

## A STEP TOWARD PREEMPTION: THE EFFECT OF THE FDA'S 2006 PREAMBLE

### I. INTRODUCTION

Everybody takes prescription drugs at some point in his life, and everybody knows about the fine print and packet inserts accompanying the prescription drugs. But who decides what the fine print actually says? Although the common response likely would be either the federal government or the drug manufacturer, prior to 2006, that response would be only partially correct.

Through the Federal Food, Drug, and Cosmetic Act<sup>1</sup> ("FDCA"), Congress delegated responsibility to the Food and Drug Administration ("FDA") for ensuring that all human drugs are safe and effective.<sup>2</sup> The centerpiece of the FDA's regulatory scheme giving effect to this statute is its control over prescription drug labeling,<sup>3</sup> which the FDA, in conjunction with the drug manufacturers, closely and continuously scrutinizes.<sup>4</sup> Despite the comprehensive federal regulation of the prescription drug field, prior to 2006, the near universal rule regarding drug labeling was that drug manufacturers in compliance with federal labeling standards could still be held liable for failure to warn under state law.<sup>5</sup> This rule effectively allowed judges and juries, rather than the FDA, the ultimate decision-making power regarding the content of drug labeling.<sup>6</sup> In concluding that compliance with federal regulations did not shield drug manufacturers from liability, courts rejected the notion that FDA drug labeling regulations preempt state tort failure-to-warn claims made against drug manufacturers.<sup>7</sup> Set against this backdrop, the FDA, in a 2006 preamble to its

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1. 21 U.S.C. §§ 301-399 (2000 & Supp. III 2003).

2. *Id.* § 393(b) (2000).

3. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314, 601) [hereinafter FDA Preemption Preamble].

4. See Brief for Amicus Curiae the United States of America at 5, *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006) (No. 05 CV 05500-MMB), available at <http://www.fileden.com/files/2007/7/10/1254845/Colacicco%20EDPA%20FDA%20amicus%20brief.pdf> [hereinafter *Colacicco Amicus*] (noting that FDA and drug manufacturers thoroughly discuss content of proposed drug labeling).

5. See, e.g., *Hill v. Searle Labs.*, 884 F.2d 1064, 1068 (8th Cir. 1989) (noting that FDA approval is no shield to state tort liability); *Wells v. Ortho Pharm. Corp.*, 788 F.2d 741, 746 (11th Cir. 1986) (stating that FDA determinations regarding sufficiency of drug warning labels may not suffice for state tort law purposes).

6. Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 779 (1990).

7. See, e.g., *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1176 n.2 (5th Cir. 1988) (noting that great majority of federal courts to address federal preemption in pharmaceutical field have ruled against preemption, and listing seventeen previous decisions to that effect); *Colacicco*

final rule on prescription drug labeling, indisputably declared its intent for its regulations to preempt contrary or conflicting state law regarding prescription drug labeling.<sup>8</sup> This assertion by the FDA is especially significant given the long-standing tradition of deference accorded to administrative agencies charged with implementing a statutory scheme.<sup>9</sup>

This Comment explores the effect of the FDA's Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products ("FDA Preemption Preamble") on federal preemption jurisprudence in the pharmaceutical field, specifically with regard to prescription drug labeling. Since the issuance of the FDA Preemption Preamble, two courts have ruled in favor of federal preemption of state tort failure-to-warn claims, basing their decisions in part on the FDA's Preemption Preamble.<sup>10</sup> This Comment examines the analytical approaches taken by courts prior to the FDA Preemption Preamble and contrasts those approaches with the approaches taken following release of the FDA Preemption Preamble. Because the two approaches to the federal preemption issue differ significantly, this Comment addresses which approach is better given the clear statement by the FDA and the tradition of deference afforded to administrative agencies. Furthermore, this Comment explores additional reasons supporting federal preemption in the prescription drug arena, most notably the FDA's expertise and experience in making determinations regarding safety and effectiveness of drugs and the need for a uniform national policy on drug labeling.

Part II.A of this Comment discusses the doctrine of federal preemption, including the types of preemption and the situations in which the doctrine is invoked. Part II.B provides background information pertaining to the FDA and the FDCA. Parts II.C-D discuss the status of federal preemption in the pharmaceutical field prior to the FDA's 2006 Preemption Preamble, while Part II.E examines the content of the FDA Preemption Preamble itself. Next, Part II.F looks at the impact of the FDA Preemption Preamble on federal preemption jurisprudence in the pharmaceutical field. Finally, Part II.G contrasts the analytical approaches taken by courts prior to the FDA Preemption Preamble with those taken after the issuance of the FDA Preemption Preamble.

Part III.A of this Comment evaluates the manner in which the FDA's 2006 Preemption Preamble fundamentally alters the approach courts take when addressing the issue of federal preemption in the pharmaceutical field. Part III.B discusses two very strong policy reasons—the expertise of the FDA and the need for national uniformity—supporting federal preemption in the pharmaceutical field, especially with regard to drug warning labels. Ultimately, this Comment

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v. Apotex, Inc., 432 F. Supp. 2d 514, 535 (E.D. Pa. 2006) (listing eight decisions in which courts ruled against preemption), *aff'd*, 521 F.3d 253 (3d Cir. 2008).

8. FDA Preemption Preamble, *supra* note 3, at 3934.

9. See *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984) (stating that agency regulations promulgated to administer statutes are controlling unless they are "arbitrary, capricious, or manifestly contrary to the statute").

10. See *infra* Part II.G.1 for a discussion of the reasoning supporting the courts' decisions finding in favor of federal preemption.

argues the FDA has affirmatively asserted its intent to preempt state tort law in the pharmaceutical field. Therefore, the courts, in accord with the long-standing tradition of deference to administrative agencies charged with statutory regulation, should find federal preemption where state tort failure-to-warn claims conflict with determinations previously made by the FDA regarding prescription drug labeling.

## II. OVERVIEW OF EXISTING LAW

### A. *General Preemption Principles*

The doctrine of federal preemption is rooted in the Supremacy Clause of the United States Constitution,<sup>11</sup> which mandates that the “Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land.”<sup>12</sup> As interpreted by the Supreme Court, the Supremacy Clause empowers Congress to enact legislation that preempts state laws governing the same subject matter.<sup>13</sup> Federal law has preemptive power over state law, whether state common law, state statute, or state regulation.<sup>14</sup> The doctrine of federal preemption is not limited to legislation passed by Congress; rather, federal regulations promulgated by administrative agencies have the same preemptive power as federal statutes.<sup>15</sup>

Federal preemption of state law arises in three situations.<sup>16</sup> The first situation, referred to as express preemption, occurs when Congress, acting within its constitutional limits, explicitly defines “the extent to which its enactments pre-empt state law.”<sup>17</sup> The next situation, known as field preemption, arises in the absence of clearly defined preemptive language.<sup>18</sup> Here, congressional intent to preempt a particular field of law may be implied where there is a “sufficiently comprehensive” federal scheme of regulation allowing for the inference that Congress intended to preclude any supplemental state law.<sup>19</sup> Field preemption can also be implied where the area involved is one in which “the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.”<sup>20</sup> The final situation in which federal preemption arises, known as conflict preemption, occurs when Congress has not entirely displaced state regulation in a particular field, and the state law conflicts

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11. *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152 (1982).

12. U.S. CONST. art. VI, cl. 2.

13. *See Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712-13 (1985) (noting that Supremacy Clause invalidates state law interfering with, or contrary to, federal law).

14. *Osburn v. Anchor Labs., Inc.*, 825 F.2d 908, 911 (5th Cir. 1987).

15. *Fid. Fed. Sav.*, 458 U.S. at 153-54.

16. *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 299-300 (1988).

17. *Id.* at 299.

18. *Hillsborough County*, 471 U.S. at 713.

19. *Id.*

20. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

with federal law.<sup>21</sup> When this happens, the state law actually conflicting with federal law is preempted.<sup>22</sup> An actual conflict between federal and state law occurs when “compliance with both federal and state regulations is a physical impossibility”<sup>23</sup> or when state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”<sup>24</sup>

Where federal preemption is implied,<sup>25</sup> particularly with regard to conflict preemption, there is a general presumption against preemption.<sup>26</sup> Because the states are independent sovereigns, the Supreme Court “presume[s] that Congress does not cavalierly pre-empt state-law causes of action.”<sup>27</sup> This presumption is especially true in areas that have traditionally been regulated by the states.<sup>28</sup> Therefore, when addressing a preemption issue, courts will begin by looking for a “clear and manifest” congressional intent to preempt state law.<sup>29</sup> Absent a finding of such intent, courts often heed the Supreme Court’s caution to avoid finding preemption too readily where definitive evidence of conflict is lacking.<sup>30</sup>

The congressional intent to preempt state law does not need to take the form of an express congressional authorization.<sup>31</sup> Rather, the statement of an administrative agency charged with regulating a particular field also serves to evidence intention to preempt state law.<sup>32</sup> An administrative agency can express

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21. *Hillsborough County*, 471 U.S. at 713.

22. *Id.*

23. *Id.* (quoting *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963)).

24. *Id.* (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)); *accord Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 886 (2000) (finding conflict preemption where state law duty to install airbags in all cars would have presented obstacle to Department of Transportation’s (“DOT”) objective of gradually developing mix of alternative passive restraint devices).

25. Preemption is implied in field preemption situations and in conflict preemption situations. Jonathan V. O’Steen & Van O’Steen, *The FDA Defense: Vioxx® and the Argument Against Federal Preemption of State Claims for Injuries Resulting from Defective Drugs*, 48 ARIZ. L. REV. 67, 70 (2006).

26. *Pokorny v. Ford Motor Co.*, 902 F.2d 1116, 1122 (3d Cir. 1990).

27. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

28. *Id.* Matters relating to health and safety are among those traditionally regulated by the states. See *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985) (acknowledging presumption against invalidating state regulation of health and safety matters under Supremacy Clause).

29. *Hillsborough County*, 471 U.S. at 715 (internal quotation marks omitted) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)).

30. See *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 885 (2000) (warning courts against finding preemption too quickly without manifest evidence of conflict); see also *McNellis ex rel. DeAngelis v. Pfizer, Inc.*, No. Civ. 05-1286 JBS, 2005 WL 3752269, at \*10 (D.N.J. Dec. 29, 2005) (expressing unwillingness to find federal preemption absent clear and compelling congressional statement), *rev’d sub nom. Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008); *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1038-39 (S.D. Ill. 2001) (refusing to find conflict between federal and state law absent clear evidence of congressional intent to preempt state law).

31. *Fid. Fed. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 154 (1982).

32. See, e.g., *Hillsborough County*, 471 U.S. at 714-15 (stating that FDA’s position on its intent or lack of intent to preempt state law is dispositive unless its position is inconsistent with clearly expressed congressional intent or later developments disclose change in that position).

its preemptive purpose through an array of means including regulations, preambles, interpretive statements, and responses to comments.<sup>33</sup> Nevertheless, courts generally will not find an intent to preempt a field based solely on the mere volume and complexity of the agency's regulations.<sup>34</sup> Where the administrative agency acts to preempt state law, the agency has substantial discretion in determining which of its rules, regulations, or other promulgations will have preemptive effect.<sup>35</sup> Furthermore, the agency's construction of the statutory scheme it administers and its interpretations of its regulations are given "considerable weight" and are entitled to deference absent contrary congressional intent.<sup>36</sup>

*B. The FDA and FDCA*

The FDA, which is part of the United States Department of Health and Human Services, has as its primary purpose to "protect consumers from dangerous prescription drugs and other products."<sup>37</sup> In passing the FDCA,<sup>38</sup> Congress charged the FDA with exclusive regulation of the prescription drug industry.<sup>39</sup> Specifically, this statute empowers the FDA to regulate the manufacture, sale, and labeling of prescription drug products.<sup>40</sup> Thus, the FDA must ensure that all prescription drugs are safe and effective and that they are not misbranded.<sup>41</sup> Through the FDCA, the FDA is the primary authority in terms of determining the labeling requirements for all prescription drugs.<sup>42</sup>

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33. *Id.* at 718.

34. *See id.* (noting that because administrative agencies usually address issues in comprehensive fashion using variety of means, it is expected that agencies will make clear their intention for their regulations to be exclusive); *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1177 (5th Cir. 1988) (noting that finding implied preemption whenever administrative agency comprehensively addresses problem is tantamount to saying that agency's regulations will be exclusive whenever it regulates within specific field (citing *Hillsborough County*, 471 U.S. at 717)).

35. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 505 (1996) (Breyer, J., concurring).

36. *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984); *see also* *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000) (placing weight on DOT's interpretation, as set forth in its amicus curiae brief, of federal regulation at issue and recognizing that DOT is "likely to have a thorough understanding of its own regulation and its objectives and is 'uniquely qualified' to comprehend the likely impact of state requirements" (quoting *Medtronic*, 518 U.S. at 496)); John Shaeffer, *Prescription Drug Advertising—Should States Regulate What Is False and Misleading?*, 58 FOOD & DRUG L.J. 629, 638 (2003) (noting that courts defer to administrative agencies where matter at issue is within unique expertise of agency).

37. *McNellis ex rel. DeAngelis v. Pfizer, Inc.*, No. Civ. 05-1286 JBS, 2005 WL 3752269, at \*3 (D.N.J. Dec. 29, 2005), *rev'd sub nom. Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008).

38. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399 (2000 & Supp. III 2003).

39. *Id.* § 355(a) (2000); *see also* *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 518 (E.D. Pa. 2006) (stating that by passing FDCA Congress "vested the FDA with authority to regulate the specifics of drug labeling, making important judgments of what is required for safety of the consuming public, what new drugs may appear in the marketplace, and what warnings their instructions and labels must carry"), *aff'd*, 521 F.3d 253 (3d Cir. 2008).

40. 21 U.S.C. §§ 321(n), 331(a)-(b), (k), 352, 355, 393(b)(2)(B) (2000 & Supp. III 2003).

41. *Id.* §§ 321(n), 331(a)-(b), (k), 352, 355(d), 393(b)(2)(B).

42. *DeAngelis*, 2005 WL 3752269, at \*3; *see also* John F. Del Giorno, Comment, *Federal*

The FDCA requires that drug manufacturers obtain FDA approval for all prescription drugs prior to their introduction on the market.<sup>43</sup> The approval process requires the submission of a new drug application, which must contain proof, supported by extensive testing, of the efficacy and safety of the drug.<sup>44</sup> The new drug application must also contain “specimens of the labeling proposed to be used” for the drug.<sup>45</sup> A new drug application will be rejected by the FDA if the application contains false or misleading labeling.<sup>46</sup> Drug labeling is false or misleading if it fails to provide sufficient directions for use or adequate warnings regarding any use of the drug that is potentially dangerous to the user’s health.<sup>47</sup>

Throughout the application process, the FDA works closely with the drug manufacturer to determine the appropriate labeling for the new drug.<sup>48</sup> In order for the drug labeling to satisfy FDA labeling requirements, the drug manufacturer must provide sufficient information regarding indications for use, as well as any relevant hazards, contraindications, side effects, and precautions associated with use of the drug.<sup>49</sup> The labeling requirements mandate the inclusion of warnings of all known risks based on reliable scientific evidence.<sup>50</sup> These requirements also ensure that medical professionals can safely use the drug for its intended purpose.<sup>51</sup> In drafting the labels, the FDA and the drug manufacturers take care to include only risks about which there is known scientific evidence, while omitting risks inadequately supported by scientific evidence.<sup>52</sup> In approving a new drug application, the FDA also “approves the precise final version of the drug labeling, including even the type size and font to be used by the manufacturer in that labeling.”<sup>53</sup>

Following the approval of a new drug application, the drug manufacturer has continued responsibility for maintaining accurate labeling information.<sup>54</sup> Under certain circumstances, the drug manufacturer may make unilateral

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*Preemption of Prescription Drug Labeling: Antidote for Pharmaceutical Industry Overdosing on State Court Jury Decisions in Products Liability Cases*, 22 J. MARSHALL L. REV. 629, 650 (1989) (emphasizing FDA’s unique expertise and ability to regulate warning label requirements for pharmaceuticals).

43. 21 U.S.C. § 355(a) (2000).

44. *Id.* § 355(a)-(i) (2000 & Supp. III 2003).

45. *Id.* § 355(b)(1)(F).

46. *Id.* § 355(d) (2000).

47. *Id.* § 352 (2000 & Supp. III 2003); *see also* Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 522 (E.D. Pa. 2006) (stating that, under FDCA, drug is unlawfully misbranded when it lacks adequate directions or warnings), *aff’d*, 521 F.3d 253 (3d Cir. 2008).

48. Colacicco Amicus, *supra* note 4, at 5.

49. 21 C.F.R. § 201.100(c)(1) (2007); Colacicco Amicus, *supra* note 4, at 4-5.

50. 21 C.F.R. §§ 201.56(a), 201.57(c).

51. *See* Colacicco Amicus, *supra* note 4, at 4-5 (emphasizing close relationship between prescription drug labeling and drug’s safety and effectiveness).

52. *Id.* at 5.

53. *Id.*

54. 21 U.S.C. § 331(a)-(b), (k) (2000); *see also* Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 522 (E.D. Pa. 2006) (noting that drug manufacturer’s obligation to prevent misbranding of drug continues after approval of new drug application), *aff’d*, 521 F.3d 253 (3d Cir. 2008).

changes to the labeling to “add or strengthen a contraindication, warning, precaution, or adverse reaction.”<sup>55</sup> The drug manufacturer must submit a supplement, containing a complete explanation of the basis for the change, to the FDA at least thirty days prior to distributing the drug with the labeling changes, but it does not need prior FDA approval to make such changes.<sup>56</sup> The FDA then has the ability to approve or disapprove the labeling change.<sup>57</sup> If the FDA disapproves the change, the drug manufacturer can be required to stop distributing the drug with the labeling change.<sup>58</sup> Thus, even though in limited circumstances a drug manufacturer may make label changes without FDA approval, the ultimate responsibility and authority for prescription drug labeling lies solely with the FDA.<sup>59</sup>

*C. Federal Preemption in the Pharmaceutical Field Prior to 2006*

The FDCA contains no provisions expressly preempting state law.<sup>60</sup> Therefore, if the FDCA preempts state law, it does so implicitly, specifically through conflict preemption.<sup>61</sup> Prior to January of 2006, a majority of federal courts refused to find an actual conflict between federal law and state law and thus held that the FDCA and the FDA’s regulations did not preempt state tort claims against drug manufacturers based on the failure-to-warn theory.<sup>62</sup> This near-universal conclusion of no federal preemption is grounded in four main reasons: (1) Congress did not intend to preempt the pharmaceutical field as it has elsewhere;<sup>63</sup> (2) no actual conflict exists because the FDA standards are

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55. 21 C.F.R. § 314.70(c)(6)(iii)(A) (2007).

56. *Id.* § 314.70.

57. *Id.*

58. *Id.* § 314.70(c)(7).

59. 21 U.S.C. § 393 (2000 & Supp. III 2003); *see also* *Henley v. FDA*, 77 F.3d 616, 621 (2d Cir. 1996) (deferring to FDA because “FDA possesses the requisite know-how to conduct such analyses, by sifting through the scientific evidence to determine the most accurate and up-to-date information regarding a particular drug, and how those data affect human usage”); Amicus Brief for the United States in Support of the Defendant-Appellee and Cross-Appellant, and in Favor of Reversal of the District Court’s Order Denying Partial Summary Judgment to Defendant-Appellee and Cross-Appellant, *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2002) (Nos. 02-55372, 02-55498), 2002 WL 32303084, at \*17 [hereinafter *Motus Brief*] (noting that ultimately FDA must approve drug warnings, not each state applying its own standards).

60. *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1176 (5th Cir. 1988).

61. *See Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876, 881 (E.D. Tex. 2005) (evaluating possible preemptive effect of FDCA solely under theory of conflict preemption).

62. *See, e.g., Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 732 (D. Minn. 2005) (concluding that state tort failure-to-warn claims are not preempted by federal law); *Zikis v. Pfizer, Inc.*, No. 04 C 8104, 2005 WL 1126909, at \*3 (N.D. Ill. May 9, 2005) (concluding that federal law does not preempt plaintiff’s state tort failure-to-warn claim); *Cartwright*, 369 F. Supp. 2d at 886-87 (holding that federal law does not preempt state tort failure-to-warn claims); *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1039 (S.D. Ill. 2001) (determining that state tort failure-to-warn claims are not preempted by federal law).

63. *See Caraker*, 172 F. Supp. 2d at 1039 (finding no evidence that Congress intended to displace state products liability regulations regarding prescription drugs).

merely minimum requirements;<sup>64</sup> (3) regulations promulgated by the FDA, particularly 21 C.F.R. § 314.70, allow drug manufacturers to strengthen warning labels without FDA approval;<sup>65</sup> and (4) the purpose of the FDA, to protect consumers,<sup>66</sup> would be frustrated by preemption of state tort claims.

### 1. Intent of Congress

Courts holding that federal law does not preempt state tort failure-to-warn claims against drug manufacturers have reasoned that Congress did not intend the FDCA and accompanying regulations to have such a preemptive effect.<sup>67</sup> Where, as in the pharmaceutical field, federal preemption is implicit rather than express, the Supreme Court has cautioned courts “not [to] find pre-emption too readily in the absence of clear evidence of a conflict.”<sup>68</sup> In fact, there is a general presumption that federal law does not preempt state law unless preemption was the clear and manifest purpose of Congress.<sup>69</sup>

Heeding the advice of the Supreme Court, lower courts have searched for evidence that Congress intended the FDCA to preempt state claims.<sup>70</sup> This inquiry has yielded a finding that, by enacting the FDCA, Congress had a purpose of protecting consumers from dangerous products<sup>71</sup> while also strengthening the protection of the law and extending that protection to the consumer.<sup>72</sup> Nevertheless, courts have reasoned that doing away with state tort failure-to-warn claims would actually undercut that congressional purpose by stripping customers of long-standing means by which to protect themselves from defective drugs.<sup>73</sup> Because Congress would not have revoked all means of judicial recovery for injured consumers without expressly stating its intention to do so, courts have concluded that Congress did not intend for the FDCA to preempt state tort failure-to-warn claims against pharmaceutical

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64. See *Cartwright*, 369 F. Supp. 2d at 882 (finding no actual conflict between FDCA and FDA’s regulations and state law because FDA regulations merely set minimum standards).

65. *McNellis ex rel. DeAngelis v. Pfizer, Inc.*, No. Civ. 05-1286 JBS, 2005 WL 3752269, at \*6 (D.N.J. Dec. 29, 2005), *rev’d sub nom. Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008).

66. See *id.* at \*3 (noting that FDA’s primary purpose is to protect consumers).

67. See, e.g., *Jackson v. Pfizer, Inc.*, 432 F. Supp. 2d 964, 968 (D. Neb. 2006) (recognizing Congress’s failure to issue directive preempting state tort failure-to-warn claims); *Caraker*, 172 F. Supp. 2d at 1039 (emphasizing lack of clear evidence showing that Congress intended to preempt state tort claims).

68. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 885 (2000).

69. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (recognizing unwillingness to effect federal preemption of sovereign laws without Congress’s express intent).

70. See, e.g., *Caraker*, 172 F. Supp. 2d at 1032 (starting its analysis with “anti-preemption presumption,” which is applied absent finding of clear congressional intent to preempt).

71. *McNellis ex rel. DeAngelis v. Pfizer, Inc.*, No. Civ. 05-1286 JBS, 2005 WL 3752269, at \*7 (D.N.J. Dec. 29, 2005) (citing *United States v. Sullivan*, 332 U.S. 689, 696 (1948)), *rev’d sub nom. Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008).

72. *Id.* (citing *United States v. Dotterweich*, 320 U.S. 277, 282 (1943)).

73. *Id.* at \*10; see also *O’Steen & O’Steen, supra* note 25, at 93 (noting that products liability lawsuits seeking to recover damages for injuries caused by prescription drugs further important goals of FDCA, notably protecting consumers from dangerous and ineffective drugs).

manufacturers.<sup>74</sup>

Additionally, courts finding that Congress did not intend for the FDCA to preempt state tort claims rely on the fact that Congress has expressly preempted state law in other areas, such as the medical device field.<sup>75</sup> Express preemption is the “normal practice Congress employs” when creating areas of federal preemption.<sup>76</sup> Because Congress clearly knows how to preempt state law and has actually done so in a similar field, courts have interpreted the absence of such a clause with reference to prescription drugs as evidence of a congressional intent not to preempt these state law claims.<sup>77</sup>

## 2. FDA Standards as Minimum Requirements

Courts rejecting the notion of federal preemption of state tort failure-to-warn claims almost universally include in their reasoning the well-established proposition that FDA requirements are merely minimum standards.<sup>78</sup> Generally, FDA regulations are viewed as minimum standards of conduct with which drug manufacturers must comply,<sup>79</sup> not as a shield from liability.<sup>80</sup> This interpretation allows states the discretion to require additional labeling and warning requirements through traditional tort law.<sup>81</sup> Thus, a determination by the FDA that a warning is adequate for federal regulatory purposes does not preclude a

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74. *Caraker*, 172 F. Supp. 2d at 1038.

75. *See, e.g., id.* at 1035 (emphasizing that Congress included express preemption provision in FDCA for medical devices). The section of the FDCA dealing with medical devices “contains a preemption clause that bars state regulation of medical devices that are ‘different from or in addition to’ federal requirements.” O’Steen & O’Steen, *supra* note 25, at 79 (quoting 21 U.S.C. § 360k(a)(1) (2000)).

76. *Caraker*, 172 F. Supp. 2d at 1035.

77. *E.g., Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876, 885 (E.D. Tex. 2005) (“Clearly, Congress knows how to enact FDA legislation that contains a preemption clause. Thus, the absence of any such clause with respect to prescription drugs demonstrates an implied intent not to preempt cases, such as this.”). Further supporting this view is the fact that Congress has “neither . . . amended the FDCA to include an express preemption clause for drugs nor . . . adopted tort measures that would directly remove the right to recover damages against drug makers.” O’Steen & O’Steen, *supra* note 25, at 94.

78. *E.g., Jackson v. Pfizer, Inc.*, 432 F. Supp. 2d 964, 967 (D. Neb. 2006) (noting FDA requirements are minimum standards); *Peters v. Astrazeneca, LP*, 417 F. Supp. 2d 1051, 1056 (W.D. Wis. 2006) (same); *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 732 (D. Minn. 2005) (same); *Caraker*, 172 F. Supp. 2d at 1033 (same).

79. *Hill v. Searle Labs.*, 884 F.2d 1064, 1068 (8th Cir. 1989) (citing *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 658 (1st Cir. 1981)); *see also Cartwright*, 369 F. Supp. 2d at 882 (asserting FDA regulations set minimum standards that drug manufacturers must satisfy); Thomas Scarlett, *The Relationship Among Adverse Drug Reaction Reporting, Drug Labeling, Product Liability, and Federal Preemption*, 46 FOOD DRUG COSM. L.J. 31, 40 (1991) (stating that rule that FDA requirements are minimum standards is premised on notion that, in setting out its requirements, FDA does not intend to “establish a ceiling on safety, only a floor below which [prescription drugs] cannot legally fall”).

80. *Hill*, 884 F.2d at 1068 (citing *Stromsodt v. Parke-Davis & Co.*, 257 F. Supp. 991 (D.N.D. 1966)).

81. *McNellis ex rel. DeAngelis v. Pfizer, Inc.*, No. Civ. 05-1286 JBS, 2005 WL 3752269, at \*10 (D.N.J. Dec. 29, 2005), *rev’d sub nom. Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008).

finding that the warning is insufficient for state tort law purposes.<sup>82</sup> It is also clear that FDA requirements may be supplemented by state law, particularly “through a jury’s verdict enforcing a manufacturer’s common law duty to warn.”<sup>83</sup>

This notion that FDA requirements are minimum standards justifies a finding of no federal preemption because there is no actual conflict between federal law and state law.<sup>84</sup> In order to find conflict preemption, there must be either an actual conflict between the federal law and the state law or the state law must act as “an obstacle to the accomplishment” of the federal purpose.<sup>85</sup> Neither of these situations is present where the FDA requirements act as minimum standards. In fact, in this situation, rather than conflicting, courts find that the federal law and the state law work in tandem to achieve a common purpose, namely, enhanced protection of the consumer.<sup>86</sup> Absent an actual conflict or frustration of federal purpose, courts have declined to find conflict preemption where FDA regulations establish only a minimum standard of safety.<sup>87</sup>

### 3. 21 C.F.R. § 314.70

Additionally, courts refusing to recognize federal preemption of state tort failure-to-warn claims against drug manufacturers rely heavily on a federal regulation promulgated by the FDA, 21 C.F.R. § 314.70.<sup>88</sup> Under certain circumstances, this regulation allows drug manufacturers to strengthen warning labels on prescription drugs without prior approval of the FDA.<sup>89</sup> Specifically, a drug manufacturer may change the labeling of its pharmaceutical to “add or strengthen a contraindication, warning, precaution, or adverse reaction.”<sup>90</sup>

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82. *Wells v. Ortho Pharm. Corp.*, 788 F.2d 741, 746 (11th Cir. 1986).

83. *Caraker*, 172 F. Supp. 2d at 1033.

84. *See Peters v. Astrazeneca*, 417 F. Supp. 2d 1051, 1057 (W.D. Wis. 2006) (finding no conflict between federal and state law when FDA did not require particular warnings on drug labels).

85. *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 728 (D. Minn. 2005) (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)).

86. *E.g., DeAngelis*, 2005 WL 3752269, at \*7 (noting that federal minimum standards do not work to conflict with state law but instead work to “protect consumers from dangerous products” (quoting *United States v. Sullivan*, 332 U.S. 689, 696 (1948))); *Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876, 882 (E.D. Tex. 2005) (stating that FDA and FDCA regulations do not conflict with state law but rather ensure consumer protection).

87. *See, e.g., Witczak*, 377 F. Supp. 2d at 732 (relying on idea that FDA labeling requirements are mere minimum standards in finding against federal preemption).

88. *See, e.g., DeAngelis*, 2005 WL 3752269, at \*6-7 (analyzing extensively relationship between 21 C.F.R. § 314.70 (2006) and FDA’s drug labeling requirements); *Zikis v. Pfizer, Inc.*, No. 04 C 8104, 2005 WL 1126909, at \*2 (N.D. Ill. May 9, 2005) (noting impact 21 C.F.R. § 314.70 has on FDA drug labeling requirements); *Cartwright*, 369 F. Supp. 2d at 882-83 (emphasizing importance of 21 C.F.R. § 314.70 and its effect on FDA drug labeling requirements). *But see Note, supra* note 6, at 788 (arguing that reliance on “minimum standards” reasoning obscures fact that state tort judgments conflict with FDA’s determination regarding proper drug labeling and thereby undermine FDA’s mission).

89. 21 C.F.R. § 314.70(c).

90. *Id.* § 314.70(c)(6)(iii)(A).

The FDA has the power to issue regulations having a preemptive effect on state law.<sup>91</sup> In this instance, however, rather than setting forth mandatory drug labels, the FDA deliberately allowed drug manufacturers to change prescription drug labels unilaterally and without prior approval.<sup>92</sup> Because the FDA's own regulations grant drug manufacturers authority to strengthen warning labels, and drug manufacturers can, and in some situations should, strengthen warning labels, courts reason that the FDA's requirements are merely minimum requirements.<sup>93</sup> Under this reasoning, had the FDA wanted to limit prescription drug labeling to the labeling explicitly approved by the FDA, it would have had the power to do so.<sup>94</sup> Because the FDA had the power but declined to use it, courts reason that the FDA did not intend its requirements to have a preemptive effect over state tort failure-to-warn claims against drug manufacturers.<sup>95</sup>

#### 4. Purpose of the FDA

Lastly, courts holding that federal law does not preempt state tort failure-to-warn claims reason that to hold that federal law does preempt these state claims would conflict with the very purpose of the FDA.<sup>96</sup> Congress explicitly charged the FDA with the responsibility of both promoting and "protect[ing] the public health by ensuring that . . . human . . . drugs are safe and effective."<sup>97</sup> In addition to FDA regulations, state tort law has long been viewed as another form of consumer protection.<sup>98</sup> Rather than conflicting with the FDA's

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91. See *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985) (noting federal regulations, as well as federal statutes, can preempt state law).

92. *Osburn v. Anchor Labs., Inc.*, 825 F.2d 908, 912 (5th Cir. 1987).

93. See, e.g., *DeAngelis*, 2005 WL 3752269, at \*6-7 (emphasizing that FDA's own regulations allow drug manufacturers to provide stronger drug warnings without prior FDA approval in regarding FDA regulations as minimum standards); *Cartwright*, 369 F. Supp. 2d at 882 (pointing to FDA's failure to ban drug manufacturers from unilaterally strengthening their warning labels as evidence that FDA regulations are merely minimum standards).

94. See *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1035 (S.D. Ill. 2001) (noting that FDA could effect state law label requirement preemption and has done so with over-the-counter drug warnings).

95. See, e.g., *id.* at 1038-39 (noting that FDA's failure to promulgate regulations unequivocally preempting state law supports conclusion that FDA did not intend its regulations to preempt state tort failure-to-warn claims).

96. See, e.g., *DeAngelis*, 2005 WL 3752269, at \*3, \*10 (noting that FDA's "primary purpose is to protect consumers from dangerous prescription drugs and other products," and observing that finding of federal preemption would strip consumers of remedy for harms caused by such dangerous products).

97. 21 U.S.C. § 393(b)(1), (2)(B) (2000); see also *DeAngelis*, 2005 WL 3752269, at \*3 (stating that FDA was created to ensure safety of prescription drugs).

98. See *DeAngelis*, 2005 WL 3752269, at \*10 (noting that state laws provide remedies to consumers injured by dangerous products); cf. Gregory C. Jackson, *Pharmaceutical Product Liability May Be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U. L. REV. 199, 208-09 (1992) (noting that manufacturer of acne medication, Accutane, motivated by desire to avoid tort liability, acted affirmatively and with approval of FDA to increase warnings of risks associated with use of Accutane); O'Steen & O'Steen, *supra* note 25, at 95 (stating that public's ability to sue drug companies over dangerous pharmaceuticals minimizes drug companies' misconduct).

regulations, state tort law actually complements and reinforces the FDA's protective regulatory scheme.<sup>99</sup> Therefore, courts reason that obviating state tort claims would actually weaken consumer protection by eliminating a significant remedy to consumers injured by dangerous products.<sup>100</sup> Because reduced consumer protection clashes with the stated purpose of the FDA—promotion and protection of the public health—recognizing federal preemption of state tort failure-to-warn claims undermines the purpose of the FDA.<sup>101</sup>

*D. The Beginning of Change—Exceptions to the General Rule of No Federal Preemption*

Although the long-standing general rule rejects federal preemption of state tort failure-to-warn claims against drug manufacturers, in recent years, the FDA has actively contested this proposition.<sup>102</sup> Since 2000 the FDA has advocated an expansion of the preemption doctrine in this area, which would provide drug manufacturers with greater protection from state tort claims.<sup>103</sup> In an effort to persuade courts to adopt a broader preemption doctrine, the FDA filed amicus curiae briefs in several failure-to-warn lawsuits brought against drug manufacturers.<sup>104</sup>

In *Motus v. Pfizer Inc.*,<sup>105</sup> the FDA submitted a brief in support of federal preemption of the plaintiff's failure-to-warn claim against Pfizer.<sup>106</sup> After her husband committed suicide while taking Zoloft, the plaintiff filed a lawsuit alleging that Pfizer negligently failed to warn of the dangers, contraindications, and side effects of Zoloft, and specifically that Pfizer failed to warn physicians and users that taking the drug could cause the user to become suicidal.<sup>107</sup> At the time plaintiff's husband was taking Zoloft, the FDA already had specifically considered mandating such a warning but determined that the scientific evidence did not support a requirement that manufacturers include additional suicide-

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99. *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 732 (D. Minn. 2005).

100. *E.g., id.* (discussing possible effects on consumers if state tort claims are precluded); *see also* O'Steen & O'Steen, *supra* note 25, at 95 (recognizing that both litigation and threat of litigation are critical safeguards in America's health care system).

101. *See Witczak*, 377 F. Supp. 2d at 732 (recognizing that primary purpose of FDA's regulatory scheme is protection of public and that state tort law reinforces, rather than frustrates, this objective).

102. *See, e.g., Motus Brief*, *supra* note 59, at \*17 (advocating federal preemption of state law because additional requirements imposed by state conflict with federal regulations prohibiting misbranding drugs and obstruct FDA's regulation of prescription drug field).

103. *See* Mark C. Levy & Gregory J. Wartman, *Amicus Curiae Efforts to Reform Product Liability at the Food and Drug Administration: FDA's Influence on Federal Preemption of Class III Medical Devices and Pharmaceuticals*, 60 FOOD & DRUG L.J. 495, 495 (2005) (stating that movements toward providing drug manufacturers with broader preemption protection began in 2000); O'Steen & O'Steen, *supra* note 25, at 69 (noting that FDA now advocates more expansive preemption doctrine that would shield drug manufacturers from state tort liability where manufacturer has satisfied FDA requirements).

104. Levy & Wartman, *supra* note 103, at 505.

105. 358 F.3d 659 (9th Cir. 2004).

106. *Motus Brief*, *supra* note 59, at \*14-15.

107. *Id.* at \*3-4.

related warnings.<sup>108</sup>

The FDA advanced two theories in its amicus brief. First, the FDA argued that had Pfizer included a warning suggesting a causal relationship between Zoloft and suicide, Pfizer would have violated the FDCA by misbranding its drug labels.<sup>109</sup> Because the FDA had previously determined that a causal relationship between Zoloft and suicide was unsupported by scientific evidence, a label containing such a warning would be false and misleading.<sup>110</sup> Even though federal regulations allow drug manufacturers to strengthen drug warning labels without prior FDA approval, the FDA ultimately must approve the label and, therefore, is the final authority as to prescription drug labeling.<sup>111</sup> The FDA advocated a finding of federal preemption in this case, because a state requirement that the drug label contain additional suicide warnings directly conflicted with the FDCA's prohibition on misbranding.<sup>112</sup>

The FDA's second argument in favor of federal preemption contended that allowing state tort failure-to-warn claims conflicted with the purposes and objectives of federal law, specifically, ensuring optimal use of a drug.<sup>113</sup> Through its regulation of the prescription drug field, the FDA intends to maximize effective use of a drug "through requiring scientifically substantiated warnings."<sup>114</sup> Therefore, the FDA argued that prescription drugs bearing scientifically unsubstantiated warnings could deter people from using the drug and thereby deprive patients of the benefits offered by the drug.<sup>115</sup> Additionally, the FDA claimed that scientifically unsubstantiated warnings on labels could "diminish the impact of valid warnings by creating an unnecessary distraction and making even valid warnings less credible."<sup>116</sup> Because application of state tort law could result in underutilization of potentially beneficial prescription drugs and result in less-than-optimal use of prescription drugs, the FDA argued for the application of federal preemption.<sup>117</sup>

Although the *Motus* court did not endorse the FDA's view on federal preemption but rather decided the case on other grounds,<sup>118</sup> two courts have deferred to the FDA and held that federal preemption barred the plaintiffs' state

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108. *Id.* at \*13.

109. *Id.*

110. *Id.*

111. 21 C.F.R. § 314.70(c)(5)(i) (2006); *see also* Motus Brief, *supra* note 59, at \*17 (stating that even if each state were to apply its own standard for prescription drug labels, FDA still must review and approve warnings).

112. Motus Brief, *supra* note 59, at \*13.

113. *Id.* at \*14-15.

114. *Id.* at \*23.

115. *Id.*

116. *Id.* at \*23-24.

117. Motus Brief, *supra* note 59, at \*23-24.

118. In this case, the prescribing physician admitted that he failed to read the drug's warning labels prior to prescribing the drug. *Motus v. Pfizer Inc.*, 358 F.3d 659, 661 (9th Cir. 2004). The court granted summary judgment to Pfizer on the grounds that the plaintiff failed to prove that stronger warning labels would have changed the patient's medical treatment or averted his suicide. *Id.*

tort failure-to-warn claims against drug manufacturers.<sup>119</sup> Both cases involved substantially similar fact patterns as *Motus*.<sup>120</sup> In reaching the conclusion that the plaintiffs' claims were preempted by federal law, both courts relied heavily on the FDA's determination that a warning label linking the drug and suicide would be false, misleading, and harmful to patients.<sup>121</sup>

After exploring the possibility of a relationship between the drug and suicide on at least four occasions and failing to find a scientific basis for a warning linking use of the drug and suicide, the government concluded that any such warning "would be false, misleading, contrary to the public interest, and should not be given."<sup>122</sup> The courts reasoned that where the FDA has conclusively determined that a particular warning would be inappropriate and would result in a misbranded drug, the FDA's requirements become mandatory.<sup>123</sup> Therefore, the courts concluded that allowing states to impose a regulation requiring drug manufacturers to include a warning that the FDA explicitly considered and rejected directly conflicts with mandatory federal regulations.<sup>124</sup> Because of the direct conflict between state law and federal law, the courts found that federal preemption barred plaintiffs' state tort failure-to-warn claims.<sup>125</sup>

Prior to 2006, despite the FDA's efforts to persuade courts to expand federal preemption, most courts rejected the FDA's position and held that federal preemption does not apply in the prescription drug field.<sup>126</sup> Instead of viewing FDA labeling requirements as both a floor and a ceiling, most courts considered FDA regulations minimum standards that could be supplemented by

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119. *Needleman v. Pfizer Inc.*, No. Civ.A. 3:03-CV-3074-N, 2004 WL 1773697, at \*5 (N.D. Tex. Aug. 6, 2004); *Dusek v. Pfizer Inc.*, No. Civ.A. H-02-3559, 2004 WL 2191804, at \*10 (S.D. Tex. Feb. 20, 2004).

120. In *Needleman v. Pfizer Inc.*, the patient was taking the prescription drug Effexor, which, like Zoloft, is a member of the class of drugs known as "selective serotonin reuptake inhibitors." 2004 WL 1773697, at \*1. After a visit to the emergency room, and on the recommendation of a doctor, the patient began taking Zoloft instead of Effexor. Shortly after this change in medication, the patient committed suicide. *Id.* Plaintiffs alleged that Pfizer failed to warn consumers about the relationship between use of the drug and suicidality. *Id.* In *Dusek v. Pfizer Inc.*, the patient was taking the prescription drug, Zoloft. 2004 WL 2191804, at \*1. As in *Motus v. Pfizer Inc.* and *Needleman*, patient committed suicide while taking the drug. *Id.* Plaintiffs contend Pfizer's failure to warn that taking Zoloft can cause suicide proximately caused patient to commit suicide. *Id.*

121. *Needleman*, 2004 WL 1773697, at \*2; *Dusek*, 2004 WL 2191804, at \*5.

122. *Needleman*, 2004 WL 1773697, at \*2.

123. *E.g.*, *Dusek*, 2004 WL 2191804, at \*9 (noting that when FDA explicitly deems warning inappropriate, its guidance becomes more than just minimum requirement).

124. *See Needleman*, 2004 WL 1773697, at \*2 (determining that allowing state imposition of contrary labeling requirements directly conflicts with federal regulations); *Dusek*, 2004 WL 2191804, at \*9-10 (concluding that plaintiff's proposed warning directly conflicts with FDA's explicit determination regarding adequacy of this warning).

125. *Needleman*, 2004 WL 1773697, at \*5; *Dusek*, 2004 WL 2191804, at \*10.

126. *Levy & Wartman*, *supra* note 103, at 506. *See supra* Part II.C for a discussion of the treatment of federal preemption in the pharmaceutical field prior to the issuance of the FDA Preemption Preamble.

state law.<sup>127</sup> Even when ruling in favor of federal preemption, the *Dusek* court explicitly limited its holding to situations in which the FDA has already expressly rejected the causal relationship between the drug and the side effect that the plaintiff advocated and the FDA has required precise language on the warning.<sup>128</sup> Thus, except in very limited circumstances, FDA regulations do not preempt state tort failure-to-warn claims brought against drug manufacturers.

*E. The FDA's Preemption Preamble*

In January of 2006, the FDA issued a preamble to its final rule on prescription drug labeling in which it unequivocally asserted its intention to preempt state tort failure-to-warn claims where the prescription drug labeling satisfies FDA requirements.<sup>129</sup> As it has several times before, the FDA preempted state law requirements relating to the drug field through its rule-making proceedings.<sup>130</sup> The FDA explained its purpose by reaffirming its position as “the expert Federal public health agency” responsible for “ensuring that [prescription] drugs are safe and effective, and that [drug] labeling adequately informs users of the [drug’s] risks and benefits.”<sup>131</sup> Drug labeling plays a prominent role in the FDA’s regulation of the prescription drug field as the labeling “reflects thorough FDA review of the pertinent scientific evidence and communicates to health care practitioners the agency’s formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively.”<sup>132</sup> The preamble also noted that given the importance of labeling, the FDA closely controls the contents of prescription drug labeling.<sup>133</sup>

In its preamble, the FDA addressed and rejected two arguments often articulated by courts supporting the dismissal of the notion of federal preemption in the prescription drug field.<sup>134</sup> The first argument is that FDA requirements are merely minimum standards that can be supplemented by state regulations.<sup>135</sup> In the preamble, the FDA expressly rejected this position and stated that it interprets its regulations to establish both a floor and a ceiling.<sup>136</sup>

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127. See *supra* Part II.C for a discussion of the courts’ treatment of FDA standards as minimum requirements.

128. *Dusek*, 2004 WL 2191804, at \*10.

129. FDA Preemption Preamble, *supra* note 3, at 3934. The preamble states that the “FDA believes that under existing preemption principles, FDA approval of labeling under the [FDCA], whether it be in the old or new format, preempts conflicting or contrary State law.” *Id.*

130. *Id.* at 3935. For example, the FDA stated its intention to preempt state law requirements regarding over-the-counter drugs in the preamble that accompanied regulations requiring tamper-resistant packaging for over-the-counter drugs. *Id.*

131. *Id.* at 3934.

132. FDA Preemption Preamble, *supra* note 3, at 3934.

133. *Id.*

134. *Id.*

135. See, e.g., *Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876, 885 (E.D. Tex. 2005) (noting that federal labeling requirements for prescription drugs are minimum standards and states have power to impose additional labeling requirements).

136. FDA Preemption Preamble, *supra* note 3, at 3935. FDA labeling regulations act as a floor in

Further, the FDA noted that inclusion of additional unsubstantiated warning information on drug labels exposes the manufacturer to potential liability for labeling that contains false and misleading information.<sup>137</sup>

In response to the second argument, which focuses on a drug manufacturer's ability to strengthen a warning label without prior FDA approval,<sup>138</sup> the FDA unequivocally asserted that the final determination as to the necessity of labeling changes rests solely with the FDA, not the individual drug manufacturers.<sup>139</sup> The FDA noted that this authority is unchanged by the provision allowing drug manufactures to strengthen warning labels unilaterally.<sup>140</sup> The FDA reasoned that in practice most drug manufacturers consult with the FDA prior to making any changes so as not to implement labeling changes that may later be rejected.<sup>141</sup>

One of the purposes of the FDA and of the FDCA is to ensure safe and effective use of prescription drugs.<sup>142</sup> The FDA believes that "[s]tate law requirements can undermine [the] safe and effective use" of prescription drugs and thereby stand as an obstacle to the achievement of the full objectives and purpose of federal law.<sup>143</sup> The FDA noted that a state law requiring the disclosure of scientifically unsubstantiated risk information could "erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use."<sup>144</sup> Furthermore, the FDA claimed that this inclusion of speculative or unsubstantiated risks in warning labels can cause meaningful and verified risk information to lose significance, which would negatively impact patient safety and public health.<sup>145</sup> Thus, the FDA reasoned that labels containing such inaccurate warnings do not truthfully convey the risks associated with taking the drug and may discourage use of the drug by patients who would actually benefit from taking it.<sup>146</sup>

Finally, the FDA stressed that "[s]tate law actions also threaten FDA's statutorily prescribed role as the expert Federal agency" charged with regulating

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that they establish a minimum safety standard with which drug manufacturers must comply. *Id.* at 3934. According to the FDA, its regulations also establish a ceiling such that disclosure of additional, unsubstantiated risk information will expose the manufacturer to liability under the FDCA. *Id.* at 3935.

137. *Id.*

138. *See, e.g.,* *Witzak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 729 (D. Minn. 2005) (emphasizing that FDA regulations expressly allow drug manufacturers to strengthen warning labels unilaterally at any time (citing 21 C.F.R. § 314.70(c)(6)(iii)(A))).

139. FDA Preemption Preamble, *supra* note 3, at 3934.

140. *Id.*

141. *Id.*

142. 21 U.S.C. § 393(b)(1)(B) (2000).

143. FDA Preemption Preamble, *supra* note 3, at 3935.

144. *Id.*

145. *Id.*

146. *Id.*

the prescription drug field.<sup>147</sup> One of the central responsibilities of the FDA is to weigh the risks and benefits of a drug to the general public and make a determination about the safety of a particular drug.<sup>148</sup> According to the FDA, state tort actions invite judges and juries to second-guess the FDA's decision regarding the risks and benefits of a particular drug.<sup>149</sup> The FDA explained that this individualized reevaluation would not only disrupt the FDA's regulatory scheme, but it also could influence drug manufacturers to include warnings neither approved nor required by the FDA.<sup>150</sup> This would result in "scientifically unsubstantiated warnings and underutilization of beneficial treatments," a result clearly in conflict with the promotion of the safe and effective use of prescription drugs.<sup>151</sup>

Based on its interpretation of the FDCA and its regulations administering the FDCA, the FDA outlined a minimum of six scenarios under which state tort claims are preempted by federal regulations.<sup>152</sup> The FDA acknowledged, however, that its regulation of drug labeling does not preempt all state tort claims.<sup>153</sup> Where state requirements are the same as the FDA requirements, federal regulation will not preempt state actions.<sup>154</sup> With this limited exception, the preamble "clarifies that [the] FDA intends to reserve complete control over warning requirements and the enforcement of information submission requirements, leaving no room for supplementation by other legal standards."<sup>155</sup>

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147. *Id.*

148. FDA Preemption Preamble, *supra* note 3, at 3935.

149. *Id.*

150. *Id.*

151. *Id.* at 3935, 3969.

152. *Id.* at 3936. The FDA intended its regulation of the prescription drug field to preempt the following state actions:

(1) [c]laims that a drug sponsor breached an obligation to warn by failing to put in Highlights or otherwise emphasize any information the substance of which appears anywhere in the labeling; (2) claims that a drug sponsor breached an obligation to warn by failing to include in an advertisement any information the substance of which appears anywhere in the labeling, in those cases where a drug's sponsor has used Highlights consistently with FDA draft guidance regarding the "brief summary" in direct-to-consumer advertising; (3) claims that a sponsor breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in this rule . . . ; (4) claims that a drug sponsor breached an obligation to warn by failing to include a statement in labeling or in advertising, the substance of which had been proposed to FDA for inclusion in labeling, if that statement was not required by FDA at the time plaintiff claims the sponsor had an obligation to warn . . . ; (5) claims that a drug sponsor breached an obligation to warn by failing to include in labeling or in advertising a statement the substance of which FDA has prohibited in labeling or advertising; and (6) claims that a drug's sponsor breached an obligation to plaintiff by making statements that FDA approved for inclusion in the drug's label (unless FDA has made a finding that the sponsor withheld material information relating to the statement).

FDA Preemption Preamble, *supra* note 3, at 3936 (citations omitted).

153. *Id.*

154. *Id.*

155. Travis J. Sales & Steven Mitby, *The New Presumption of Adequate Warnings in Texas Pharmaceutical Litigation*, 69 TEX. B.J. 612, 618 (2006).

*F. Judicial Response to the FDA's Preemption Preamble*

Following the issuance of the FDA's Preemption Preamble, courts faced the question of what effect, if any, the FDA's position should have on federal preemption in the prescription drug field. Some courts neglected to address the issue at all,<sup>156</sup> while another shrugged off the FDA's statement by finding the claim of preemption unpersuasive.<sup>157</sup> More recently, two courts, after extensive analysis, found that federal regulations do preempt state tort failure-to-warn claims brought against drug manufacturers.<sup>158</sup> These courts accorded significant deference to the FDA's position that its regulations have a preemptive effect on state law.<sup>159</sup>

In reaching the conclusion that federal preemption applies to state actions in the prescription drug field, these courts went through a much different analysis than did courts addressing the same issue prior to January 2006.<sup>160</sup> Before the FDA's Preemptive Preamble, courts began their analyses with the presumption against preemption since there was no express evidence of intent for FDA regulations to have a preemptive effect.<sup>161</sup> Because the FDA has now issued a clear statement of its intention to preempt state tort claims, courts no longer have to search for implicit intent.<sup>162</sup> Rather, since the FDA's position is expressly stated, courts must decide the amount of weight to which the FDA's position is entitled.<sup>163</sup>

Two courts have specifically addressed the issue of deference to the FDA's position on the preemptive effect of its regulations and have conclusively determined that the "FDA's interpretation of the preemptive effect of its regulations is entitled to deference."<sup>164</sup> In making this decision, the courts pointed to Congress's designation of the FDA as the agency responsible for

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156. *Laisure-Radke v. Par Pharm., Inc.*, No. C03-365RSM, 2006 WL 901657, at \*2-6 (W.D. Wash. Mar. 29, 2006); *Peters v. Astrazeneca, LP*, 417 F. Supp. 2d 1051, 1054-58 (W.D. Wis. 2006).

157. *Jackson v. Pfizer, Inc.*, 432 F. Supp. 2d 964, 968 (D. Neb. 2006).

158. *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M: 05-1699 CRB, 2006 WL 2374742, at \*12 (N.D. Cal. Aug. 16, 2006); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 538 (E.D. Pa. 2006), *aff'd*, 521 F.3d 253 (3d Cir. 2008).

159. *In re Bextra & Celebrex*, 2006 WL 2374742, at \*6; *Colacicco*, 432 F. Supp. 2d at 530.

160. *Compare Colacicco*, 432 F. Supp. 2d at 525 (beginning analysis with significant deference to FDA's interpretation of its regulations to preempt plaintiff's failure-to-warn claim), *with Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1032 (S.D. Ill. 2001) (beginning analysis with antipreemption presumption).

161. *See, e.g., Caraker*, 172 F. Supp. 2d at 1032 (beginning analysis by noting that, "[i]n the absence of express preemption, there is a strong 'basic assumption' that Congress did not intend to displace state law" (citing *Maryland v. Louisiana*, 451 U.S. 725, 726 (1981))).

162. *See In re Bextra & Celebrex*, 2006 WL 2374742, at \*5-6 (recognizing FDA's intent that its regulations preempt certain state tort claims).

163. *Colacicco*, 432 F. Supp. 2d at 530.

164. *In re Bextra & Celebrex*, 2006 WL 2374742, at \*6; *accord Colacicco*, 432 F. Supp. 2d at 525 (noting that "Supreme Court precedent dictates that an agency's interpretation of the statute and regulations it administers is entitled to deference" (citing *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984))).

implementing the FDCA.<sup>165</sup> The courts reasoned that since the subject matter is extensive and technical in nature, the FDA, given its thorough understanding of its own regulations and objectives, is uniquely qualified to assess the likely effect of additional state requirements.<sup>166</sup> Furthermore, neither courts nor juries are authorized to substitute their judgment in place of the FDA's regarding medical issues, especially when the FDA has acted within its authority.<sup>167</sup> Because the FDA is better able to determine whether state law directly conflicts with federal law and the FDA's regulatory scheme, these two courts accorded significant deference to the FDA's position that certain state actions are preempted by federal regulations.<sup>168</sup> Based on this reasoning, the courts rejected plaintiffs' failure-to-warn claims as preempted by federal law.<sup>169</sup>

*G. Two Different Analytical Approaches—Post-Preemption Starting Point Versus Pre-Preemption Starting Point*

1. Post-FDA Preemption Preamble Starting Point

The 2006 FDA Preemption Preamble issued by the FDA fundamentally altered the preemption analysis engaged in by federal courts.<sup>170</sup> After the issuance of the FDA Preemption Preamble, courts addressing the issue of whether FDA regulations preempt state tort failure-to-warn claims against drug manufacturers have started their analyses with deference to the FDA's position.<sup>171</sup> In *Colacicco v. Apotex, Inc.*,<sup>172</sup> the court noted at the outset of its analysis the importance of the FDA's view on the issue because "Supreme Court precedent dictates that an agency's interpretation of the statute and regulations it administers is entitled to deference."<sup>173</sup> Furthermore, the court acknowledged that, absent a clear expression of congressional intent, the FDA's position on the

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165. *E.g.*, *In re Bextra & Celebrex*, 2006 WL 2374742, at \*6 (comparing this case to deference Supreme Court afforded DOT in its view that its airbag regulation preempted certain state laws).

166. *Id.*

167. *Colacicco*, 432 F. Supp. 2d at 530; *see also Chevron*, 467 U.S. at 843-44 ("If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute.").

168. *E.g.*, *In re Bextra & Celebrex*, 2006 WL 2374742, at \*6-9.

169. *See, e.g., Colacicco*, 432 F. Supp. 2d at 536-38 (relying on FDA's express statement of its interpretation that FDCA and federal regulations preempt state failure-to-warn claims in concluding that plaintiff's failure-to-warn claim was preempted by federal law).

170. *Compare In re Bextra & Celebrex*, 2006 WL 2374742, at \*5-6 (beginning analysis with FDA position as stated in FDA Preemption Preamble and giving deference to FDA's view), *with Peters v. Astrazeneca, LP*, 417 F. Supp. 2d 1051, 1055 (W.D. Wis. 2006) (beginning analysis by applying antipreemption presumption due to absence of clear evidence Congress or FDA intended to preempt state law).

171. *In re Bextra & Celebrex*, 2006 WL 2374742, at \*5; *Colacicco*, 432 F. Supp. 2d at 525.

172. 432 F. Supp. 2d 514 (E.D. Pa. 2006), *aff'd*, 521 F.3d 253 (3d Cir. 2008).

173. *Colacicco*, 432 F. Supp. 2d at 525.

preemptive scope of its regulatory authority is dispositive.<sup>174</sup>

From this starting point, the court then examined the FDA's position on federal preemption in the pharmaceutical field, specifically looking at the amicus brief filed by the government and the FDA Preemption Preamble.<sup>175</sup> The amicus brief filed in *Colacicco* expressly rejected the proposition advanced by plaintiff<sup>176</sup> and asserted that federal law preempts plaintiff's failure-to-warn claims.<sup>177</sup> While the court found the FDA's position, as expressed through the government's amicus brief, was entitled to deference,<sup>178</sup> most courts have not.<sup>179</sup> The *Colacicco* court then focused on the FDA Preemption Preamble in which the FDA unequivocally stated that the FDCA preempts conflicting or contrary state law, including state tort failure-to-warn claims.<sup>180</sup> Based on the amicus brief and the FDA Preemption Preamble, the court concluded the FDA unambiguously set forth its view that "the Supremacy Clause bars state tort liability specifically for failure to include a warning on a drug label that is in conflict with or contrary to the warnings approved by the FDA," and that the FDA's position was entitled to deference.<sup>181</sup> This court reasoned that Congress explicitly authorized the FDA to implement and regulate the introduction of new drugs, and, in accordance with this responsibility, the FDA determined that state tort failure-to-warn claims are inconsistent with its administrative regime.<sup>182</sup> Because this position does not conflict with express congressional intent and the FDA acted within its authority, the court in *Colacicco* afforded the FDA an amount of deference in accord with Supreme Court precedent.<sup>183</sup>

Likewise, the *In re Bextra & Celebrex*<sup>184</sup> court began its analysis with the FDA's position of federal preemption of state tort failure-to-warn claims, specifically the FDA Preemption Preamble.<sup>185</sup> In reaching its conclusion, the

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174. *Id.*

175. *Id.* at 526-29.

176. The plaintiff alleged that adult use of the antidepressant Paxil or its generic equivalent increases the risk of suicidal behavior in the person taking the drug. *Id.* at 518. The FDA specifically addressed and rejected this claim based on the lack of reasonable evidence supporting the connection between use of the drug and increased risk of suicide behavior. *Id.* at 527. Furthermore, the FDA asserted that such a warning would have been false and misleading and would have caused the drug to be mislabeled. *Colacicco*, 432 F. Supp. 2d at 527.

177. *Colacicco* Amicus, *supra* note 4, at 17-22.

178. *Colacicco*, 432 F. Supp. 2d at 528.

179. See, e.g., *McNellis ex rel. DeAngelis v. Pfizer, Inc.*, No. Civ. 05-1286 JBS, 2005 WL 3752269, at \*10 (D.N.J. Dec. 29, 2005) (refusing to treat statements made in amicus briefs as declarations afforded preemptive force of law), *rev'd sub nom.* *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008); *Witezak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 730 (D. Minn. 2005) (declining to afford preemptive force of law to statements made in FDA legal brief).

180. *Colacicco*, 432 F. Supp. 2d at 529-34 (citing FDA Preemption Preamble, *supra* note 3, at 3934, 3936).

181. *Id.* at 532.

182. *Id.* at 536.

183. *Id.* (citing *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984)).

184. No. M: 05-1699 CRB, 2006 WL 2374742 (N.D. Cal. Aug. 16, 2006).

185. *In re Bextra & Celebrex*, 2006 WL 2374742, at \*5.

court focused not only on the FDA's belief that certain "[s]tate laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law"<sup>186</sup> but also on the FDA's express disagreement with cases holding that state tort failure-to-warn claims are not preempted by federal law.<sup>187</sup> Based on the FDA's position, the court ultimately afforded deference to the FDA's interpretation of the preemptive effect of its regulations.<sup>188</sup> The court reasoned that Congress charged the FDA with the responsibility for implementing the FDCA, and "such responsibility implies the authority and expertise to determine which state laws conflict with its regulations."<sup>189</sup> Because the subject matter, the prescription drug field, is technical in nature and substantively complex, the court reasoned that the FDA is likely to have a comprehensive understanding of its own regulations and objectives as well as the potential impact of state laws.<sup>190</sup> Based on this analysis, the *Bextra* court concluded that because "[p]laintiffs' state law failure-to-warn claims conflict with the FDA's determination of the proper warning and pose an obstacle to the full accomplishment of the objectives of the FDCA," those claims are preempted.<sup>191</sup>

## 2. Pre-FDA Preemption Preamble Starting Point

The analyses undertaken in *Colacicco* and *In re Bextra & Celebrex* fundamentally differ from most courts' analyses prior to the issuance of the FDA Preemption Preamble.<sup>192</sup> Prior to the FDA Preemption Preamble, courts started the analysis with a presumption *against* preemption.<sup>193</sup> Because the FDCA does not contain an express preemption provision, the type of preemption involved is implied conflict preemption,<sup>194</sup> which is based on the presumed intent of Congress.<sup>195</sup> To make a finding of federal preemption, the courts engaged in an analysis geared toward determining whether an actual conflict existed between state law and federal law.<sup>196</sup> In making this decision, courts have evaluated

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186. FDA Preemption Preamble, *supra* note 3, at 3935.

187. *In re Bextra & Celebrex*, 2006 WL 2374742, at \*5-6.

188. *Id.*

189. *Id.* at \*7.

190. *Id.* at \*6.

191. *Id.* at \*10.

192. *Compare* *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 525-38 (E.D. Pa. 2006) (analyzing question of federal preemption from position of deference to FDA's interpretation of FDCA and its regulations administering FDCA), *aff'd*, 521 F.3d 253 (3d Cir. 2008), *with* *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1032 (S.D. Ill. 2001) (conducting analysis on issue of federal preemption by applying presumption against preemption).

193. *E.g.*, *Peters v. Astrazeneca, LP*, 417 F. Supp. 2d 1051, 1055 (W.D. Wis. 2006) (stating that court will apply antipreemption presumption absent clear evidence of congressional intent to preempt state law); *McNellis ex rel. DeAngelis v. Pfizer, Inc.*, No. Civ. 05-1286 JBS, 2005 WL 3752269, at \*3 (D.N.J. Dec. 29, 2005) (noting presumption against conflict preemption), *rev'd sub nom.* *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008); *Caraker*, 172 F. Supp. 2d at 1032 (stating that analysis begins with antipreemption presumption).

194. *Peters*, 417 F. Supp. 2d at 1055.

195. *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 728 (D. Minn. 2005).

196. *See* *Jackson v. Pfizer, Inc.*, 432 F. Supp. 2d 964, 967-68 (D. Neb. 2006) (analyzing whether

whether Congress or the FDA actually intended for the FDCA and the subsequent regulations administering the FDCA to preempt state tort failure-to-warn claims.<sup>197</sup> Because this analysis required courts to deal with implied congressional intent rather than express intent, courts applied federal preemption sparingly.<sup>198</sup> This approach and its results accorded with the instruction from the Supreme Court that “a court should not find pre-emption too readily in the absence of clear evidence of a conflict.”<sup>199</sup> Courts have been especially hesitant to find implied preemption in areas historically dominated by state law, such as the protection of health and safety.<sup>200</sup> As a result of an analysis colored by the presumption against federal preemption, the majority of courts addressing the issue of federal preemption in the pharmaceutical field refused to find federal preemption of state tort failure-to-warn claims against drug manufacturers.<sup>201</sup>

### III. DISCUSSION

Given the FDA’s clear statement expressing its intention for its regulations to preempt conflicting or contrary state law regarding prescription drug labeling, combined with the long-standing tradition of affording deference to an administrative agency interpretations of its regulatory scheme, courts should find federal preemption in the pharmaceutical field. The 2006 FDA Preemption Preamble fundamentally changed the analysis undertaken by courts addressing the issue of federal preemption in the pharmaceutical field. The introduction of

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conflict exists between Nebraska state law and federal law); *Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876, 882-84 (E.D. Tex. 2005) (undertaking analysis to determine whether conflict exists between state law and federal law).

197. See, e.g., *Witzak*, 377 F. Supp. 2d at 730-32 (looking for congressional intent to preempt state tort claims); *Caraker*, 172 F. Supp. 2d at 1035-36 (evaluating whether Congress or FDA intended to eliminate state tort claims against drug manufacturers by enacting FDCA and subsequent regulations).

198. *Witzak*, 377 F. Supp. 2d at 728; see also *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1176 (5th Cir. 1988) (observing that most federal courts considering federal preemption have not found preemption); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 535 (E.D. Pa. 2006) (providing examples of federal court decisions declining to find preemption), *aff’d*, 521 F.3d 253 (3d Cir. 2008).

199. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 885 (2000) (citing *English v. Gen. Elec. Co.*, 496 U.S. 72, 90 (1990)).

200. See *Peters v. Astrazeneca, LP*, 417 F. Supp. 2d 1051, 1055 (W.D. Wis. 2006) (noting that protection of health and safety is area traditionally occupied by states); see also *McNellis ex rel. DeAngelis v. Pfizer, Inc.*, No. Civ. 05-1286 JBS, 2005 WL 3752269, at \*3 (D.N.J. Dec. 29, 2005) (stating that courts should presume that historic police power of states is not preempted absent clear congressional intent), *rev’d sub nom. Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008); *Caraker*, 172 F. Supp. 2d at 1032 (noting presumption against preemption is even stronger when federal law involves areas traditionally occupied by states).

201. See *Hurley*, 863 F.2d at 1176 (noting seventeen federal court decisions addressed and rejected preemption in pharmaceutical field); *Colacicco*, 432 F. Supp. 2d at 535 (listing eight decisions in which courts ruled against preemption); *Levy & Wartman*, *supra* note 103, at 506 (noting that majority of courts have not accepted FDA’s position that FDCA and its regulations preempt state tort failure-to-warn claims in pharmaceutical field).

this clear statement by the FDA asserting the preemptive effect of its regulations makes inappropriate the analysis undertaken by courts prior to the FDA Preemption Preamble.

Thus, in light of the FDA Preemption Preamble, the courts in *Colacicco v. Apotex, Inc.*<sup>202</sup> and *In re Bextra & Celebrex*<sup>203</sup> took the proper analytical approach to the issue of federal preemption in the pharmaceutical field. These courts afforded deference to the FDA's interpretation of its regulations as preempting contrary and conflicting state law as expressed in the FDA Preemption Preamble and concluded that the plaintiffs' state tort failure-to-warn claims were preempted.<sup>204</sup> In addition to the strong tradition of deference to an administrative agency's interpretation of its regulations, there are two strong policy rationales—the FDA's expertise in the field of prescription drug labeling and the need for a uniform national policy regarding prescription drug labeling—supporting federal preemption in the pharmaceutical field.

A. *The Proper Analytical Approach to Federal Preemption in the Pharmaceutical Field*

In the wake of the 2006 FDA Preemption Preamble, the proper analysis of the preemptive effect of the FDCA and the FDA's regulations begins with deference to the FDA's interpretation of the statute and its regulations administering the statute.<sup>205</sup> The Supreme Court has long recognized the FDA's authority to issue regulations having a preemptive effect on state law.<sup>206</sup> Furthermore, the FDA may express its preemptive intent in a variety of ways, including preambles.<sup>207</sup> The FDA did just that regarding its view on the preemptive effect that its regulations administering the FDCA have on state law. In the preamble to a final rule, the FDA expressly stated its intention that its regulations to preempt certain state law failure-to-warn claims against drug manufacturers.<sup>208</sup> The FDA clearly possesses the power and authority to make

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202. 432 F. Supp. 2d 514 (E.D. Pa. 2006).

203. No. M: 05-1699 CRB, 2006 WL 2374742 (N.D. Cal. Aug. 16, 2006).

204. See *supra* Part II.G.1 for a discussion of the analyses undertaken by the *Colacicco* and *In re Bextra & Celebrex* courts.

205. See *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M: 05-1699 CRB, 2006 WL 2374742, at \*5-10 (N.D. Cal. Aug. 16, 2006) (analyzing preemption issue in manner deferential to FDA's position); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 525-38 (E.D. Pa. 2006) (showing deference to FDA's interpretation in court's analysis of preemption issue), *aff'd*, 521 F.3d 253 (3d Cir. 2008).

206. See *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 721 (1985) (stating that FDA has authority to promulgate regulations preempting state law regulating collection of blood plasma from paid donors); *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982) (asserting that "[f]ederal regulations have no less pre-emptive effect than federal statutes").

207. See *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000) (acknowledging that administrative agency's views expressed through amicus curiae brief should be taken into consideration); *Hillsborough County*, 471 U.S. at 718 (recognizing that administrative agency may communicate its intention that its regulations to have preemptive effect through regulations, preambles, interpretive statements, and responses to comments).

208. See FDA Preemption Preamble, *supra* note 3, at 3934 ("FDA believes that under existing

such a pronouncement.<sup>209</sup>

The significance of such a pronouncement is that it fundamentally alters the courts' analyses of the issue.<sup>210</sup> Where courts previously fumbled around searching for Congress or the FDA's implied intent to preempt state law,<sup>211</sup> courts now have a clear statement of preemptive intent.<sup>212</sup> Instead of struggling to assess whether a conflict between FDA regulations and state law actually exists,<sup>213</sup> courts now have the FDA's express statement of the circumstances under which, in its view, state law clashes with FDA regulations.<sup>214</sup> Courts now have a clear statement by the FDA expressing its plain intention for its regulations to preempt state law.<sup>215</sup> Therefore, under Supreme Court precedent, the only questions remaining for the courts to decide are whether the FDA's interpretation conflicts with clearly expressed congressional intent and whether the FDA's interpretation "represents a reasonable accommodation of conflicting policies that were committed to the agency's care."<sup>216</sup> So long as the FDA's interpretation does not conflict with express congressional intent and the interpretation is reasonable, courts should not disturb the FDA's interpretation.<sup>217</sup> The Supreme Court has expressly stated that "a court may not substitute its own construction of a statutory provision for a reasonable

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preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law.").

209. See 21 U.S.C. § 393(b)(1)-(2) (2000) (empowering FDA to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products" and to protect public health by ensuring that "human . . . drugs are safe and effective"); *Hillsborough County*, 471 U.S. at 714 (recognizing that under certain conditions FDA's statement is dispositive on issue of intent to preempt state law).

210. Compare *Colacicco*, 432 F. Supp. 2d at 525-38 (analyzing preemption issue after issuance of FDA Preemption Preamble from standpoint of deference to FDA's position), with *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1032 (S.D. Ill. 2001) (analyzing preemption issue prior to issuance of FDA Preemption Preamble from starting point of antipreemption presumption).

211. See, e.g., *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 732 (D. Minn. 2005) (finding against drug manufacturer based in part on failure to ascertain specific congressional intent to preempt state tort failure-to-warn claims); *Caraker*, 172 F. Supp. 2d at 1032 (searching for "intent on the part of Congress or the FDA to impliedly preempt state products liability claims").

212. See FDA Preemption Preamble, *supra* note 3, at 3934 (stating FDA's belief that its regulations preempt conflicting or contrary state law).

213. See, e.g., *Jackson v. Pfizer, Inc.*, 432 F. Supp. 2d 964, 966-68 (D. Neb. 2006) (analyzing whether FDCA and FDA regulations conflict with Nebraska state law); *Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876, 882 (E.D. Tex. 2005) (determining that FDCA and FDA regulations do not conflict with Texas failure-to-warn claims).

214. See FDA Preemption Preamble, *supra* note 3, at 3935-36 (listing several types of state tort claims that FDA believes its regulations preempt).

215. See *id.* at 3934 (stating unequivocally FDA's intention to preempt conflicting or contrary state law).

216. *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 154 (1982) (quoting *United States v. Shimer*, 367 U.S. 374, 383 (1961)); see also *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984) (noting that where statute is silent or ambiguous, court must determine only if administrative agency's interpretation "is based on a permissible construction of the statute").

217. *Fid. Fed. Sav.*, 458 U.S. at 154.

interpretation made by the administrator of an agency.”<sup>218</sup>

After the issuance of the FDA Preemption Preamble, courts have a clear statement of the FDA’s intention that its regulations preempt state tort failure-to-warn claims against drug manufacturers.<sup>219</sup> Based on the Supreme Court’s long-espoused position of deference to administrative agencies’ interpretations of statutes and regulations, the proper analysis for the courts is limited to the reasonableness of the FDA interpretation and whether the FDA interpretation conflicts with clear congressional intent.<sup>220</sup> Therefore, the courts’ analyses of the preemptive effect of the FDCA and FDA’s regulations on state tort failure-to-warn claims in the pharmaceutical field clearly should be governed by deference to the FDA’s position. Indeed, the *Colacicco* and *In re Bextra & Celebrex* courts engaged in such analysis and correctly concluded that state tort failure-to-warn claims against drug manufacturers are preempted by federal law.<sup>221</sup>

Prior to the FDA Preemption Preamble, courts lacked such an express statement by the FDA regarding the preemptive effect of its regulations,<sup>222</sup> and, therefore, the courts had a greater opportunity to consider whether the FDA regulations did indeed conflict with, and therefore preempt, state law.<sup>223</sup> The courts themselves reached the ultimate conclusion as to the preemptive effect, if any, of the federal regulations.<sup>224</sup> The question to be resolved involved the actual interpretation of the regulations, rather than the reasonableness of the FDA’s previously made interpretation.<sup>225</sup> Since the issuance of the FDA Preemption

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218. *Chevron*, 467 U.S. at 844.

219. See FDA Preemption Preamble, *supra* note 3, at 3934 (positing that FDA’s regulation of prescription drug field preempts conflicting state law); see also *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 529 (E.D. Pa. 2006) (noting FDA’s unambiguous position that its regulations have preemptive effect over state law in pharmaceutical field), *aff’d*, 521 F.3d 253 (3d Cir. 2008).

220. See *Chevron*, 467 U.S. at 842-44 (reaffirming principles of deference to administrative agency interpretations and asserting that agency’s interpretations are “given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute”).

221. *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M: 05-1699 CRB, 2006 WL 2374742, at \*5-10 (N.D. Cal. Aug. 16, 2006); *Colacicco*, 432 F. Supp. 2d at 525-38.

222. The FDA did express its views through amicus curiae briefs filed by the government, most notably in *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2002). Motus Brief, *supra* note 59, at \*15-24. Unlike the FDA’s broad pronouncement of preemption in the FDA Preemption Preamble, the amicus briefs tended to be more fact specific and relied on the FDA’s previous consideration and rejection of plaintiffs’ proposed stronger warning labeling. Levy & Wartman, *supra* note 103, at 507.

223. See, e.g., *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1032-39 (S.D. Ill. 2001) (engaging in extended analysis to determine if FDCA and FDA’s regulations preempt state tort law and ultimately concluding that they do not).

224. See, e.g., *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 732 (D. Minn. 2005) (concluding that FDCA and FDA regulations do not preempt state law due to lack of implied congressional intent to preempt); *Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876, 886-87 (E.D. Tex. 2005) (concluding that FDA regulations do not preempt state law because there is no conflict between state law and objectives of FDA).

225. See *McNellis ex rel. DeAngelis v. Pfizer, Inc.*, No. Civ. 05-1286 JBS, 2005 WL 3752269, at \*6-8 (D.N.J. Dec. 29, 2005) (engaging in extensive analysis regarding interpretation of FDA regulations, specifically regulation allowing drug manufacturers to strengthen warning labels unilaterally and without prior FDA approval), *rev’d sub nom. Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008); *Witczak*, 377 F. Supp. 2d at 729-30 (attempting to interpret FDA regulations administering FDCA).

Preamble, the FDA has definitively answered the question of how its regulations should be interpreted and the preemptive effect they have.<sup>226</sup> Because there now is clear evidence of the FDA's preemptive intent, courts no longer have to address this issue and the presumption against preemption no longer comes into play.<sup>227</sup> Instead, in accordance with the Supreme Court's mandate, courts have only to decide whether the FDA's interpretation is reasonable and whether it conflicts with clear congressional intent.<sup>228</sup> Therefore, a court oversteps its authority when it engages in an analysis involving its own interpretation of the FDA regulations in terms of possible conflict with state law.<sup>229</sup> While that type of analysis may have been appropriate prior to the FDA Preemption Preamble, in light of the FDA's clear statement of its intention to preempt state tort law, it is no longer proper for the courts to address the issue of federal preemption in the pharmaceutical field.<sup>230</sup>

For this reason, the three courts refusing to find federal preemption of state tort failure-to-warn claims against drug manufacturers after the issuance of the FDA Preemption Preamble<sup>231</sup> engaged in an improper analysis of the issue. Two courts, the *Laisure-Radke v. Par Pharmaceutical, Inc.*<sup>232</sup> court and the *Peters v. Astrazeneca, LP*<sup>233</sup> court, failed to consider the FDA Preemption Preamble in any way in their analyses.<sup>234</sup> The *Laisure-Radke* court acknowledged, but ignored, the issuance of the FDA Preemption Preamble,<sup>235</sup> while the *Peters* court neglected to mention it at all.<sup>236</sup> The *Jackson v. Pfizer, Inc.*<sup>237</sup> court addressed the FDA Preemption Preamble in its analysis but only so far as to brush it off as unpersuasive on the issue of the FDA's intent to preempt state law.<sup>238</sup> These

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226. See FDA Preemption Preamble, *supra* note 3, at 3934 (expressing unequivocally FDA's intention for its regulations to preempt state law and reaffirming FDA's interpretation of its regulations as retaining FDA's ultimate authority to determine necessity of labeling changes).

227. See *Caraker*, 172 F. Supp. 2d at 1032 (stating that antipreemption presumption applies in absence of clear evidence of FDA's intent to preempt state products liability claims).

228. *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 154 (1982).

229. See *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984) (cautioning that court should not substitute its interpretation of provision when agency with responsibility for administering that provision has already provided reasonable interpretation).

230. See *id.* at 843 (stating expressly that courts may not impose their own constructions of statute where agency tasked with administering statute has its own interpretation of statute).

231. See *Jackson v. Pfizer, Inc.*, 432 F. Supp. 2d 964, 968 (D. Neb. 2006) (interpreting federal law so as not to conflict with state law and affording negligible weight to FDA's Preemption Preamble); *Laisure-Radke v. Par Pharm., Inc.*, No. C03-365RSM, 2006 WL 901657, at \*3-6 (W.D. Wash. Mar. 29, 2006) (analyzing and interpreting federal regulations as not conflicting with state law and largely neglecting FDA's Preemption Preamble); *Peters v. Astrazeneca, LP*, 417 F. Supp. 2d 1051, 1054-58 (W.D. Wis. 2006) (failing to acknowledge FDA's intention to preempt state law as expressed in FDA Preemption Preamble).

232. No. C03-365RSM, 2006 WL 901657 (W.D. Wash. Mar. 29, 2006).

233. 417 F. Supp. 2d 1051 (W.D. Wis. 2006).

234. *Laisure-Radke*, 2006 WL 901657, at \*3-6; *Peters*, 417 F. Supp. 2d at 1054-58.

235. *Laisure-Radke*, 2006 WL 901657, at \*3-6.

236. *Peters*, 417 F. Supp. 2d at 1054-58.

237. 432 F. Supp. 2d 964 (D. Neb. 2006).

238. *Jackson*, 432 F. Supp. 2d at 968 (stating that FDA Preemption Preamble is "not persuasive")

courts, like those prior to the issuance of the FDA Preemption Preamble, framed the issue in terms of whether the federal regulations actually conflict with state tort failure-to-warn claims.<sup>239</sup>

This type of analysis clearly violates the Supreme Court's long-standing position of deference to interpretations made by an administrative agency charged by Congress with administration of the statute.<sup>240</sup> Under the principles of deference, these courts should never reach the issue of whether an actual conflict exists between state law and federal law because the FDA has already interpreted its regulations to conflict with state law.<sup>241</sup> Rather, their analyses should be limited solely to the issues of whether the FDA's interpretation clashes with clear congressional intent and whether the FDA's interpretation is reasonable.<sup>242</sup> Because these courts failed to heed the Supreme Court's mandate of deference to the FDA's interpretation of its regulations and instead substituted their own analyses regarding existence of an actual conflict between federal law and state law, these courts erroneously analyzed the issue of federal preemption in the pharmaceutical field.

*B. Policy Reasons Supporting Federal Preemption in the Pharmaceutical Field*

Deference of courts to the FDA's position on federal preemption in the pharmaceutical field not only complies with long-standing Supreme Court precedent<sup>243</sup> but also accords with policy reasons in favor of federal preemption. Even though prior to the FDA Preemption Preamble courts almost always rejected the notion of federal preemption in the pharmaceutical field,<sup>244</sup> there were, and still are, strong policy reasons supporting federal preemption.<sup>245</sup> There

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as indication of congressional intent to preempt state law).

239. See *id.* at 966 (stating issue as "whether there is a conflict between state and federal law"); *Laisure-Radke*, 2006 WL 901657, at \*3 (framing issue to be resolved as "whether there is a conflict between Washington State law and federal laws concerning drug labeling"); *Peters*, 417 F. Supp. 2d at 1053 (stating issue as whether FDA's regulations preempt state tort claims).

240. See *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 714 (1985) (asserting that "FDA's statement is dispositive on the question of implicit intent to pre-empt" unless it conflicts with clear congressional intent); *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984) (reaffirming principle of deference to administrative agency interpretations of statutory scheme it has been entrusted to regulate).

241. See FDA Preemption Preamble, *supra* note 3, at 3935-36 (setting forth circumstances under which FDA believes state tort law conflicts with its regulations by obstructing achievement of full objectives and purposes of its regulatory scheme).

242. *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 154 (1982) (citing *U.S. v. Shimer*, 367 U.S. 374, 381-82 (1961)).

243. See *supra* notes 32-36 and accompanying text for a discussion of the Supreme Court's position of deference to administrative agencies regarding their interpretation of statutes they are empowered to administer.

244. See *supra* Part II.C for a discussion of the majority rule regarding federal preemption in the pharmaceutical field prior to the issuance of the 2006 FDA Preemption Preamble.

245. See *Jackson*, *supra* note 98, at 209-20 (discussing how concurrent regulation of pharmaceutical field by both FDA and state tort law can lead to anomalous results such as state tort law judgments directly conflicting with FDA determinations).

are two critical reasons in favor of federal preemption in the pharmaceutical field. The first is that the FDA is better able to assess whether a particular drug is safe and to provide for its effective use than is the judiciary or a jury.<sup>246</sup> The second policy reason is the need for national uniformity of labeling standards in the pharmaceutical field.<sup>247</sup>

1. FDA Is More Experienced and Better Qualified to Make Decisions Regarding the Adequacy of Prescription Drug Warning Labels

The FDA is in a better position than the judiciary or a jury to determine whether particular drugs are safe and effective. In enacting the FDCA, Congress explicitly charged the FDA with the responsibility to “promote the public health” and to “protect the public health.”<sup>248</sup> Specifically, the FDA must ensure that all “drugs are safe and effective.”<sup>249</sup> With the FDCA, Congress entrusted to the FDA the authority and responsibility for regulation of the pharmaceutical field.<sup>250</sup> In so doing, Congress recognized that the FDA is best able to administer and regulate the complex pharmaceutical field.<sup>251</sup> Congress had the option of leaving regulation of the pharmaceutical field to the individual states but instead deliberately elected to empower the FDA with administrative authority in this area.<sup>252</sup>

Administration of the pharmaceutical field is complex and involves extensive and intricate regulations.<sup>253</sup> In an effort to maximize health benefits from pharmaceutical use and minimize risks of injury from drug use,<sup>254</sup> the FDA comprehensively regulates every aspect of drug formulation, production, testing, and labeling.<sup>255</sup> This includes oversight of the initial determination of whether a

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246. See Note, *supra* note 6, at 780-83 (recognizing dangers of lay judges and jurors, rather than specialists in the field, acting as final authority on matters involving complex scientific issues, such as dangerousness of particular drug).

247. Del Giorno, *supra* note 42, at 650-53.

248. 21 U.S.C. § 393(b) (2000).

249. *Id.*

250. *Id.*; see also *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843-44 (1984) (noting that where Congress has left gap to be filled in by administrative agency, there is express delegation of authority to agency to regulate that area).

251. See Del Giorno, *supra* note 42, at 648-49 (emphasizing importance of prescription drugs and recognizing that Congress specifically entrusted FDA with responsibility for ensuring that all drugs are as safe and effective as possible).

252. See 21 U.S.C. § 393 (empowering FDA and defining its regulatory mission); see also Shaeffer, *supra* note 36, at 638-39 (stating that Congress’s “grant to FDA of exclusive federal jurisdiction over prescription drug advertising clearly indicates a congressional belief that FDA has unique expertise in this area”).

253. See *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 530 (E.D. Pa. 2006) (recognizing that pharmaceutical field involves technical subject matter that is “complex and extensive” (quoting *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 883 (2000))), *aff’d*, 521 F.3d 253 (3d Cir. 2008).

254. Note, *supra* note 6, at 773.

255. See Del Giorno, *supra* note 42, at 629, 647 (noting pervasiveness of FDA involvement in getting drugs on market); see also Jackson, *supra* note 98, at 210-16 (describing FDA’s comprehensive role in regulation of pharmaceuticals from preapproval testing of new drugs through postapproval

particular drug is safe for human use and as well as the labeling specifications necessary for safe and effective use of the drug.<sup>256</sup> The FDA engages in extensive scientific testing prior to approval of the new drug<sup>257</sup> and continuing after the drug is on the market in an effort to make sure the benefits of the drug's use continue to outweigh its risks.<sup>258</sup> The FDA relies on this scientific research and will only include a particular warning on the drug labeling if supported by scientific evidence.<sup>259</sup> Through its pervasive regulation of this field, the FDA has become uniquely qualified to make determinations regarding the labeling necessary to make a particular drug safe and effective for use.<sup>260</sup>

While the FDA is uniquely qualified to regulate the pharmaceutical field, judges and juries are not. The long-held view that FDA regulations are merely minimum standards and do not shield drug manufacturers from tort liability premised on the failure-to-warn theory<sup>261</sup> has incorrectly allowed judges and juries the opportunity to pass judgment on the adequacy of FDA-approved warnings.<sup>262</sup> While the FDA conducts extensive research over a period of several years prior to making a determination regarding the appropriate labeling for a particular drug,<sup>263</sup> the judge and jury make their determinations based solely on the scientific evidence presented at trial. Furthermore, judges and jurors frequently lack the scientific expertise necessary to understand and properly evaluate the validity of the scientific data presented at trial.<sup>264</sup> This results in decisions based on the credibility and demeanor of the competing expert

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supervision for adverse drug reactions).

256. 21 U.S.C. § 393(b); *see also* Del Giorno, *supra* note 42, at 645-46 (describing requirements new drug must meet before FDA will approve drug); Note, *supra* note 6, at 773 (discussing FDA's oversight power with regard to both initial determination of drug's availability and labeling requirements that inform physicians' treatment decisions).

257. *See* FDA Preemption Preamble, *supra* note 3, at 3934 (stating FDA "makes approval decisions based not on an abstract estimation of [the drug's] safety and effectiveness, but rather on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling").

258. *See, e.g.*, Colacicco Amicus, *supra* note 4, at 5-6 (describing extensive postapproval testing and review conducted by FDA as well as affirmative obligation of drug manufacturer to change approved drug's label to reflect scientifically verifiable hazard of drug).

259. *Id.* at 9.

260. *See* Del Giorno, *supra* note 42, at 650 (noting that "the FDA has developed the special competence which places it in the unique position to expertly regulate the warning requirements of pharmaceutical products").

261. *See supra* Part II.C.2 for a discussion of cases holding that FDA regulations are merely minimum standards.

262. *See* FDA Preemption Preamble, *supra* note 3, at 3935 (expressing concern that state tort actions invite and encourage judges and juries to second-guess FDA's previously conducted risk-benefit analysis of particular drug); Jackson, *supra* note 98, at 218 (noting that state tort actions permit juries to conduct their own analyses of risks and benefits of particular drug despite fact that FDA had previously approved drug and its labeling).

263. *See* Colacicco Amicus, *supra* note 4, at 6-8 (identifying requirements that must be satisfied prior to FDA approval of new drug (citing 21 U.S.C. § 355(b), (d) (2000 & Supp. 2003))).

264. Note, *supra* note 6, at 780.

witnesses rather than on the substance of the underlying scientific issue.<sup>265</sup> Allowing judges and juries to decide the adequacy of warning labels has led to incongruous results in which courts require inclusion of warnings that have been specifically rejected by the FDA due to lack of scientific evidence.<sup>266</sup> In such situations, the drug manufacturer could be held liable in tort for failing to include a warning, which, if included, would have constituted unlawful misbranding under the FDA's regulations.<sup>267</sup> Results such as this not only illustrate the absurdity of allowing lay judges and juries to override determinations made by an independent agency specializing in such analysis, but they also act to usurp the FDA's authority as ultimate decision maker regarding adequacy of drug labeling.<sup>268</sup>

As recognized by Congress and several courts, the FDA is uniquely qualified to make determinations regarding the sufficiency of drug warning labels.<sup>269</sup> It is the FDA, not the judiciary or lay juries, that has "the institutional capacity and collective expertise" to weigh the potential benefits and risks of a particular drug and determine the appropriate warning labeling after extensive scientific testing.<sup>270</sup> When the courts afford deference to the FDA's stated position of federal preemption in the pharmaceutical field, the courts properly ensure that the FDA, and not the judiciary or juries, makes the ultimate decision regarding the adequacy of warning labels for a particular drug.

## 2. Need for National Uniformity of Prescription Drug Labeling Requirements

The pharmaceutical field should be uniformly regulated throughout the nation, especially with regard to drug labeling. This need for uniformity is partly because of the size and complexity of the pharmaceutical field but also because

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265. See, e.g., *id.* at 781-82 (highlighting situation in which court resolved issue of medical causation based on credibility of expert witnesses rather than on underlying substance of scientific issues).

266. See, e.g., *Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876, 884 (E.D. Tex. 2005) (acknowledging FDA's position that any warning of causal relationship between use of drug Zoloft and suicide would misbrand drug, but still maintaining that requirement to include such warning would not conflict with federal law).

267. See *Motus Brief*, *supra* note 59, at \*13, 15-16 (stating unequivocally that if Pfizer had included in its labeling of Zoloft a warning as to causal relationship between drug and suicide, which was warning plaintiffs claimed should have been included, such warning would have misbranded drug).

268. See *Note*, *supra* note 6, at 779 (noting that state tort law "establishes the jury as the final arbiter of whether and how a medication should be marketed").

269. See 21 U.S.C. § 393(b)(1) (2000) (describing FDA mission as to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products"); see also *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 530 (E.D. Pa. 2006) (refusing to substitute its judgment for that of FDA regarding medical issues and affirming FDA's expertise in determining whether warning labels comply with federal law), *aff'd*, 521 F.3d 253 (3d Cir. 2008); *Shaeffer*, *supra* note 36, at 639 (noting courts have long recognized FDA's expertise in area of drug safety and efficiency).

270. *Note*, *supra* note 6, at 785.

of the importance of drug labeling.<sup>271</sup> The FDA has, numerous times, emphasized the significance of drug labeling and the absolute necessity that the labeling be accurate.<sup>272</sup> In fact, the FDA's comprehensive and rigorous regulation of drug labeling<sup>273</sup> illustrates its policy of promoting national uniformity in that realm.<sup>274</sup> If the FDA did not value a policy of national uniformity of labeling, it would not regulate everything from the content of the labeling down to the size and typeface of the warnings.<sup>275</sup> Additionally, such a policy of national uniformity is essential to ensuring the safe and effective use of pharmaceuticals.<sup>276</sup> To have any other policy would involve variable labeling requirements based on state lines rather than on which labeling best informs of the attendant risks and benefits of the drug. Furthermore, drug labeling required by one state could differ from the drug labeling required by another state, and both could differ from the drug labeling approved by the FDA.<sup>277</sup> The resulting confusion as to which labeling accurately reflects the actual risks and benefits of the drug would prevent safe and effective use of the drug.<sup>278</sup> Also, permitting state court judges and juries to impose labeling requirements different from those mandated by the FDA serves to severely undercut the FDA's policy of uniform labeling.<sup>279</sup> Because accurate drug labeling is of preeminent

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271. See FDA Preemption Preamble, *supra* note 3, at 3934 (asserting that labeling is "FDA's principal tool for educating health care professionals about the risks and benefits of the approved product to help ensure safe and effective use"); see also Scarlett, *supra* note 79, at 33 (noting utmost importance of drug labeling and its effects on patient safety, medical judgment, drug promotion, and agency regulation of prescription drug market).

272. See FDA Preemption Preamble, *supra* note 3, at 3934 (calling drug labeling "centerpiece of risk management for prescription drugs"); see also Colacicco Amicus, *supra* note 4, at 4 (stating that FDA's "evaluation of a drug's safety and effectiveness is inextricably linked with the drug labeling").

273. See Colacicco Amicus, *supra* note 4, at 5 (noting FDA approves even type size and font to be used by manufacturers in drug's labeling).

274. See Del Giorno, *supra* note 42, at 650-51 (describing FDA's mission of promoting national uniformity in drug labeling).

275. See 21 C.F.R. § 201.57 (2007) (outlining labeling requirements with which drug manufacturer must comply, including exact phrasing which must be used verbatim); see also Colacicco Amicus, *supra* note 4, at 5 (noting that not only does FDA approve precise final version of new drug's labeling, but it also approves type size and font of labeling).

276. See Del Giorno, *supra* note 42, at 650-51 (recognizing necessity of uniform federal drug labeling standards to furnish prescribing physicians with comprehensive information that would enable them to make informed treatment decisions).

277. See Jackson, *supra* note 98, at 218-19 (noting case-by-case determinations regarding adequacy of drug labeling sometimes leads to findings in clear conflict with FDA conclusions); Note, *supra* note 6, at 790 (recognizing lack of uniformity resulting from judicial determinations regarding sufficiency of drug labeling).

278. See FDA Preemption Preamble, *supra* note 3, at 3935 (acknowledging that state tort law's "attempts to impose additional warnings can lead to labeling that does not accurately portray a product's risks, thereby potentially discouraging safe and effective use of approved products"); see also Del Giorno, *supra* note 42, at 652 (arguing that lack of uniform requirements will cause manufacturers to include additional warnings even though such warnings may not be properly substantiated in effort to protect themselves from accusations of inadequate warning, which will adversely affect physicians attempting to make treatment decisions regarding use of drug).

279. Del Giorno, *supra* note 42, at 651.

importance,<sup>280</sup> allowing labeling standards to differ based on geography undermines the FDA's goal of protecting and promoting the public health by ensuring the safe and effective use of all drugs and that such drug labels are truthful and not misleading.<sup>281</sup>

Additionally, national uniformity of drug labeling is necessary to ensure the safe and effective use of drugs because it protects against superfluous labeling.<sup>282</sup> The FDA has long expressed its belief that more warnings are not always better.<sup>283</sup> Similar to underwarning, overwarning can negatively impact patient safety and public health.<sup>284</sup> This is because labeling that includes warnings or side effects not based on scientific evidence can cause the substantiated information to lose significance.<sup>285</sup> Moreover, the primary purpose of drug labeling is to provide physicians the necessary information to prescribe the drug safely and effectively.<sup>286</sup> Overloading the labeling with extraneous warnings offers physicians no help in making risk-benefit assessments about the drug.<sup>287</sup> Instead, the superfluous information may cause physicians to ignore completely a drug's official labeling since part of the labeling would be misleading and confusing.<sup>288</sup> For this reason, the FDA has determined that "allowing unsubstantiated warnings would likely diminish the impact of valid warnings by creating an unnecessary distraction and making even valid warnings less credible."<sup>289</sup> Nevertheless, the inclusion of unfounded warnings sometimes results from state tort judgments holding drug manufacturers liable for inadequate warnings.<sup>290</sup> The jury effectively makes an independent determination that the drug manufacturer should have included a warning not required by the FDA.<sup>291</sup> Such a warning imposed by juries is precisely the type causing the FDA concern because it does not accurately reflect the drug's risks.<sup>292</sup> If scientific evidence

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280. FDA Preemption Preamble, *supra* note 3, at 3934.

281. *See Colacicco Amicus, supra* note 4, at 16 (stating that "[j]udicial imposition of liability for failure to warn would interfere with FDA's ability to protect the public from unsubstantiated warnings that would deter appropriate uses of a drug and diminish the impact of valid warnings").

282. *See Del Giorno, supra* note 42, at 652 (recognizing danger that, absent uniform standards, drug manufacturers will include warnings unsupported by scientific evidence solely to avoid tort liability).

283. *Colacicco Amicus, supra* note 4, at 13.

284. FDA Preemption Preamble, *supra* note 3, at 3935.

285. *Id.*

286. *Id.* at 3968.

287. *Del Giorno, supra* note 42, at 652.

288. *Id.*

289. *Colacicco Amicus, supra* note 4, at 13-14.

290. FDA Preemption Preamble, *supra* note 3, at 3935.

291. *See Note, supra* note 6, at 779 (describing how juries have held drug manufacturers liable in tort for failure to include warning that was expressly rejected by FDA as unsupported by scientific evidence).

292. *See FDA Preemption Preamble, supra* note 3, at 3935 (expressing FDA's concern that possibility of juries imposing additional warning requirements could encourage drug manufacturers to include warnings unsubstantiated by scientific evidence in effort to avoid tort liability); *see also Note, supra* note 6, at 789 (arguing that state tort failure-to-warn claims "frustrate the FDA objective of

substantiated such a warning, the FDA would have required the warning.<sup>293</sup> The FDA's policy of national uniformity of drug labeling guards against the danger of overwarning because, under the policy, the FDA alone has final approval regarding drug labeling.<sup>294</sup>

A policy of national uniformity of drug labeling also prevents deterring the use of particular drugs through overwarning. Not only does overwarning have the potential to confuse and mislead physicians, but it also has the effect of deterring effective use of the particular drug.<sup>295</sup> A physician, concerned or confused about side effects that in actuality have no basis in scientific fact, could refrain from prescribing a particular drug even though the drug may be beneficial to the patient.<sup>296</sup> This could result in underuse of a helpful drug, which conflicts with the FDA's stated goal of promoting safe and effective use of a drug.<sup>297</sup> Underutilization of drugs based on inclusion of unsubstantiated warnings in drug labeling could also deprive patients of effective treatment.<sup>298</sup> Since the FDA seeks to promote not only safe use of drugs but also effective use of drugs, overwarning of unfounded risks could potentially result in underutilization of beneficial treatments and thereby undermine an important objective of the federal regulatory scheme.<sup>299</sup> A national policy of uniformity prevents such a result by ensuring that only warnings grounded in scientific evidence and that are not misleading are included in drug labeling.<sup>300</sup> Additionally, such a policy furthers the FDA's position that its prescription drug labeling is the authority for risk information regarding a particular drug.<sup>301</sup>

The important policy of national uniformity of drug labeling in the pharmaceutical field ensures safe and effective use of drugs by preventing the inclusion of extraneous warnings on drug labeling and encouraging maximum utilization of beneficial drug treatments. Under this policy, the FDA is able to confirm that only the most accurate and scientifically substantiated information

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ensuring the effective communication of information necessary to an informed medical decision").

293. See FDA Preemption Preamble, *supra* note 3, at 3968 (emphasizing FDA's careful control of drug labeling regarding risks and benefits of drug in effort to maximize safe and effective use of drug).

294. *Id.* at 3934.

295. See Motus Brief, *supra* note 59, at \*23 (expressing concern that unsubstantiated warnings will result in underutilization of drug).

296. See Note, *supra* note 6, at 783 (noting that even if physician understands entire warning, "use of the medication may be inappropriately restricted if the label contains warnings that are scientifically irrelevant").

297. 21 U.S.C. § 393(b) (2000).

298. Colacicco Amicus, *supra* note 4, at 13.

299. *Id.*

300. See FDA Preemption Preamble, *supra* note 3, at 3967-68 (stating that FDA labeling approval is based on comprehensive scientific evaluation of drug's benefits and risks and that FDCA allows only labeling supported by scientific evidence and that does not mislead with regard to any particular element of drug).

301. See *id.* at 3936 (stating FDA's belief that physicians should "be able to rely on prescription drug labeling for authoritative risk information").

is included on the drug labeling.<sup>302</sup> Federal preemption of state tort claims enforces the FDA's policy of national uniformity by preventing individual judges and juries from requiring warnings over and above those required by the FDA. Such additional warnings act to undermine the FDA's regulation of the pharmaceutical field.<sup>303</sup>

#### IV. CONCLUSION

The FDA's issuance of the 2006 FDA Preemption Preamble in which it unequivocally stated its intention for its regulations to preempt conflicting or contrary state tort law fundamentally alters the analytical approach to be taken by courts addressing the issue of federal preemption.<sup>304</sup> Prior to the FDA Preemption Preamble, courts searched for an implied intention of the FDA to preempt state law.<sup>305</sup> Absent such a finding, courts applied an antipreemption presumption, which was rebutted only in very limited circumstances.<sup>306</sup> The FDA Preemption Preamble changed this analytical approach. Because courts now have a clear statement of the FDA's intention, they no longer have to find implied intent.<sup>307</sup> Rather, courts should engage in the limited analysis mandated by Supreme Court precedent when dealing with administrative agency interpretations of the agency's regulations.<sup>308</sup> Therefore, courts should confine their analysis to whether the FDA's interpretation is reasonable and whether it conflicts with clear congressional intent.<sup>309</sup> As long as the FDA's interpretation meets these requirements, under the long-standing tradition of deference, courts should give effect to the FDA's interpretation.<sup>310</sup> Because of the FDA's clear statement of its preemptive intent and the policy of deference to administrative agencies, courts should find federal preemption of state tort failure-to-warn claims against drug manufacturers.

Strong policy reasons also support the finding of federal preemption in the pharmaceutical field, most notably the FDA's experience and expertise in the field and the need for a nationally uniform policy regarding prescription drug

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302. Del Giorno, *supra* note 42, at 651.

303. See Note, *supra* note 6, at 788 (recognizing that state tort judgments undercut FDA's mission to determine which drugs should be available and what labeling should accompany each drug).

304. See *supra* Part II.G for a discussion on the different analytical approaches taken by courts before and after the issuance of the 2006 FDA Preemption Preamble.

305. See *supra* Part II.G.2 for an examination of courts' analyses prior to the 2006 FDA Preemption Preamble.

306. See *supra* Part II.G.2 for a discussion of courts' use of the antipreemption presumption prior to the issuance of the FDA Preemption Preamble.

307. See *supra* Part III.A for an analysis of how the 2006 FDA Preemption Preamble changed the analytical approach taken by courts when addressing federal preemption in the prescription drug field.

308. See *supra* Part III.A for a discussion of the Supreme Court's policy of deference to an administrative agency's interpretation of its own regulations.

309. See *supra* Part III.A for a deeper analysis of the deference issue.

310. See *supra* Part III.A for a discussion of the reasons the courts should defer to the determinations of the FDA.

labeling.<sup>311</sup> Congress specifically charged the FDA with the responsibility for ensuring the safety and effectiveness of all human drugs.<sup>312</sup> Nonetheless, the allowance of state tort failure-to-warn claims undermines the FDA's ability to accomplish its purpose by empowering state judges and juries to make decisions regarding proper drug labeling.<sup>313</sup> Moreover, while the FDA has the resources and scientific expertise to accomplish this objective, judges and juries often lack the requisite scientific evidence or knowledge regarding prescription drugs.<sup>314</sup> Given the importance and prevalence of prescription drugs, it is imperative that the organization best positioned to ensure safety and effectiveness of prescription drugs—the FDA—be allowed to do so without interference from less qualified sources.

Additionally, the need for a uniform national policy of drug labeling supports federal preemption.<sup>315</sup> A uniform policy of drug labeling promotes the safe and effective use of drugs by avoiding confusion that could arise from drug labeling requirements that vary based on state lines, protecting against superfluous labeling, and preventing deterrence of use of a particular drug caused by overwarning.<sup>316</sup> A uniform policy on drug labeling best promotes the safe and effective use of prescription drugs, and federal preemption helps achieve a uniform policy by ensuring that the FDA is the sole organization responsible for determining the adequacy of prescription drug labeling.

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311. See *supra* Part III.B for a discussion of the policy reasons favoring federal preemption of prescription drug labeling.

312. 21 U.S.C. § 393(b) (2000).

313. See *supra* Part III.B.1 for an explanation of why the FDA is better positioned to make decisions regarding drug labeling than are state judges and juries.

314. See *supra* Part III.B.1 for a comparison of the resources and abilities of the FDA to those of judges and juries.

315. See *supra* Part III.B.2 for a discussion of the importance of a uniform national policy with regard to prescription drug labeling.

316. See *supra* Part III.B.2 for an outline of the potential benefits of a uniform labeling policy.

\* I would like to thank my parents, Chuck and Susan, for their constant love and support and for believing in me even when I doubted. Thanks also to my brother, David, and my sisters, Beth and Nicole, for your advice, patience, and, most importantly, your love and friendship.

