, the audience is now the public, not just medical professionals.<sup>160</sup> Consumers believe labels and advertisements of prescription drugs are being regulated by the government, therefore lack of FDA approval for off-label use claims mislead the consumer into thinking the off-label information is FDA approved.<sup>161</sup> Also, consumers lack the ability to independently verify the off-label claims being promoted.<sup>162</sup>

157. 21 U.S.C. § 352 (1994 & Supp. 1998). *See also supra* notes 66-68, 71-72 (discussing the FDA's authority to misbrand drugs).

158. Gilhooley, *Constitutionalizing Law*, *supra* note 81, at 834.

159. *See Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 66 (D.D.C. 1998). Courts have consistently rejected the FDA's assertion that conduct is illegal because it is prohibited in the FDCA; therefore prohibitions on off-label claims do not make the conduct illegal. *See id.* *See also Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995) (unconstitutional prohibition of alcohol content on beer labels). In *Rubin*, the Supreme Court did not entertain any argument that the statute prohibiting disclosure of alcohol content on beer labels inherently made the speech at issue concern an illegal activity. *See id.* at 482-43.

160. *See Washington Legal Foundation*, 13 F. Supp. 2d at 66-67 (noting a distinction between audiences composed of medical professionals and lay persons). *But see supra* note 155 (distinguishing the availability of labels to influence consumer decisions). By definition, prescription drug labels and advertisements cannot adequately inform consumers. Noah, *Advertising Prescription Drugs*, *supra* note 73, 176 n.131. "Prescription drugs are sold on a prescription basis. . . because the special expertise of a trained physician is necessary for their safe use. Thus, an effective warning could go only to the medical profession, and not to an untrained patient." *Dunkin v. Syntex Lab., Inc.*, 443 F. Supp. 121, 123 (W.D. Tenn. 1977). The current FDA regulations for labels and advertising are insufficient to prevent consumer confusion because originally the regulations were intended to regulate activities aimed at medical professionals. Michelle D. Ehrlich, Note, *Doctors Can "Just Say No": The Constitutionality of Consumer-Directed Advertising of Prescription Drugs*, 12 HASTINGS COMM. & ENT. L.J. 535, 537 (1990).

161. *See Polubinski*, *supra* note 77, at 1026 (noting this argument is valid only when the audience is consumers, not physicians). However, the *Pearson* court has seemingly rejected the argument. *See supra* note 133 and accompanying text (discussing the courts reasoning).

162. *See Polubinski*, *supra* note 77, at 1026. As Vladeck explains:

[b]ecause of the complexity of health claims, consumers cannot conceivably evaluate them on their own. Indeed, no one realistically expects consumers to wade through volumes of preliminary and often conflicting and inconclusive scientific literature involving clinical trials, laboratory animal experiments, and epidemiological studies to assess whether a particular health claim is well founded. That task often confounds experts.

Vladeck, *supra* note 138. *See also Ehrlich*, *supra* note 160, at 550. Advertisements shift the con-

This information can also be misleading because there is an incentive for manufacturers to only disclose selected information or fail to provide a balanced view.<sup>163</sup> Audience manipulation occurs when a commercial transaction is proposed, encouraging the consumer to act without consulting opposing viewpoints, making this type of speech inherently misleading.<sup>164</sup> An example of such an opportunity includes manufacturer promotion of off-label uses directly to consumers. Advertisements for prescription drugs often play upon the insecurities and vanities of consumers.<sup>165</sup> Other advertisements offer premiums, such as re-

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sumer's attention on the economic decision to purchase a drug, rather than a physiological evaluation to determine the need for the drug. Barbara Marticelli McGarey, Comment, *Pharmaceutical Manufacturers and Consumer-Directed Information—Enhancing the Safety of Prescription Drug Use*, 34 CATH. U. L. REV. 117, 141-42 (1984). The information given to the consumer does not promote safe use of the prescription drug. *Id.* at 142. Scientific, medical knowledge is required to understand information provided in a drug's labeling and advertisement. *Id.* For example, an antibiotic may be contraindication for patients with kidney disease. *Id.* However, a physician is aware that the antibiotic may be safely used in such a patient by administering a lower dose of the antibiotic, thereby negating the warning included with the drug. *Id.*

163. Gilhooley, *Constitutionalizing Law*, *supra* note 81, at 835. Advertisements create a unique problem because of their "brevity." White, *supra* note 3, at 758. They are misleading because they are so short, often leaving the consumer with the need for more information. *Id.* The format of DTC advertisements is not patient friendly. See Teresa Moran Schwartz, Esq., *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L.J. 829, 846 (1991). Warnings are usually located on a separate page after the actual advertisement, which is printed in very small type size. *Id.* But see Smith, *supra* note 36, at 1046-47. Manufacturer selectivity of information contained in advertisements and labels is unlikely because the potential liability and competitors functioning as industry watchdogs will deter any manufacturer selectivity. *Id.*

164. Geyh, *supra* note 17, at 66-67. There is some justification for regulation of speech, specifically when there is opportunity for audience manipulation. *Id.* at 66. When the audience is manipulated, it impairs their ability to rationally interpret information. *Id.* at 66-67. Once the audience is no longer capable of understanding the information, the purpose of the First Amendment, providing free flow of information, is diminished. *Id.* The danger to the public now outweighs the danger of speech suppression. *Id.* at 68. These proposals are suspect because the speaker has an economic incentive to embellish his claim, the audience has little chance to review opposing information and often involve appeals to irrational needs. *Id.* at 71.

165. Schwartz, *supra* note 163, at 836. Some examples of advertisements, which play upon consumer insecurities, include Estraderm, Nicorette, and Rogaine. *Id.* at 836-37. The advertisements make statements such as: "[h]ot flashes and night sweats certainly don't make women feel very attractive;" the smoker will "feel better, even look better. And your family and friends will feel more comfortable being around you;" and a bald spot may "damage your ability to get along with others, influence your chances of obtaining a job or a date or even interfere with your job performance." *Id.* Praying on a person's fears manipulates the consumer by reinforcing the consumer's beliefs, which indirectly suggests that the beliefs are true or factual and therefore there is no need to consult opposing viewpoints. Some companies even use celebrities to endorse the prescription drug. Fushman, *supra* note 75, at 1171. Others also believe the manufacturers are manipulating consumers by catching them when they are vulnerable. White, *supra* note 3, at 756 & nn.74-75. "Male fears of baldness were enough to push alopecia products to the No. 5 position on the list of largest gainers by therapeutic class for 1999. [The number of prescriptions] were up 51%, to 1.7

bates and coupons, to encourage quick purchases.<sup>166</sup> However, one may argue that there is no manipulation because manufacturers are required to advise consumers to visit a doctor, thereby fulfilling the requirement of seeking opposing viewpoints.<sup>167</sup>

### 3. Does the Government Have a Substantial Interest?

If the speech is found to be legal and not inherently misleading, the government must then assert a substantial interest behind the regulation.<sup>168</sup> As the courts noted in both *Pearson* and *WLF*, protecting the health and safety of the public is a substantial interest.<sup>169</sup> The government also has interests in providing ample incentives for manufacturers to pursue FDA approval of the off-label use,<sup>170</sup> as well as preventing consumer fraud and/or confusion.<sup>171</sup>

### 4. Does the Regulation Directly Advance the Government Interest?

Because the FDA has deemed prescription drugs inherently dangerous, the regulations would directly advance the government's interest in promoting the public's health and safety.<sup>172</sup> More specifically, off-label uses of prescription drugs are even more dangerous because, as the use of a prescription drug changes, so too does its safety.<sup>173</sup> Because the au-

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million." Gebhart, *supra* note 2, at 39.

166. Schwartz, *supra* note 163, at 837.

167. At the same time, the ad also encourages the consumer to seek more information. *Id.* at 838. The advertisement provides either a 1-800 number or Internet web-site, which is run by the manufacturer. *Id.*

168. See *supra* note 34 and accompanying text (discussing the *Central Hudson* test).

169. See *Pearson v. Shalala*, 164 F.3d 650, 655-56 (D.C. Cir. 1999); *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 69 (D.D.C. 1998).

170. See *Washington Legal Foundation*, 13 F. Supp. 2d at 70.

171. See *Pearson*, 164 F.3d at 655-56.

172. See *Pearson*, 164 F.3d at 656 (arguing that because dietary supplements are not prescription drugs, the risk of harm is decreased, whereas the risk of harm from prescription drugs is much greater). Regulations directly advance the state interest because they do not prohibit all speech, but regulated only speech aimed at consumers, which protects only the government interests. Ehrlich, *supra* note 160, at 552.

173. Gilhooly, *Constitutionalizing Law*, *supra* note 81, at 828-29. The drug may be unsafe, ineffective or less effective. *Id.* at 829 n.54. Examples of new dangers resulting from off-label uses include anti-arrhythmic and calcium channel blockers. See *Citizen Petition*, *supra* note 77, at 59,824. Medical research found that after a heart attack, persons with high rates of ventricular premature beats had a higher mortality (death) rate. *Id.* Anti-arrhythmic drugs, which decrease ventricular premature beat rates, were being promoted by manufacturers to decrease mortality. *Id.* The FDA attempted to label the drugs to emphasize that there was no actual evidence to prove the result. *Id.* In a later clinical trial, it was discovered that the use of anti-arrhythmic drugs in this

dience is now the public at large, the impact of such labeling and advertising has significantly increased.<sup>174</sup> As noted previously, DTC advertising will impact more consumers, therefore, manufacturers will have even less incentive to pursue subsequent FDA approval if the off-label information can be freely promoted on the label and in advertisements to the public.

##### 5. Is the Proposed Regulation No More Extensive than Necessary?

Under this scenario, drug manufacturers would only be prohibited from placing off-label use claims on labels and in advertisements, however manufacturers would be free to promote off-label uses to medical professionals using other avenues.<sup>175</sup> Also, research and dissemination of off-label uses by other sources would not be prohibited, therefore the regulations are narrowly tailored to achieve the government's interest in protecting the public's health and safety.

However, courts have also looked to the availability of other alternatives to achieve the government goal to determine if the regulation is no more extensive than necessary.<sup>176</sup> An alternative available to the

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condition actually increased mortality. *Id.* Another similar situation occurred with the substitution of calcium-channel blockers for beneficial beta-blockers after heart attacks. *Id.* It was later discovered that the substituted drug had no benefit and decreased the chance of survival. *Id.* Another more recent example is the controversial off-label combination of fenfluramine and phentermine for weight loss. After combining the drugs, medical researchers discovered an unexpected, abnormal incidence of heart valve disease in patients. *Id.*

*But see generally* Beck, *supra* note 78 (arguing off-label uses are not dangerous). Off-label uses are not harmful because the FDA's pre-market approval process ensures the product is safe for the labeled and general use. *Id.* at 82. "Off-label" is only a regulatory description or legal status of the drug use, not a medical status. *Id.* at 83. Because the opposite of "approved" is "unapproved," there is a suggestion that the use is therefore "disapproved" or too unsafe or risky for the off-label use. *Id.* at 83-84. An "unapproved" use is not "disapproved," it has merely not been reviewed by the FDA. *Id.* "Thus it is not possible to draw any conclusion about the safety or effectiveness of a particular use of a drug. . . from the. . . legal status of that use as off-label." *Id.* at 84. However, a conclusion may be drawn: the FDA has not found the drug to be safe and effective for the off-label use. Also, because the promotion will also involve DTC advertising, the potential for harm will be exacerbated because more consumers will request and be prescribed the off-label use. Noah, *Liberating Speech*, *supra* note 155, at 203.

174. Gilhooley, *Constitutionalizing Law*, *supra* note 81, at 836-37. *See also supra* notes 74-75 (discussing the increased impact of DTC advertising). In *WLF*, the audience was only medical professionals who made the decision based upon the individual patient's interest. *Id.* at 836.

175. Manufacturers could continue to communicate off-label information to physicians using package inserts, the Physician's Desk Reference, product cards, "Dear Doctor" letters and pharmaceutical representatives. McGarey, *supra* note 161, at 118 & n.5.

176. *See, e.g.,* 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 507 (1996) ("It is perfectly obvious that alternative forms of regulation that would not involve any restriction on speech would be more likely to achieve the State's goal. . ."); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 491 (1995) ("[T]he availability of these options. . . indicates that [the statute] is more extensive than nec-

FDA is to ban any product with an off-label use, however such a regulation would be more deceptive to consumers and more extensive than necessary to protect the public.<sup>177</sup> Another alternative is to mandate disclaimers on all labels and advertisements, similar to the disclaimers suggested in *Pearson*,<sup>178</sup> which disclose to the consumer that the claimed use is off-label, or not approved by the FDA. *Pearson* is the first decision to mandate the use of disclaimers to avoid misleading speech.<sup>179</sup> Although some may consider disclaimers compelled speech,<sup>180</sup> similar to *International Dairy Foods Ass'n v. Amestoy*,<sup>181</sup> the Supreme Court has hinted at supporting the use of such speech to counteract any possible misleading information.<sup>182</sup> Courts may approve of compelling limited disclaimers, since they are less speech restrictive than complete prohibition.<sup>183</sup>

The purpose of disclaimers is to combat any misleading information, but can disclaimers truly fulfill this purpose? Disclaimers may

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essary.”).

177. See Gilhooley, *Constitutionalizing Law*, *supra* note 81, at 875. The consumer would not have any information concerning the use of the drug, or any way to receive such treatment. *Id.* See also Salbu, *supra* note 76, at 188-89 (commenting that it would also be impossible to ban off-label prescribing). By restricting the dissemination of off-label uses, such as under the FDAMA, the physician still has access to off-label use information, which may be provided to the patient. Previously, it has been ruled that the FDA does not have the authority to ban products merely to avoid misuse. Margaret Gilhooley, *When Drugs are Safe for Some, But Not Others: The FDA Experience and Alternatives for Products Liability*, 36 HOUS. L. REV. 927, 941-42 (1999) [hereinafter *Safe for Some*] (discussing *American Pharm. Ass'n v. Weinberger*, 377 F. Supp. 824 (D.D.C. 1974), in which the FDA attempted to limit the distribution of methadone to hospital pharmacies to avoid diversion).

178. See *infra* note 179 (discussing the disclaimers suggested by the court in *Pearson v. Shalala*).

179. Gilhooley, *Constitutionalizing Law*, *supra* note 81, at 828; Vladeck, *supra* note 138. The *Pearson* court supported disclaimers such as: “[t]he FDA does not approve this claim,” or including adverse effects, which the manufacturer fails to include on the label. *Pearson v. Shalala*, 164 F.3d 650, 659 (D.C. Cir. 1999).

180. Noah, *Liberating Speech*, *supra* note 155, at 105; Harrison, *supra* note 48, at 634. In *Friedman*, “there is no First Amendment rule. . .requiring a State to allow deceptive or misleading commercial speech whenever the publication of additional information can clarify or offset the effects of the spurious communication.” *Friedman v. Rogers*, 440 U.S. 1, 12 n.11 (1979) (prohibition of practicing optometry under a trade name is constitutional).

181. See *supra* notes 49-54 and accompanying text (discussing the issue of compelled speech in *International Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67 (2d Cir. 1996)).

182. See, e.g., *In re R.M.J.*, 455 U.S. 191, 201 (1982) (“[A] warning or disclaimer might be appropriately required. . .in order to dissipate the possibility of consumer confusion or deception.”); *Virginia St. Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 772 n.24 (1976) (“They may also make it appropriate to require that a commercial message appear in such a form, or include such additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive.”).

183. Noah, *Liberating Speech*, *supra* note 155, at 105.

actually increase consumer confusion, rather than help to enlighten consumers.<sup>184</sup> Some research indicates that FDA warnings do not adequately educate the reader, and as a result, the reader will ultimately dismiss the warning.<sup>185</sup> Other concerns include the possibility of diluting the strength of warnings, and overreaction to numerous warnings.<sup>186</sup> Disclaimers may also draw attention away from products with a proven benefit.<sup>187</sup> There is also the possibility that evidence supporting the claim is outweighed by contradictory evidence, a situation which *Pearson* gives no direction.<sup>188</sup> The claim may be based upon preliminary, inconclusive or deficient studies; if so, this information would also need to be disclosed in order to prevent any deception.<sup>189</sup> Most importantly, disclaimers will not provide ample incentive for manufacturers to receive FDA approval of the off-label use.<sup>190</sup> It is ironic that courts are able to

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184. Vladeck, *supra* note 138. The disclaimers suggested in *Pearson* do not contain any information about the safety, effectiveness or risks associated with the off-label use. *Id.* Also, the disclaimers suggested by the court in *Pearson* are insufficient because they do not disclose to the consumer the actual standard used to validate health claims. Gilhooley, *Constitutionalizing Law*, *supra* note 81, at 848. To be considered a full disclosure to the consumer, the disclaimer should indicate the reason for the lack of FDA approval, such as the lack of significant scientific agreement. *Id.*

185. Fushman, *supra* note 75, at 1173.

186. Noah, *Liberating Speech*, *supra* note 155, at 107 n.217. The FDA has expressed its opinion of disclaimers on product warnings as “a warning must be unencumbered and unambiguous.” Food, Drug, Cosmetic, Device Labeling- FDA Proposed Regulations Regarding Failure to Reveal Material Facts, 39 Fed. Reg. 33,229, 33,232 (1974). And “where warnings are required, disclamatory opinions necessarily detract from the warning in such a manner as to be confusing and misleading.” *Id.* Other agencies have prohibited the use of disclaimers accompanying warnings. *See, e.g.*, 16 C.F.R. § 1500.122 (2000) (CPSC labeling requirements for hazardous substances); 40 C.F.R. § 156.10(a)(5) (2000) (EPA label warnings for pesticides).

187. Gilhooley, *Constitutionalizing Law*, *supra* note 81, at 853.

188. *Id.* at 850. An example involves a study to determine whether beta carotene supplements would provide the same cancer prevention benefits as provided in fruits and vegetables. *Id.* The study was stopped because researchers actually found an increase in the risk of cancer. *Id.* Therefore, health claims based upon benefits received from foods do not necessarily show the same benefits will result when the “active ingredient” is isolated and taken in supplement form. *Id.* at 851.

189. *Id.* at 837-38. Possible solutions to prevent deception would be to provide more information on the label as part of the disclaimer or mandating package inserts to disclose the same or more information. Gilhooley, *Constitutionalizing Law*, *supra* note 81, at 851. Such extra information would include a description of the studies relied on and limits of the studies. *Id.* However, as the amount of information increases, package inserts would be more beneficial in order to avoid label cluttering. Schwartz, *supra* note 163, at 847.

190. *E.g.*, Gilhooley, *Constitutionalizing Law*, *supra* note 81, at 837; J. Howard Beales, III, *Economic Analysis and the Regulation of Pharmaceutical Advertising*, 24 SETON HALL L. REV. 1370, 1386-87 (1994). Manufacturers will not attempt to gain subsequent approval of the off-label use because the costs are too substantial and the benefits are considerably smaller than the initial approval. *Id.* Although ANDA’s used for approval of off-label uses presumably involve less investigation into safety and efficacy, therefore requiring less time, than a NDA for a new drug, actual ANDA approval involves the same amount of time because they are given lower priority. *Id.* at

justify allowing drug manufacturers to disseminate unapproved information, as well as place unapproved health claims on labels, by relying on the public's right to know truthful, nonmisleading information,<sup>191</sup> whereas it is an insufficient reason to require such truthful, non-misleading information on food labels.<sup>192</sup>

### B. Implications for Drug Manufacturer Liability

The purpose of FDA approval is to ensure the safety and efficacy of all labeled uses.<sup>193</sup> If a manufacturer is able to include off-label information on labels and in advertisements, is there any impact on the manufacturer's liability?

#### 1. Learned Intermediary Doctrine

Currently, drug manufacturers are exempted from the general rule of law requiring product manufacturers to provide an adequate warning to the ultimate consumer to avoid product liability.<sup>194</sup> Drug manufacturers fulfill the legal duty to warn by providing adequate warnings to physicians, coined the "learned intermediary."<sup>195</sup> An adequate warning to

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1392. One suggestion is to amend the existing FDAMA to require the FDA to give priority review to manufacturers seeking FDA approval for off-label uses and only require notification of off-label information distribution, rather than pre-approval. Elizabeth A. Weeks, *Is it Worth the Trouble? The New Policy on Dissemination of Information on Off-Label Drug Use Under the Food and Drug Administration Modernization Act of 1997*, 54 FOOD & DRUG L.J. 645, 663-64 (1999). Others have pushed for legislative incentives such as market exclusivity or awarding royalties. Gilhooley, *Constitutionalizing Law*, *supra* note 81, at 856 n.216.

191. See *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 69 (D.D.C. 1998) (reasoning that the free flow of information is essential to a working democracy, therefore "a State's paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely cannot justify a decision to suppress it." (quoting *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 497 (1996)); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) (commenting that regulations that are justified by beneficial public interest or keep consumers in the dark are suspect).

192. See *International Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 72 (2d Cir. 1996). The state asserted a substantial government interest based on "strong consumer interest and the public's right to know." *Id.* "Unfortunately, mere consumer concern is not, in itself, a substantial interest." *Id.* at 72 n.1. The court remarked that if consumer interest alone was sufficient to justify disclosure, the government would be free to mandate disclosure of any relevant product information. *Id.* at 73.

193. See *supra* notes 55-63 and accompanying text (discussing the drug approval process in the FDCA).

194. Catherine A. Paytash, Note, *The Learned Intermediary Doctrine and Patient Package Inserts: A Balanced Approach to Preventing Drug-Related Injury*, 51 STAN. L. REV. 1343, 1344 (1999).

195. *Id.* The learned intermediary doctrine was first created back in the 1960s. See, e.g., *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966) (manufacturer has a duty to warn prescribing physicians of newly discovered side effects of an anti-arthritis medication); *Love v. Wolf*, 38 Cal. Rptr. 183 (1964) (manufacturer has no duty to warn consumer since there is no contact with the

the physician will clearly convey any risk or contraindication that the manufacturer knows, or should know, is associated with the use of the prescription drug.<sup>196</sup> The rationale for placing the ultimate duty to warn on physicians is: (1) to preserve the doctor-patient relationship, (2) physicians are in a better situation to inform patients, (3) manufacturers do not have a useful means to convey warnings to patients, (4) physicians make the ultimate decision to prescribe a drug, (5) patients are unable to understand the medical language, and (6) it is too difficult to warn patients because the risks and benefits are so varied and dependent upon the patient's characteristics.<sup>197</sup>

## 2. Recognizing Exceptions to the Learned Intermediary Doctrine

The courts have carved out a limited number of exceptions to the learned intermediary doctrine including mass immunizations,<sup>198</sup> contraceptives,<sup>199</sup> and the controversial "FDA-Mandate" exception.<sup>200</sup> How-

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consumer); *Marcus v. Specific Pharm. Inc.*, 77 N.Y.S.2d 508 (App. Div. 1948) (manufacturer not liable when failed to include proper infant dosages in ad to consumer, when provided to the prescribing physician). If a manufacturer fails to adequately warn the physicians, the manufacturer is directly liable to the patient. *See, e.g., McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522 (Or. 1974) (any breach of the duty to warn the physician will result in direct liability to the patient); *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919 (8th Cir. 1970) (manufacturer directly liable to patient by not warning physicians of the risk of blindness after prolonged use of the drug).

196. *Paytash*, *supra* note 194, at 1345. The duty to warn is never entirely fulfilled because the manufacturer must notify physicians of any risks or contraindications which are later discovered. *Id.* at 1345-46. The legal standard for manufacturer warnings is one of reasonableness: warnings must be "given in a form that could reasonably be expected to catch the attention of a reasonably prudent physician." *Harrison*, *supra* note 48, at 625 (quoting *Bean v. Baxter Healthcare Corp.*, 965 S.W.2d 656 (Tex. App. 1998)).

197. The rationale for the learned intermediary doctrine for prescription drugs may be best described as:

[P]rescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighting the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.

*Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974).

198. *See Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968). The plaintiff received a polio vaccination at a clinic, as part of a mass immunization against the spread of polio. *Id.* at 122. The court reasoned that the underlying premise of the learned intermediary doctrine was that manufacturers are not in a position to make an informed decision about whether or not to prescribe a drug for an individual patient, but physicians are capable of making such an "individualized balancing . . . of the risks involved." *Id.* at 130-31. However, in a mass immunization setting, the physician does not perform such a role. *Id.* at 131. In this case, the manufacturer also actively assured the community of the safety of the vaccine. *Id.*

199. *See, e.g., Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379 (E.D. Mich. 1985); *Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867 (E.D. Mich. 1985). *See also White*, *supra* note 3, at 751-55;

ever, many scholars are pushing for change as the many justifications<sup>201</sup> for the learned intermediary doctrine have changed. Critics argue that physicians do not adequately warn patients, many drugs now have FDA mandated patient package inserts, and the doctor-patient relationship no longer exists in its original form.<sup>202</sup> Many people urge that the learned intermediary doctrine should be abolished,<sup>203</sup> while others compromise by advocating a DTC exception.<sup>204</sup> Of course, there are still learned in-

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Schwartz, *supra* note 163, at 832-34 (offering in-depth discussions on the learned intermediary exceptions). However, most jurisdictions decline to recognize a contraceptive exception. *See, e.g.,* MacPherson v. Searle & Co., 775 F. Supp 417 (D.D.C. 1991); Reaves v. Ortho Pharm. Corp., 765 F. Supp. 1287 (E.D. Mich. 1991); Zanzuri v. G.D. Searle & Co. 748 F. Supp. 1511 (S.D. Fla. 1990).

200. *See* Fushman, *supra* note 75, at 1167-68. Under the FDA-Mandate exception, failure to comply with FDA regulations precluded the use of the learned intermediary doctrine. *See id.* (discussing *Edwards v. Basel Pharm.*, 116 F.3d 1341 (10th Cir. 1997)). *But see* *In re Norplant Contraceptive Products Liability Litigation*, 165 F.3d 374 (5th Cir. 1999) (rejecting an FDA-mandate exception to the learned intermediary doctrine). In *Norplant*, the court held that the rationale behind the doctrine is to enable manufacturers to supply unavoidably unsafe products to consumers by shielding them from liability. *Id.* at 379. And the court found no reason to expose manufacturers to liability when the FDA has determined that the drug requires additional warnings due to the severity of side effects. *Id.*

201. *See supra* note 195 and accompanying text (discussing the reasons for the learned intermediary doctrine).

202. Schwartz, *supra* note 163, at 831. Other factors including the nature of the product, marketing techniques, and the increasing patient involvement also support limited the learned intermediary doctrine. *Id.* at 835. The learned intermediary doctrine contradicts the theory of informed consent and the trend of patient self-determination. Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 WM. MITCHELL L. REV. 931, 957 (1993).

203. *See* White, *supra* note 3, at 770. As consumers have become more knowledgeable, the physician-patient relationship has changed dramatically. Physicians no longer exercise independent judgment. Manufacturers actively pursue and encourage consumers to try products. *Id.* at 777. Physicians are in the middle because they do not like the new “aggressive” patient, however, they often succumb to the patients desire for fear the patient will visit another doctor. *Id.* *See also* Schwartz, *supra* note 163, at 844.

204. *See, e.g.,* Fushman, *supra* note 75, at 1183; Schwartz, *supra* note 163, at 839-41 (analogizing to the abolishment of privity for warranties because of massive advertising and overpromotion). In the preliminary draft of the Restatement (Third) of Torts: Products Liability, drafters included three exceptions to the learned intermediary doctrine:

- i. the manufacturer knew or had reason to know that no medical provider was in the position to receive the warnings and to reduce the risks of harm]; or
- ii. Food and Drug Administration regulations required that direct warnings be provided; or
- iii. the manufacturer advertised or otherwise promoted the drug or medical device directly to users and consumers.

Noah, *Advertising Prescription Drugs*, *supra* note 73, at 163. However, the drafters ultimately deleted the advertising exception because it is “a relatively new phenomenon and has as yet not generated case law.” *Id.* at 164. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (1998) (failing to include a DTC advertising exception). Only the Supreme Court of New Jersey has recognized a DTC exception. *See* *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245 (N.J. 1999). However, *Perez's* reach may be limited because rebuttable presumption that compliance with FDA regulations

termediary supporters.<sup>205</sup>

Another such change could be the advent of off-label use advertising and labeling. Just as the recent push for a direct-to-consumer advertising exception, the inclusion of off-label use information to consumers strengthens the justifications for an exception.<sup>206</sup> Under the learned intermediary doctrine, manufacturers must provide the physician with all known risks and continually monitor drug use for any new risks.<sup>207</sup> However, as explained in Section IV, an off-label use has not been approved by the FDA, therefore manufacturers do not know all the risks associated with the particular off-label use. One possible solution is to hold manufacturers liable because they have a duty to warn physicians of risks they should know. Manufacturers would then have a duty to adequately test the off-label use, or else be liable for any harm cause by the drug. Physicians should not be required to get informed consent, because that would require physicians to know the regulatory status of drugs and understand the process.<sup>208</sup>

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provides an adequate warning, a plaintiff must also prove that they detrimentally relied on the actual advertisement, which caused the resulting harm. Fushman, *supra* note 75, at 1180.

*But see* Presto v. Sandoz Pharm. Corp., 487 S.E.2d 70 (Ga. Ct. App. 1997); Polley v. Ciba-Geigy Corp., 658 F. Supp. 420 (D. Alaska 1987); Mikell v. Hoffman-Laroche, Inc., 649 So. 2d. 75 (La. Ct. App. 1994). *See also* Harrison, *supra* note 48, at 613-14 (discussing these cases which expressly reject a DTC exception).

205. Harrison, *supra* note 48, at 606. Even with the advent of DTC, the learned intermediary doctrine is still relevant because the physician-patient relationship has not changed. *Id.* Carving out a DTC exception would interfere with manufacturer's First Amendment rights, in an already tightly regulated field. *Id.* at 606-07. Also result in costs to technological advancements and litigation, adequate warnings are too difficult to convey to consumers. *Id.* at 619-37. Others warn that creating manufacturer liability will result in the conveyance of less information to consumers. Noah, *Advertising Prescription Drugs*, *supra* note 73, at 169. Rather, manufacturer involvement in informing patients should only function as a supplement to the information provided by the physician, without creating liability for the manufacturer. *Id.* at 175; McGarey, *supra* note 162, at 148-49.

206. Physicians have been exposed to massive advertising campaigns by manufacturers, and have been able to decipher what information they will use, however; consumers have not been in this position. *See* Harrison, *supra* note 48, at 621.

207. Paytash, *supra* note 194, at 1345-46. If the manufacturer fails to monitor for new risks or fails to inform the physician of newly discovered risks, the manufacturer will be directly liable to the patient. *Id.* at 1346.

208. Beck, *supra* note 78, at 86, 100. Although details of state informed consent laws vary, they generally require physicians to explain to patients the medical risks, medical benefits, the nature of the treatment and the medical condition intended to remedy. *Id.* at 86. Informed consent does not require physicians to know or disclose the state of the informed consent law because it is not relevant to the medical risk. *Id.* This type of information is more akin to the function of an attorney, who is able to assess the legal status of a drug. *Id.* at 87.

### 3. Evidence of Off-Label Use in Medical Malpractice

Recently, a Tennessee Court of Appeals held that evidence regarding a drug's off-label use in a medical malpractice action was relevant and did not pose any risk of unfair prejudice.<sup>209</sup>

In this case, the physician prescribed a drug to retard a patient's premature contractions, which was an off-label use.<sup>210</sup> Ultimately, the patient suffered a heart attack after complaining of chest pains after each dose of the drug. The trial court granted the physician's motion to prevent the patient from introducing evidence indicating that the FDA had not approved the drug for use in preventing premature labor.<sup>211</sup> The jury returned a verdict in favor of the physician.<sup>212</sup>

On appeal, the court reviewed the FDA regulatory process and the role of off-label uses within the medical practice.<sup>213</sup> The court held that the labeling and reference information is admissible to prove the standard of care, but do not establish the standard of care by themselves.<sup>214</sup> Therefore, any deviation from the manufacturer labeling, in and of itself, does not constitute a breach of the standard of care.<sup>215</sup> The court discarded the contention that the evidence concerning the off-label use would confuse the issues or mislead the jury.<sup>216</sup> The court believed the exclusion of the off-label use evidence hampered the patient's ability to prove malpractice and, more probable than not, affected the outcome of the trial; therefore the court vacated and remanded for a new trial.<sup>217</sup>

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209. Richardson v. Miller, 2000 WL 1157246, at \*15 (Tenn. Ct. App. Apr. 16, 2000).

210. The drug, terbutaline, was approved by the FDA to treat asthma. However, terbutaline is also widely used as a tocolytic agent because its smooth muscle relaxation effects can cause relaxation of the uterus, thereby preventing premature labor and birth. The physician did not have any personal experience with this off-label use, however he was aware of this off-label use from professional articles and the drug manufacturer's seminar. *Id.* at \*2.

211. *Id.* at \*3.

212. *Id.* at \*4.

213. Richardson, 2000 WL 1157246 at \*4-\*9.

214. *Id.* at \*10. If the information established the standard of care, it in effect allows the drug manufacturer rather than the medical profession to do so. *Id.* The information on the label may not be easily understood by the jury without expert assistance because the documents are prepared for the medical profession. *Id.* The labels reflect the requirements of FDA regulations in order to provide guidelines for promotion and liability. *Id.* Finally, the information can not be cross-examined. *Id.* However, some courts have used labeling and reference information to establish the standard of care. *See, e.g.,* Haught v. Macelich, 681 F.2d 291 (5th Cir. 1982); Mueller v. Mueller, 221 N.W.2d 30 (S.D. 1974); Ohligschlager v. Proctor Cmty. Hosp., 303 N.E.2d 392 (Ill. 1973).

215. Richardson v. Miller, 2000 WL 1157246, at \*10 (Tenn. Ct. App. Apr. 16, 2000).

216. *Id.* at \*15. The information would not mislead or confuse the jury because the jury would be presented with expert testimony to the standard of care, subject to cross-examination, contrary evidence and the appropriate instructions for weighing such evidence. *Id.*

217. *Id.* at \*16

## VII. CONCLUSION

In essence, the *WLF* and *Pearson* decisions may have actually undermined a large portion of the FDA regulatory power over prescription drugs.<sup>218</sup> Although manufacturers are still required to receive pre-market approval of a new drug, once approved the manufacturer could promote, label, and advertise the drug for other indications. This provides manufacturers with a prime opportunity to get approval for a “cheap, narrow indication and the next day begin selling the drug for multiple broad, and profitable other indications.”<sup>219</sup> As the use of a prescription drug changes, the safety and efficacy changes as well.<sup>220</sup> By allowing drug manufacturers to label and advertise off-label uses to the general public, the potential harm to the public’s health and safety increases dramatically.<sup>221</sup> The off-label use claims do not contribute to more enlightened consumers. Instead, consumers are misled and confused because they do not possess the requisite medical knowledge to understand the off-label use claim being made and its associated risks.<sup>222</sup> Congress enacted the FDCA for the purpose of protecting the public’s health and safety, and gave the FDA the authority to pass regulations in pursuance of this goal. The FDA has exercised its authority using the approval process and misbranding provisions for over 60 years. Only recently has this authority been questioned, as manufacturers realized large profits, attributable to direct-to-consumer advertising, and consum-

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218. Gilhooley, *Constitutionalizing Law*, *supra* note 81, at 820. Congress may only be able to require disclaimers as to the lack of FDA approval for new uses. *Id.* However, the decisions do not implicate the initial FDA approval of an entirely new drug. *Id.* However, the Supreme Court has upheld the principle that all claims by the manufacturer need FDA approval. *See Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 667-68 (1973). The courts should avoid deciding on constitutional grounds. Gilhooley, *Constitutionalizing Law*, *supra* note 81, at 821. The actions should be analyzed using standards of administrative agency review, wherein courts will not substitute their own judgment if there is a reasonable decision by the agency. *Id.* at 821, 867. Courts are ill-equipped to determine issues of acceptable risks to public health and safety in such specialized and advanced practices. *See id.* at 836. Congress delegated and instructed the FDA to determine a “procedure and standard” for determining the validity of a health claim for dietary supplements and regulations involving prescription drugs. *Id.* at 852. Therefore, these decisions have also questioned Congress’ authority to protect the public’s health and safety. *Id.* at 828.

219. Salbu, *supra* note 76, at 206 (quoting James G. Dickinson, FDA Letter, Deputy’s Speech, Define a Dilemma, *Med. Mktg. Media*, Oct. 1996, at 12).

220. *See supra* note 173 and accompanying text (discussing examples of harmful off-label uses of prescription drugs); *But see supra* note 173 (arguing that off-label uses do not affect the safety and efficacy profile of a prescription drug).

221. *See supra* notes 74-75, 174 and accompanying text (discussing the increased impact of DTC advertising).

222. *See supra* notes 160-62 and accompanying text (distinguishing between medical professional and consumer knowledge regarding prescription drugs).

ers enjoyed the wealth of information and power to influence prescribing habits of physicians. However, under the *Central Hudson* analysis,<sup>223</sup> the government's substantial interest in protecting the public's health and safety is directly advanced by prohibiting drug manufacturers from labeling and advertising off-label uses on prescription drugs.<sup>224</sup> This prohibition is no more extensive than necessary because it still allows physicians access to the off-label use information using other forms of communication with the drug manufacturer and the alternative, mandating disclaimers, is not sufficient to prevent consumer confusion.<sup>225</sup> Therefore, the FDA's prohibition of off-label use labeling and advertising does not violate the drug manufacturer's First Amendment rights.

*Nicole Endejann*

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223. See *supra* note 34 and accompanying text (discussing the *Central Hudson* test).

224. See *supra* notes 168-74 and accompanying text (analyzing whether the asserted governmental interest is substantial and directly advanced by the regulation under the *Central Hudson* test).

225. See *supra* notes 175-92 and accompanying text (analyzing the extensiveness of the government regulation under the *Central Hudson* test).