

# THE FDA DEFENSE: VIOXX<sup>®</sup> AND THE ARGUMENT AGAINST FEDERAL PREEMPTION OF STATE CLAIMS FOR INJURIES RESULTING FROM DEFECTIVE DRUGS

Jonathan V. O'Steen<sup>\*</sup> and Van O'Steen<sup>\*\*</sup>

## INTRODUCTION

On September 30, 2004, Merck & Co. announced an immediate withdrawal of its arthritis drug Vioxx following a clinical study indicating it more than doubled the risk of heart attack and stroke.<sup>1</sup> A Food and Drug Administration ("FDA") study published after the recall estimated that Vioxx caused as many as 140,000 heart-related injuries and may have led to as many as 56,000 deaths in the United States alone in the five years the drug was on the market.<sup>2</sup> In the days and weeks following the withdrawal, law firms were flooded with calls from Vioxx patients seeking representation for injury claims. By March 9, 2005, Merck was already facing 1357 claims in connection with its defective drug.<sup>3</sup> It is likely that thousands more will be filed in the foreseeable future.

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\* Partner, O'Steen & Harrison, PLC, Phoenix, Arizona. I am grateful to Kathryn McCormick and Professor Betsy Grey, Arizona State University College of Law, for valuable editorial input.

\*\* Founding partner, O'Steen & Harrison, PLC, Phoenix, Arizona.

1. Gina Kolata, *A Widely Used Arthritis Drug Is Withdrawn*, N.Y. TIMES, Oct. 1, 2004, at A1.

2. Thomas H. Maugh II, *Banned Report on Vioxx Published*, L.A. TIMES, Jan. 25, 2005, at A18; *see also F.D.A. Releases Memo on Vioxx*, N.Y. TIMES, Nov. 3, 2004, at C8; Memorandum from David J. Graham, Assoc. Dir. of Sci., Office of Drug Safety, to Paul Seligman, Acting Dir., Office of Drug Safety, Risk of Acute Myocardial Infarction and Sudden Cardiac Death in Patients Treated with Cox-2 Selective and Non-Selective NSAIDS (Sept. 30, 2004), *available at* <http://www.fda.gov/cder/drug/infopage/vioxx/vioxxgraham.pdf> (estimating that Vioxx caused approximately 27,000 heart attacks and strokes between 1999 and 2002).

3. Theresa Agovino, *Pretrial Process for Vioxx Litigation Begins*, LAW.COM, Mar. 21, 2005, <http://www.law.com/jsp/article.jsp?id=1111140312583> (noting that 127 of the 1357 cases filed were transferred to Judge E. Fallon of the U.S. District Court for the Eastern District of Louisiana for pretrial hearings). Even firms outside the United States are actively soliciting cases. *See, e.g., Hundreds of Lawsuits Expected Over Vioxx*,

The problems with Vioxx were apparent long before Merck publicly announced its recall in September 2004. In 2000, Merck forwarded to the FDA results of a study that showed patients taking Vioxx were at a greater risk of suffering heart attacks and strokes compared to those taking naproxen, a comparable pain reliever.<sup>4</sup> Merck officials dismissed this study and maintained that the findings were misleading. The company contended that Vioxx did not increase the risk of heart attack and stroke—instead, naproxen actually protected the heart and reduced the risk of cardiovascular problems.<sup>5</sup> Contrary to Merck's claim, naproxen never had been shown to have any beneficial effect on the heart.<sup>6</sup>

In 2001, the FDA became concerned over claims Merck made in the marketing of Vioxx, declaring that the company's advertising minimized the incidence of cardiovascular problems.<sup>7</sup> One year later, the FDA asked that Merck modify the drug's label to warn patients of an increased risk of heart attack and stroke.<sup>8</sup> Numerous studies published in 2002 and 2003 reached a consistent conclusion—Vioxx increased the risk of cardiovascular problems.<sup>9</sup> Among them was a clinical study funded by Merck that found elevated cardiovascular risks.<sup>10</sup> Company officials did not immediately publicize the results of that study.

Notwithstanding these ominous signs, the FDA never required that Merck withdraw the drug from the market. In fact, in February 2005 an advisory panel for the FDA voted to permit Merck to resume sales of Vioxx.<sup>11</sup> The vote came less than five months after the voluntary withdrawal and occurred in spite of the group's finding that the cardiovascular risk was considerable.<sup>12</sup> It is doubtful that

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CBC NEWS, Apr. 14, 2005, <http://www.cbc.ca/story/science/national/2005/04/14/Vioxx-lawsuit050414.html> (noting that a Canadian firm is preparing to file "hundreds of lawsuits" on behalf of Vioxx patients who suffered a heart attack or stroke).

4. Barry Meier, *Merck and Vioxx: The Clinical Tests; For Merck, Defense of a Drug Crumbles at a Difficult Time*, N.Y. TIMES, Oct. 1, 2004, at C1. On March 9, 2000, Edward Scolnick, Merck's research chief, admitted in an e-mail that cardiovascular problems were "clearly there." *Vioxx Malpractice*, BOSTON GLOBE, Nov. 8, 2004, at A10, available at [http://www.boston.com/news/globe/editorial\\_opinion/editorials/articles/2004/11/08/vioxx\\_malpractice/](http://www.boston.com/news/globe/editorial_opinion/editorials/articles/2004/11/08/vioxx_malpractice/).

5. Eric J. Topol, *Failing the Public Health—Rofecoxib, Merck and the FDA*, 351 NEW ENG. J. MED. 1707, 1707–08 (2004).

6. See Meier, *supra* note 4, at C1 (noting that a study published in 2002 concluded "naproxen did not have a significant protective cardiovascular effect").

7. *Id.*

8. *Id.*

9. *See id.*

10. Barry Meier, *Earlier Merck Study Indicated Risks of Vioxx*, N.Y. TIMES, Nov. 18, 2004, at C1 (explaining the company position that the study was based on patient records and not a clinical trial and the results therefore were inconclusive); see also Merck, *FDA Grilled at Senate Hearing*, CNN MONEY, Nov. 18, 2004, <http://money.cnn.com/2004/11/18/news/fortune500/merck/>.

11. Marc Kaufman, *FDA Panel Opens Door for Return of Vioxx*, WASH. POST, Feb. 19, 2005, at A1. This recommendation will be forwarded to FDA officials who possess the authority to permit the reintroduction of Vioxx. As of the date of publication, the FDA has not approved the reintroduction of Vioxx.

12. *Id.*

the FDA has any intentions of actually permitting Vioxx to reenter the market. The vote more likely was symbolic and intended to undercut the claims of injured patients who contend the drug's side effects outweighed its benefits.<sup>13</sup>

In recent years, the FDA has intervened frequently in cases where injured patients turn to courts to redress injuries caused by defective drugs and medical devices. The FDA now is encouraging courts to recognize a broad preemption doctrine that would immunize manufacturers from civil liability when the FDA previously approved a product for sale.<sup>14</sup> Historically, courts have not been amenable to the argument that claims for injuries caused by defective drugs are preempted by FDA approval and regulation of the drug. The recent trend, however, of finding preemption in cases involving medical devices with FDA approval requires closer examination of the federal preemption doctrine and the affirmative defense of FDA approval. In an attempt to sidestep the courts, the FDA in January 2006 introduced a new rule declaring that federal requirements for drug labels preempt state tort liability claims for failure to warn.<sup>15</sup> Further, some pharmaceutical companies are skirting the federal issues by urging state legislatures to enact laws that explicitly eliminate the right to sue for injuries caused by FDA-approved drugs.

Part I of this Article provides a background of the federal preemption doctrine and a history of recent preemption cases that have reached the U.S. Supreme Court. Part II extends this analysis to the FDA and discusses preemption of medical device and pharmaceutical cases. Part II further examines the impact of the Vioxx recall on attempts to extend federal preemption to defective drug cases. Part III discusses a Michigan statute that precludes tort actions against manufacturers of drugs approved for use by the FDA. Part IV discusses a federal rule proposed by the FDA in January 2006 intended to preempt state tort claims for failure to warn. Part V argues that policy considerations favor abandoning the doctrine of preemption as applied to drugs and medical devices regulated and approved by the FDA.

## I. FEDERAL PREEMPTION

Federal preemption is an affirmative defense to liability for a claim arising under state law. The defense arises when a state law claim conflicts with federal regulations that specify design, marketing, or manufacturing standards for products.<sup>16</sup> Assuming drug manufacturers succeed in extending preemption to defective pharmaceutical cases, the defense would be a bar to recovery in every "failure to warn" or "defective design" drug case. The availability of this defense would place a significant burden on plaintiffs by reducing the ability of an injured

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13. See, e.g., Juliann Walsh & Erin Burnett, *Merck Works for Vioxx Return*, TAMPA TRIB., Apr. 23, 2005, at C1 (observing that "[a] nod by the FDA to resume selling the drug may help Merck fight personal-injury lawsuits more than it would lift profit").

14. See *infra* Part II.

15. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 21 C.F.R. §§ 201, 314, 601 (2006).

16. DAVID G. OWEN ET AL., *PRODUCTS LIABILITY* § 14.4 (3d ed. 2005).

party to recover damages or even secure adequate representation.<sup>17</sup> More importantly, preemption of tort claims for defective drugs would remove an essential protection our legal system has long provided to consumers of prescription medications.

#### A. Types of Preemption

The critical component in evaluating any preemption defense is a determination of the intent of Congress.<sup>18</sup> There are two types of federal preemption: express preemption and implied preemption.<sup>19</sup> Express preemption occurs when Congress, by way of a “preemption clause,” specifically declares that a particular statute preempts state law.<sup>20</sup> This provision typically describes the scope of preemption. The effect of a preemption clause is that states are prohibited from adopting conflicting requirements or standards.<sup>21</sup> Similarly, statutes sometimes contain a “savings clause,” which provides that compliance with the statute does not exempt a party from liability in a tort action.<sup>22</sup>

The second category of preemption is implied preemption. This category is divided into two parts—implied field preemption and implied conflict preemption. Implied field preemption arises when federal regulation of a field is so complete as to indicate there is no room for states to supplement the regulation.<sup>23</sup> It also occurs when the federal interest is so important that state regulation is prohibited. Implied conflict preemption is more easily identified—it occurs when federal and state provisions directly conflict, preventing a party from complying with both regulations simultaneously.<sup>24</sup>

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17. James O’Reilly recognized the significant benefits that preemption provides drug companies: “The manufacturer’s immunity from products liability would dramatically reduce liability exposure and insurance costs for the new drug, and would dramatically reduce the financial incentives for plaintiffs’ attorneys to pursue contingent fee litigation against drug makers.” James T. O’Reilly, *A State of Extinction: Does Food and Drug Administration Approval of a Prescription Drug Label Extinguish State Claims for Inadequate Warning?*, 58 FOOD & DRUG L.J. 287, 289 (2003).

18. See, e.g., *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 96 (1992) (declaring that “[t]he purpose of Congress is the ultimate touchstone” in every preemption case (quoting *Allis-Chalmers Corp. v. Lueck*, 471 U.S. 202, 208 (1985))).

19. In *Jones v. Rath Packing Co.*, the Court recognized that preemption need not be express and noted that preemption “is compelled whether Congress’s command is explicitly stated in the statute’s language or implicitly contained in its structure and purpose.” 430 U.S. 519, 525 (1977); see also *Savage v. Jones*, 225 U.S. 501, 533–40 (1912) (discussing express and implied preemption).

20. See OWEN ET AL., *supra* note 16, § 14.4; see also *Pac. Gas. & Elec. Co. v. State Energy Res. Conservation & Dev. Comm’n*, 461 U.S. 190, 203 (1983).

21. A critical question in any state tort claim where the defendant is asserting federal preemption as a defense is whether such preemption applies only to legislative enactments or whether it extends to judicial action in tort claims.

22. See, e.g., *Spreitsma v. Mercury Marine Inc.*, 537 U.S. 51 (2002).

23. OWEN ET AL., *supra* note 16, § 14.4.

24. Federal preemption generally—and implied conflict preemption specifically—is premised on the Supremacy Clause of the U.S. Constitution.

States clearly should be prohibited from enacting regulations that would prevent pharmaceutical manufacturers from complying with FDA regulations, as contemplated by implied conflict preemption. It is readily apparent, however, that Congress never intended compliance with FDA regulations to absolve drug manufacturers from liability for either failure to warn or defective design.<sup>25</sup> Holding pharmaceutical companies liable to consumers for producing and marketing dangerous drugs is a critical safeguard for public health. Although the Supreme Court has acted inconsistently in federal preemption cases involving defective products,<sup>26</sup> it is unlikely courts will extend the preemption doctrine to prescription drugs.

### ***B. Products Liability Cases***

In recent years, the Supreme Court considered a number of cases that required it to address preemption defenses in products liability cases. The following cases provide important insight into the Court's philosophy on the preemption doctrine.

#### *1. Cipollone v. Liggett Group, Inc.*

*Cipollone*<sup>27</sup> marked the first instance in which the Supreme Court applied federal preemption to a products liability claim.<sup>28</sup> The case involved a lifelong smoker who died of lung cancer in 1984.<sup>29</sup> The executor of Rose Cipollone's estate brought an action against three cigarette manufacturers for failure to provide adequate warning of the dangers of smoking.<sup>30</sup> The jury returned a \$400,000 verdict for the victim's husband after finding that Liggett breached its duty to warn.<sup>31</sup>

The question in *Cipollone* was whether federal warning requirements preempted all or some of the claims. Congress passed the 1965 Federal Cigarette

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This 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; and the Judges in every state shall be bound thereby, any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.

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

25. See *infra* Part II.

26. See *infra* Part I.B.

27. 505 U.S. 504 (1992).

28. Many legal commentators argue that the Supreme Court failed to clarify the field of federal preemption when it announced the decision in *Cipollone*. See, e.g., Richard C. Ausness, *Preemption of State Tort Law by Federal Safety Statutes: Supreme Court Preemption Jurisprudence Since Cipollone*, 92 KY. L.J. 913, 924 (calling the decision a "well-intentioned, but unsuccessful, attempt by the Court to rationalize its preemption doctrine").

29. *Cipollone*, 505 U.S. at 508.

30. *Id.*

31. *Id.* at 512. The jury did not award damages to the victim's estate, however, after finding that Rose Cipollone was eighty-percent responsible for her injuries. *Id.*

Labeling and Advertising Act (“1965 Act”) in an effort to inform the public that smoking is dangerous and to provide uniform standards for labeling and advertising of tobacco products.<sup>32</sup> The 1965 Act required that the following warning appear on all cigarette packages: “CAUTION: CIGARETTE SMOKING MAY BE HAZARDOUS TO YOUR HEALTH.”<sup>33</sup> The 1965 Act also contained a clause titled “Preemption” that contained the following vague language relating to the preemptive effect of the Act:

(a) No statement relating to smoking and health, other than the statement required by section 4 of this Act, shall be required on any cigarette package,

(b) No statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.<sup>34</sup>

In 1969, Congress amended the Act. Among other changes, the 1969 Act strengthened the warning requirement and modified the preemptive effect of the legislation. The new preemption clause provided:

No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.<sup>35</sup>

The Court held that the 1969 Act preempted state tort claims for inadequate health warnings<sup>36</sup> but did not preempt claims for breach of express warranty, misrepresentation, or conspiracy.<sup>37</sup> The Court further found that the 1965 Act did not preempt any of the tort claims.<sup>38</sup>

The relevant inquiry was to determine the scope of the preemption clauses in the 1965 and 1969 Acts. The significant modification in the preemption clause between the 1965 Act and the 1969 Act was the change from “statement”<sup>39</sup> to “requirements or prohibition[s].”<sup>40</sup> Justice Stevens, writing for the Court, held that the failure-to-warn claim was predicated on a legal duty under state law and, therefore, imposed a “requirement or prohibition” on manufacturers of cigarettes.<sup>41</sup> Further, the reference in the 1965 Act to “imposed under State law” included

32. *Id.* at 514; *see also* Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, § 4, 79 Stat. 272 (1965) (codified as amended at 15 U.S.C. §§ 1331–41 (2000)).

33. *Cipollone*, 505 U.S. at 514.

34. *Id.*

35. *Id.* at 515; *see also* Public Health Cigarette Smoking Act, Pub. L. No. 91-222, 84 Stat. 87 (1970) (codified at 15 U.S.C. § 1334 (2000)).

36. *Cipollone*, 505 U.S. at 524.

37. *Id.* at 525–30.

38. *Id.* at 519–20. Ironically, Justices Scalia and Thomas, who frequently argue for greater recognition of states’ rights, found that the 1969 Act preempted *all* of the plaintiff’s state tort claims and that the 1965 Act preempted the failure to warn claim. *See id.* at 544–49 (Scalia, J., dissenting).

39. *See supra* text accompanying note 34.

40. *See supra* text accompanying note 35.

41. *Cipollone*, 505 U.S. at 522.

damage awards against cigarette manufacturers.<sup>42</sup> These holdings appear inconsistent with prefatory remarks made by Justice Stevens to the effect that courts should engage in a “narrow reading” of preemptive clauses.<sup>43</sup> Irrespective of the *Cipollone* decision, the Court’s long-standing policy of applying a narrow analysis to preemption clauses has not changed.<sup>44</sup>

The opinion further complicates an understanding of the preemption doctrine by confusing express preemption with implied preemption. Although the decision should have rested entirely on the language of the preemption clause, Justice Stevens developed an analysis of implied preemption—a discussion that was unnecessary given the express clause.<sup>45</sup> Because of the strong presumption against preemption, it is unclear why Justice Stevens would engage in such an analysis when, as here, the plain language of the 1969 Act did not preempt state tort claims.<sup>46</sup>

## 2. *Geier v. American Honda Motor Co.*

In 1992, a Honda Accord driven by Alexis Geier careened off the road, striking a tree.<sup>47</sup> Although Geier was wearing her seatbelt at the time of the accident, she was seriously injured in the collision.<sup>48</sup> Geier filed suit against American Honda Motor Co. (“Honda”), contending that her car was negligently designed because it did not have a driver’s side airbag.<sup>49</sup>

In 1984, the Department of Transportation promulgated Federal Motor Vehicle Safety Standard 208 (“FMVSS 208”), which required car manufacturers to equip some of their vehicles with passive restraints.<sup>50</sup> The question in *Geier* was whether this regulation preempted a claim alleging that Honda should have exceeded the regulatory requirements and installed airbags on the plaintiff’s 1987

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42. *See id.*

43. *Id.* at 524 (calling for courts to examine express preemption clauses under a “fair but narrow reading”).

44. *Id.* at 518 (noting that the Court “must construe these provisions in light of the presumption against the pre-emption of state police power regulations”).

45. *Id.*

46. Justice Blackmun recognized the faults in engaging in an implied preemption analysis when an express clause speaks to the issue.

The principles of federalism and respect for state sovereignty that underlie the Court’s reluctance to find pre-emption where Congress has not spoken directly to the issue apply with equal force where Congress has spoken, though ambiguously. In such cases, the question is not *whether* Congress intended to pre-empt state regulation, but to what *extent*. We do not, absent unambiguous evidence, infer a scope of pre-emption beyond that which clearly is mandated by Congress’ language.

*Id.* at 533 (Blackmun, J., dissenting).

47. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 865 (2000).

48. *Id.*

49. *Id.*

50. *Id.* at 864–65.

Honda Accord.<sup>51</sup> The Court first addressed whether the claims were foreclosed by an express preemption provision in the National Traffic and Motor Vehicle Safety Act<sup>52</sup> (“Safety Act”).<sup>53</sup> The express preemption clause provided:

Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment[,], any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard.<sup>54</sup>

The Safety Act also included a savings clause that stated, “Compliance with a federal safety standard does not exempt any person from any liability under common law.” The Court found that a reading of the preemption clause, coupled with the savings clause, revealed that Congress did not intend the Safety Act (or regulations promulgated under its authority) to preempt common law tort claims.<sup>55</sup>

The opinion did not conclude with the Court’s finding that the plaintiff’s claims were not expressly preempted. The Court also addressed whether implied conflict preemption<sup>56</sup> protected Honda from liability.<sup>57</sup> The Court found that the Department of Transportation intended FMVSS 208 to gradually introduce safety improvements over time.<sup>58</sup> It reasoned that holding manufacturers liable, even when they complied with the provision, would frustrate the objectives of the Department of Transportation.<sup>59</sup> Accepting that claims brought under state common law would frustrate the purpose of federal motor vehicle safety regulation, the Court found the plaintiff’s claims were preempted.<sup>60</sup>

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51. When the Supreme Court granted certiorari in *Geier*, state courts were split on the issue of whether FMVSS 208 preempted airbag claims. *See, e.g.,* *Munroe v. Galati*, 938 P.2d 1114, 1120 (Ariz. 1997) (finding that “automobile safety standards are minimum, mandatory requirements” and holding preemption did not protect car manufacturers in airbag cases); *Drattell v. Toyota Motor Corp.*, 699 N.E.2d 376, 379–86 (N.Y. 1998) (analyzing and rejecting defenses of express preemption, implied preemption, and implied conflict preemption).

52. National Traffic and Motor Vehicle Safety Act of 1966, Pub. L. No. 85-563, 80 Stat. 718 (codified as amended at 49 U.S.C. §§ 30101–30169 (2000)).

53. *Geier*, 529 U.S. at 867.

54. *Id.* (quoting 15 U.S.C. § 1392(d) (alteration in original)).

55. *Id.* at 868.

56. *See supra* text accompanying notes 23–24.

57. *Geier*, 529 U.S. at 870–86.

58. *Id.* at 874–75.

59. *Id.* at 875. The Court described those objectives as “lower[ing] costs, overcom[ing] technical safety problems, encourag[ing] technological development, and win[ning] widespread consumer acceptance.” *Id.*

60. *Id.* at 874.

### 3. *Sprietsma v. Mercury Marine*

The Court unanimously held in *Sprietsma*<sup>61</sup> that a regulation promulgated by the Coast Guard under the authority of the Federal Boat Safety Act of 1971<sup>62</sup> (“Boat Safety Act”) did not preempt a claim for injuries suffered in a boating accident.<sup>63</sup> In July 1995, Jeanne *Sprietsma* died after being thrown overboard from a recreational ski boat.<sup>64</sup> Her injuries occurred when her body struck the propeller. *Sprietsma*’s husband brought a claim against the boat manufacturer, alleging the motor was unreasonably dangerous because it did not include a propeller guard.<sup>65</sup> The trial court dismissed the case on preemption grounds.<sup>66</sup>

The Supreme Court granted certiorari to determine whether petitioner’s claims were barred by preemption. The Coast Guard regulates recreational boats pursuant to authority granted to it by Congress as part of the Boat Safety Act.<sup>67</sup> In 1988, the Coast Guard began a study aimed at examining the risk posed by propellers.<sup>68</sup> Following an eighteen-month investigation, the Coast Guard determined it “should take no regulatory action to require propeller guards.”<sup>69</sup>

The Court first looked to the express preemption clause contained in the Boat Safety Act, which provided:

Unless permitted by the Secretary . . . , a State or political subdivision of a State may not establish, continue in effect, or enforce a law or regulation establishing a recreational vessel or associated equipment performance or other safety standard or imposing a requirement for associated equipment . . . that is not identical to a regulation prescribed under . . . this title.<sup>70</sup>

The Court held that the language of the clause did not contemplate barring state claims derived from common law.<sup>71</sup> The Court based its decision in

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61. 537 U.S. 51 (2002).

62. Pub. L. No. 92-75, 85 Stat. 213 (1971) (codified as amended at 46 U.S.C. §§ 4301–4311 (1994 & Supp. V 1999)).

63. *Sprietsma*, 537 U.S. at 53, 69–70.

64. *Id.* at 54.

65. *Id.* at 55.

66. *Id.* The decision of the trial court was affirmed by an intermediate appellate court on the basis of express preemption. The Illinois Supreme Court rejected the court’s rationale on express preemption but affirmed on grounds of implied preemption. *Id.*

67. *Id.* at 60.

68. *Id.* The Coast Guard reported that propeller injuries occur approximately one hundred times per year. A study conducted by the Johns Hopkins University Injury Prevention Center and the Institute for Injury Reduction suggests that, due to underreporting, the true number is closer to 2000–3000 per year. *Id.* at 60 n.8.

69. *Id.* at 61 (quoting the conclusions of the study conducted by the Coast Guard).

70. *Id.* at 58–59.

71. *Id.*

part on the language of the savings clause contained in the Boat Safety Act.<sup>72</sup> Of equal importance to the Court was a statement in the act that called for a federal agency to establish “minimum safety standards.”<sup>73</sup> This “minimum” standard implies Congress contemplated allowing states to formulate regulations more stringent than the federal guidelines.

After rejecting express preemption of state common law claims, the Court then discussed whether the claims were impliedly preempted by federal regulation. The Court found that Congress did not intend to displace state regulation of recreational boats in passing the Boat Safety Act.<sup>74</sup> More important to the analysis of the FDA Defense, discussed in Part II, the Court held that a decision by a federal agency not to impose a regulation is not evidence that the regulation is undesirable.

[The Coast Guard statement] reveals only a judgment that the available data did not meet the FBSA’s “stringent” criteria for federal regulation. The Coast Guard did not take the further step of deciding that, as a matter of policy, the States and their political subdivisions should not impose some version of propeller guard regulation, and it most definitely did not reject propeller guards as unsafe.<sup>75</sup>

The Court further reasoned that the structure and framework of the Boat Safety Act did not convey a “clear and manifest” intent to occupy the entire field.<sup>76</sup>

## II. FEDERAL PREEMPTION OF DRUG AND MEDICAL DEVICE CLAIMS

Liability for injuries caused by defective drugs and dangerous medical devices generally is premised on the failure of manufacturers to warn physicians of the risks associated with the product. Prescription drugs and medical devices are regulated by the FDA pursuant to the federal Food, Drug and Cosmetic Act (“FDCA”).<sup>77</sup> Federal regulation by the FDA clearly raises the question whether the agency’s authority and action expressly or impliedly preempts common law tort claims for injuries caused by defective drugs or medical devices.

Traditionally, courts have taken the position that FDA regulation of prescription drugs and medical devices imposes only minimum standards.<sup>78</sup> Compliance with FDA regulations, therefore, is admissible as evidence that a

72. *Id.* The savings clause states that “[c]ompliance with this chapter or standards, regulations, or orders prescribed under this chapter does not relieve a person from liability at common law or under state law.” *Id.* (quoting 46 U.S.C. § 4311(g) (1971)).

73. *Id.* (quoting 46 U.S.C. § 4302(a)(1)).

74. *Id.* at 65.

75. *Id.* at 66–67.

76. *Id.* at 69 (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)).

77. 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–393 (1992)).

78. *See, e.g., Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1033, 1036 (S.D. Ill. 2001) (“[T]he FDA’s drug labeling decisions impose only ‘minimum’ standards that are open to supplementation by state law through a jury’s verdict enforcing a manufacturer’s common law duty to warn.”).

product is not defective, but it is not dispositive.<sup>79</sup> In some states, statutes direct that manufacturers of prescription drugs cannot be found liable for punitive damages if they are labeled and sold in accordance with FDA approval.<sup>80</sup> These statutes generally provide an exception if the manufacturer knowingly withheld from the FDA important information about the drug.<sup>81</sup>

The FDA once considered products liability lawsuits to be beneficial to the agency's goal of promoting drug and medical device safety.<sup>82</sup> As late as 1997, the FDA said that its approval of prescription drugs and medical devices set only a minimum standard and that states were free to provide patients with additional protections.<sup>83</sup> The agency has since changed its position on the benefits of civil litigation and now contends that tort claims interfere with its ability to regulate the market.<sup>84</sup>

The FDA's current position reflects the Bush Administration's expressed attitude that consumers should not recover damages for injuries caused by defective drugs if the FDA approved those products for use.<sup>85</sup> The Bush Administration contends that lawsuits encourage drug manufacturers to withdraw beneficial medications from the market or provide warnings that overemphasize risks, to the detriment of patients.<sup>86</sup>

This philosophical shift by the FDA supports the interests of drug companies in eliminating their potential liability for designing and manufacturing

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79. See David G. Owen, *Proving Negligence in Modern Products Liability Litigation*, 36 ARIZ. ST. L.J. 1003, 1015 (2004).

80. See, e.g., ARIZ. REV. STAT. ANN. § 12-701 (2005) ("The manufacturer or seller of a drug is not liable for exemplary or punitive damages if the drug alleged to cause the harm . . . [w]as manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the [FDA] . . ."); OHIO REV. CODE ANN. § 2307.80(C)(1) (West 2005) ("[I]f a claimant alleges in a product liability claim that a drug or device caused harm to the claimant, the manufacturer of the drug or device shall not be liable for punitive or exemplary damages . . . if the drug or device . . . was manufactured and labeled in relevant and material respects in accordance with the [FDA] . . .").

81. See, e.g., ARIZ. REV. STAT. ANN. § 12-701 ("[This rule] does not apply if the plaintiff proves, by clear and convincing evidence, that the defendant, either before or after making the drug available for public use, knowingly, in violation of applicable [FDA] regulations, withheld from or misrepresented . . . information known to be material and relevant to the harm which the plaintiff allegedly suffered.").

82. OWEN ET AL., *supra* note 16, §14.4.

83. Robert Pear, *In a Shift, Bush Moves to Block Medical Suits*, N.Y. TIMES, July 25, 2004, at A1.

84. See generally Brief for the United States as Amicus Curiae 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. 2004) (Nos. 02-55372, 02-55498), 2002 WL 32303084 [hereinafter FDA Brief].

85. See Pear, *supra* note 83, at A1 (noting that the Bush Administration believes lawsuits "undermine public health" and "interfere with federal regulation of drugs and devices").

86. See *id.* The Bush Administration contends strongly worded warnings lead to underutilization of pharmaceuticals. *Id.*

defective products. Although a court has never held that FDA regulation of the pharmaceutical industry preempts tort claims for injuries caused by a defective drug, manufacturers continue to assert this defense in civil actions brought against them. The drug companies are encouraged by some recent successes achieved by medical device manufacturers in asserting a preemption defense.<sup>87</sup> Because medical devices and prescription drugs are treated differently by the FDCA, we discuss each separately.

### A. Medical Devices

The FDA began its regulation of medical devices in the 1970s pursuant to the Medical Device Amendments of 1976 (“MDA”) in response to a number of safety problems with various devices (including IUDs, artificial heart valves, catheters, and pacemakers).<sup>88</sup> The FDA classifies medical devices in three different categories: Class I devices, Class II devices, and Class III devices. Class I devices pose little risk to human health; Class II devices pose a somewhat greater risk; and Class III devices are potentially more harmful and are subject to greater oversight.<sup>89</sup>

The FDA requires that Class III devices undergo a rigorous screening process to determine their efficacy and safety before they are introduced to the market.<sup>90</sup> The pre-market approval (“PMA”) process is subject to two exemptions. The first is a grandfather exemption for devices marketed before 1976.<sup>91</sup> The second—and most important exemption—applies to devices that are “substantially equivalent” to pre-1976 devices.<sup>92</sup> This exemption is intended to prevent the manufacturer of a grandfathered medical device from holding an unfair competitive advantage in the industry.<sup>93</sup> While the purpose behind the exemption is reasonable, the practical effect is often that manufacturers develop new medical devices—and the FDA permits the sale of them—without the lengthy PMA process to determine the safety of the product.

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87. See, e.g., *Horn v. Thoratec*, 376 F.3d 163 (3d Cir. 2004) (finding preemption in a tort claim involving a Class III medical device that had been approved by the FDA under the more rigorous PMA process discussed in text accompanying notes 90–93).

88. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996) (noting that Congress was concerned with health risks evidenced by devices such as the Dalkon Shield, catheters, artificial heart valves, defibrillators, and pacemakers). Congress gave the FDA authority to monitor medical device manufacturers with the passage of the Medical Device Amendments of 1976 and directed the agency to regulate safety and monitor the effectiveness of medical devices. See 21 U.S.C. § 360 (2000).

89. *Medtronic*, 518 U.S. at 477 (outlining requirements that a medical device manufacturer “provide the FDA with a ‘reasonable assurance’ that the device is both safe and effective) (quoting 21 U.S.C. § 360e(d)(2) (2000)).

90. *Id.*

91. *Id.* at 477–78 (explaining that devices could be removed from the market while the FDA was evaluating a pre-1976 device). This exemption lasts only until such time as the FDA has had time to complete a PMA for the grandfathered device.

92. 21 U.S.C. § 360e(b)(1).

93. *Id.*

The failure of the FDA to protect the public from defective pharmaceuticals will be discussed in detail in Part II.B.2. It is worth noting that the Agency has done no better with its scrutiny of medical devices. In March 2005, the Agency acknowledged that it failed to properly monitor the safety of medical devices post-approval.<sup>94</sup> An internal audit revealed that manufacturers of twenty-six medical devices approved between 1998 and 2000 failed to provide the FDA with required safety studies.<sup>95</sup> That number represents more than half of the devices approved by the Agency during that period.<sup>96</sup> The FDA has substantially failed to provide critical oversight of medical device manufacturers, preventing the Agency from assessing the safety risk of new devices.

Drug companies urging judicial recognition of a preemption defense commonly cite decisions in medical device cases that have found preemption. The companies disregard differences in the FDA regulation of medical devices that clearly make the precedent inapplicable to drug cases. The FDCA contains a preemption clause that bars state regulation of medical devices that are “different from or in addition to” federal requirements.<sup>97</sup> It does not contain a preemption clause applicable to prescription drugs—therefore, there is no express preemption of claims for a drug manufacturer’s failure to warn of a known or suspected risk. Courts do not agree on the applicability of the medical device clause, with some finding preemption and others finding none. The Supreme Court’s decision in *Medtronic, Inc. v. Lohr*<sup>98</sup> did little to clarify the issue.

#### I. Medtronic, Inc. v. Lohr

In October 1982, Medtronic petitioned the FDA for approval of its pacemaker based on the “substantial equivalence” exemption clause.<sup>99</sup> Medical devices subject to this exemption are approved for sale under a less rigorous FDA

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94. Barry Meier, *FDA Report Criticizes Oversight of Medical Device Makers*, N.Y. TIMES, Apr. 1, 2005, available at <http://www.nytimes.com/2005/04/01/health/01device.html> (“The FDA review concluded that the agency could not find evidence that more than half the manufacturers had performed the required studies. It also found that the FDA’s oversight of postmarketing studies of medical devices was hobbled by sloppy record-keeping.”).

95. *Id.*

96. *Id.* (noting that the FDA approved forty-five new medical devices between 1998 and 2000).

97. 21 U.S.C. § 360k(a) (2000). The full text of subsection (a) of the preemption clause reads:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

*Id.*

98. 518 U.S. 470 (1996).

99. *Id.* at 480. Medtronic compared its device to a number of other pacemakers already on the market. *Id.*

examination process.<sup>100</sup> The following month, the FDA approved Medtronic's application under the less stringent § 510(k) standards following a finding that the model was "substantially equivalent to devices introduced into interstate commerce" prior to the enactment of the 1976 amendment.<sup>101</sup>

Lara Lohr received a Medtronic pacemaker in 1987.<sup>102</sup> The device failed on December 30, 1990, requiring emergency surgery. Lohr alleged in her complaint against Medtronic that the device failed due to a defectively designed and manufactured wire lead.<sup>103</sup> The complaint further alleged that Medtronic was aware of this problem and failed to warn patients or physicians of this risk.<sup>104</sup> The trial court dismissed the case, finding that the cause of action was preempted by the FDCA.<sup>105</sup> The court of appeals reversed in part, finding that the negligent design claims were not preempted as a result of FDA approval.<sup>106</sup> Medtronic and Lohr both appealed, and the Supreme Court granted certiorari.<sup>107</sup>

The Court held that the design defect claims were not barred by the preemption clause in the MDA. The Court ruled that the FDA's cursory § 510(k) determination process did not impose specific design requirements and, therefore, did not preempt state regulation of the device.<sup>108</sup> The Court similarly found the defective warning and manufacturing claims to be cognizable because general FDA regulations pertaining to labeling and manufacturing applicable to every medical device were too general to be "applicable . . . to the device"<sup>109</sup> or "specific . . . to a particular device"<sup>110</sup> as required by the preemption clause in the MDA.

Because the Court's decision did not address medical devices approved under the more rigorous PMA process, it did little to clarify the issue of preemption claims in the bulk of medical device cases. Some courts find claims against manufacturers of medical devices approved under the PMA to be preempted notwithstanding the Supreme Court's refusal to apply preemption in the case of a § 510(k) device.<sup>111</sup> At some point, the Court likely will be forced to address the question of preemption in medical device claims involving devices approved under the more rigorous PMA process. Until then, the waters will remain murky.

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100. *Id.* at 478.

101. *Id.* at 480; 21 U.S.C. § 510(k).

102. *Medtronic*, 518 U.S. at 480.

103. *Id.* at 481.

104. *Id.*

105. *Id.* at 483.

106. *Id.*

107. *Id.* at 484.

108. *Id.* at 497.

109. *Id.* at 500.

110. *Id.*

111. *See, e.g.,* *Martin v. Teletronics Pacing Sys., Inc.*, 105 F.3d 1090, 1099 (6th Cir. 1997) (preempting a claim against a manufacturer of a pacemaker that was subject to PMA approval); *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1243 (7th Cir. 1997) (holding that strict liability and breach of implied warranty claims were preempted by MDA, but that a negligent manufacture claim was not preempted).

2. *Fraud on the FDA*—Buckman Co. v. Plaintiffs' Legal Committee

Like *Medtronic*, *Buckman*<sup>112</sup> also involved a device approved under the abbreviated § 510(k) substantial equivalence process. In 1984, AcroMed petitioned the FDA for approval of its bone screw device.<sup>113</sup> The FDA denied the application based on its determination that the device was not substantially equivalent to an existing device.<sup>114</sup> Following this first rejection, AcroMed sought the assistance of the Buckman Company in securing FDA approval of the device.<sup>115</sup> AcroMed and Buckman again petitioned the FDA for approval of the device in September 1985, supplementing the original application with additional information about the device and its intended use.<sup>116</sup> The FDA again rejected the application.<sup>117</sup> In December 1985, AcroMed submitted a third application under § 510(k), but this time made substantial alterations to the description of the device as well as its intended use.<sup>118</sup> With the assistance of Buckman, AcroMed split the device into its component parts and filed separate applications for each component.<sup>119</sup> The company claimed that instead of being used for spinal surgeries, the device would be used only in the bones of arms and legs.<sup>120</sup> The FDA approved both applications after concluding the devices were substantially equivalent to other devices on the market.<sup>121</sup>

Following FDA approval, the devices were widely used by surgeons for spinal surgery. Problems with them led more than 2300 people to file claims against AcroMed and Buckman. The cases were transferred to the District Court for the Eastern District of Pennsylvania after receiving multi-district litigation (“MDL”) status.<sup>122</sup> Many of the 2300 claims included causes of action against Buckman and AcroMed for committing fraud on the FDA.<sup>123</sup> The plaintiffs alleged that Buckman and AcroMed made fraudulent representations to the FDA about the intended use of the device, causing the agency to improperly approve the application. The trial court dismissed the fraud-on-the-FDA claims,<sup>124</sup> but the Third Circuit Court of Appeals later reversed.<sup>125</sup>

The Supreme Court granted certiorari and unanimously held that fraud-on-the-FDA claims were impliedly preempted.<sup>126</sup> The Court noted that policing fraud committed against federal agencies is not a field typically occupied by

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112. 531 U.S. 341 (2001).

113. *Id.* at 346.

114. *Id.*

115. *Id.*

116. *Id.*

117. *Id.*

118. *Id.*

119. *Id.*

120. *Id.*

121. *Id.*

122. *Id.*

123. *Id.* at 347.

124. *Id.*

125. *Id.*

126. *Id.* at 341–42.

states.<sup>127</sup> The FDA has the power to investigate suspected fraud, and it can take action against offenders.<sup>128</sup> The agency can seek injunctive relief,<sup>129</sup> pursue civil penalties,<sup>130</sup> seize the device,<sup>131</sup> and initiate criminal prosecutions.<sup>132</sup> The Court held that permitting state tort claims for fraud on the FDA would be unnecessary and frustrate the efforts of the FDA to protect itself from fraud.<sup>133</sup> *Buckman* left unresolved the issue of whether medical device claims based on conventional products liability claims—and grounded solely on state tort law—are preempted by the FDCA.

### *B. Prescription Drug Cases*

Unlike the MDA that proscribes FDA regulation of medical devices, the FDCA does not contain a preemption clause applicable to prescription drugs. As such, there is no claim for express preemption of drug claims. The question is, then, whether Congress intended FDA approval of prescription drugs to preempt common law tort claims for injuries caused by defective drugs. The plain language and legislative history of the FDCA clearly show that Congress did not intend these claims to be preempted.<sup>134</sup>

#### *1. “Special Supplements for Changes Being Effected” Provision*

As discussed above,<sup>135</sup> most civil actions brought against a pharmaceutical manufacturer for liability from a defective drug hinge on the company’s failure to warn of a known risk.<sup>136</sup> The FDA encourages drug manufacturers to promptly warn of risks when available data justify such a warning.<sup>137</sup> In fact, the FDA developed a mechanism to facilitate rapid labeling changes by a drug manufacturer. The Special Supplements for Changes Being Effected (“SSCBE”) federal regulation permits a drug manufacturer to warn of newly discovered risks without first securing FDA approval.<sup>138</sup>

127. *Id.* at 347.

128. *See* 21 U.S.C. § 372 (2000); 21 C.F.R. § 5.35 (2005).

129. 21 U.S.C. § 332.

130. *Id.* § 333(f)(1)(A).

131. *Id.* § 334(a)(2)(D).

132. *Id.* § 333(a).

133. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350 (2001) (noting that fraud claims “inevitably conflict with the FDA’s responsibility to police fraud consistently with the Administration’s judgment and objectives”).

134. Clearly, any state regulation that could not be accomplished without violating a federal regulation—like one promulgated by the FDA—would be prohibited under the doctrine of implied conflict preemption. The Supremacy Clause provides for preemption when it would be impossible to satisfy conflicting federal and state requirements.

135. *See supra* Introduction and Parts I–II.

136. *See infra* Part III.

137. *See* 21 C.F.R. § 314.126(b) (2006) (calling for drug manufacturers to revise labels “as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved”).

138. 21 C.F.R. § 314.70(c)(2)(i) (2006).

The availability of SSCBE undercuts popular arguments made by drug manufacturers that labeling is within the exclusive control of the FDA. The SSCBE led the Fifth Circuit Court of Appeals to reject defense arguments that a failure to warn claim was preempted by FDA regulation because “federal law neither made it practically (nor legally) impossible, nor would [tort claims] have posed an obstacle to accomplishing the objectives of the FDCA.”<sup>139</sup>

In *Motus v. Pfizer, Inc.*,<sup>140</sup> Flora Motus brought an action against pharmaceutical manufacturer Pfizer for failing to adequately warn about suicide risks associated with the antidepressant drug Zoloft.<sup>141</sup> Although the Ninth Circuit did not reach the merits of the preemption argument,<sup>142</sup> *Motus* represents an interesting case study due to the intervention of the FDA during the appellate process.

The FDA took the position that any warning on Zoloft describing an association with suicidal behavior would have been false or misleading and, therefore, contrary to federal law.<sup>143</sup> According to the FDA, the agency had studied the safety of all antidepressants, including Zoloft, and found no causal relationship between the drug and increased risk of suicide.<sup>144</sup> Because there was no causal relationship, the FDA contended, Pfizer was prevented from amending the label because any changes would be false or misleading.<sup>145</sup> The FDA argued that a finding of liability would effectively create a state regulation that impliedly conflicted with FDA regulations and, accordingly, was preempted.<sup>146</sup>

The FDA’s amicus brief argument flatly contradicts its own requirement that manufacturers warn of potential risks *even when a causal relationship cannot be proven*.<sup>147</sup> Manufacturers have a duty to warn when reasonable evidence of an

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139. Osburn v. Anchor Labs., Inc., 825 F.2d 908, 913 (5th Cir. 1987).

140. 358 F.3d 659 (9th Cir. 2004).

141. *Id.* at 660.

142. The court avoided the issue of preemption by holding the failure to warn could not be supported because the prescribing physician failed to read the labeling instructions for Zoloft. The court’s rationale was that, even if the label were adequate and included information about the risk of suicide among those taking Zoloft, the patient would not have been protected because the doctor would not have learned about the risk. The duty of pharmaceutical companies to warn about potential risks extends only to physicians and not to consumers of drugs. *Id.* at 660–61.

143. FDA Brief, *supra* note 84, at \*2.

144. *Id.*

145. *Id.*

146. A strong argument can be made that recovery of damages in a tort claim does not amount to regulation of the drug. These claims do not involve injunctive relief. If the plaintiff prevails in an action for damages due to a defective product, the only requirement placed on the manufacturer will be to compensate the plaintiff in the amount determined by the court. The manufacturer will not be required to modify labels (either with or without the consent of the FDA). It is possible, therefore, for a company to comply with FDA regulations and court decisions. This undercuts the argument that state tort actions impliedly conflict with FDA regulations.

147. See FDA Action on Applications and Abbreviated Applications, 21 C.F.R. § 314.126(b) (2005).

association exists—a lesser standard than recognizing a causal relationship. Even if one were to assume that a warning suggesting a causal relationship would have been false or misleading, it would be a substantial leap to argue that a warning noting a *possible association* would similarly be untruthful.<sup>148</sup>

It is well settled that a decision by a federal agency not to impose a particular requirement does not prohibit regulation by the states. In *Sprietsma v. Mercury Marine*, discussed in Part I.B.3, the Supreme Court rejected a preemption defense in similar circumstances. The Court explained that “[i]t is quite wrong to view that decision as the functional equivalent of a regulation prohibiting all States and their political subdivisions from adopting such a regulation.”<sup>149</sup> Applied to drugs, the failure or refusal of the FDA to require a warning does not absolve a drug manufacturer of the responsibility to warn physicians of a potential danger.

## 2. *The Vioxx Recall*

Some say the FDA works harder to protect pharmaceutical companies than the public it is supposed to serve.<sup>150</sup> The withdrawal of Vioxx in September 2004 highlighted the FDA’s apparent inability to protect consumers from dangerous drugs. The Vioxx recall provides a timely illustration as to why FDA approval and regulation of drugs should not prevent states from developing and enforcing stronger standards and protections.<sup>151</sup> The internal failures of the FDA, coupled with statutory restrictions that prevent the agency from adequately responding to reports of adverse effects in drugs already approved for sale, are

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148. The FDA frequently mischaracterizes its regulation of drug labeling when trying to justify preemption of tort claims. The FDA’s Chief Counsel said in a *Boston Globe* interview that a company “can’t put anything on the label without coming to us first or getting our blessing. We have absolute control over the label.” Michael Kranish, *FDA Counsel’s Rise Embodies U.S. Shift*, BOSTON GLOBE, Dec. 22, 2002, at A1. This statement fails to address the availability of SSCBE to make truthful changes to labels to warn physicians of potential risks. Further, the FDA’s lack of power to force label changes indicates there is much left to regulate—because they do not occupy the entire field, preemption is inappropriate. See Jim Drinkard, *Label Quibble Helped Cause Vioxx Lapse*, Mar. 1, 2005, [http://www.usatoday.com/news/health/2005-03-01-vioxx\\_x.htm](http://www.usatoday.com/news/health/2005-03-01-vioxx_x.htm).

149. 537 U.S. 51, 66 (2002).

150. In a congressional hearing held less than two months after the withdrawal of Vioxx, Senate Finance Committee Chairman Charles Grassley called the relationship between the FDA and pharmaceutical companies “far too cozy” and charged the Agency ignored warnings from FDA scientists about the dangers of Vioxx. *Merck, FDA Grilled at Senate Hearing*, *supra* note 10.

This “cozy” relationship represents a dramatic shift from the 1960s when the Agency was seen as vigilant for refusing to approve Thalidomide for sale in the United States. Thalidomide resulted in birth defects in thousands of newborns across the world and was widely available throughout Europe and South America. See *FDA Gives Restricted Approval to Thalidomide*, July 16, 1998, <http://www.cnn.com/HEALTH/9807/16/thalidomide/>. In 1998, the FDA reversed itself when it approved use of Thalidomide in restricted applications. *Id.*

151. States long have been involved in the regulation of prescription drugs. For a description of the FDA’s limited involvement in regulating prescription drugs for the better part of the twentieth century, see O’Reilly, *supra* note 17, at 291.

pertinent to the question of whether the FDA completely occupies the field of drug regulation.

a. FDA Lacks Authority To Require Label Changes

The FDA lacks authority to require labeling changes to drugs already approved for sale.<sup>152</sup> In February 2001, the FDA pressed drugmaker Merck to add a warning on the Vioxx label alerting users to risks of cardiovascular problems.<sup>153</sup> The warning did not appear on labels until April 2002.<sup>154</sup> The delay was the result of negotiations between the FDA and Merck—negotiations that would not have been necessary had Congress provided the FDA with statutory authority to demand label changes to drugs already approved for sale.<sup>155</sup> Testifying before the Senate Committee on Health, Education, Labor and Pensions, Dr. Sandra Kweder of the FDA blamed the delay on Merck, saying the company “rejected many of our proposals.”<sup>156</sup> The fourteen-month delay in alerting physicians and patients to potential dangers placed the lives of millions of Vioxx users at risk.

The FDA’s inability to force label changes on drug makers undercuts arguments for preemption of tort claims on the basis of failure to warn. The FDA lacks any significant power to regulate warnings for drugs already approved for sale. Drug manufacturers possess strong leverage in rejecting efforts by the FDA to strengthen warnings on labels. To the extent that this gap exists in the enforcement and regulation of prescription drugs, the FDA cannot be said to occupy the entire field.

b. Regulation of Approved Drugs

The FDA does not play an active role in regulating prescription drugs already approved for sale—its actions generally are reactionary and occur only after problems with drugs are well recognized and publicized. Part of the problem stems from the manner in which the agency is funded. Approximately half the FDA’s drug evaluation budget comes directly from pharmaceutical companies in the form of fees for expedited approval of drugs.<sup>157</sup> Some believe that dependence on this money has caused the FDA to lose control over the drug industry and has

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152. See Christopher Rowland, *FDA Seeks More Say on Drug Labels*, BOSTON GLOBE, Mar. 2, 2005, available at [http://www.boston.com/business/articles/2005/03/02/fda\\_seeks\\_more\\_say\\_on\\_drug\\_labels/](http://www.boston.com/business/articles/2005/03/02/fda_seeks_more_say_on_drug_labels/).

153. Gardiner Harris, *FDA Official Admits ‘Lapses’ on Vioxx*, N.Y. TIMES, Mar. 2, 2005, at A15, available at <http://www.nytimes.com/2005/03/02/politics/02fda.html>; see also Drinkard, *supra* note 148 (noting that the FDA “lacks the authority to order new language onto a drug label if safety concerns crop up after it has been approved for marketing”).

154. Harris, *supra* note 153.

155. *Id.*

156. *Id.*

157. MARCIA ANGELL, *THE TRUTH ABOUT DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* 208 (2004). Pharmaceutical companies now pay approximately \$576,000 per new drug application. Each year, the FDA receives approximately \$260 million from drug companies—money that mainly is used to get drugs to the market quickly. *Id.*

given the agency the incentive to quickly approve medications without undertaking thorough studies to determine the safety or effectiveness of new drugs.<sup>158</sup> The emphasis on rushing drugs to the market also has compromised the agency's ability to regulate other aspects of the pharmaceutical industry. "As drugs enter the market faster, it becomes increasingly difficult for the FDA to perform its other functions—including monitoring drug safety, ensuring manufacturing standards, and regulating marketing."<sup>159</sup>

Although the agency once was praised for its commitment to a thorough evaluation of the safety and efficacy of new drugs before permitting their sale in the United States, in 1992 the FDA announced a "fast track" approval process for medications used to treat life-threatening diseases.<sup>160</sup> Drugs considered under the "fast track" process are evaluated by the FDA for only six months before approval.<sup>161</sup> Such a short clinical study is inadequate to recognize many problems with drugs, the dangers of which are apparent only after long-term use.<sup>162</sup>

Merck utilized the "fast-track" process in gaining approval of Vioxx.<sup>163</sup> The "fast-track" approval process was created by the FDA Modernization Act of 1997 and allows drug manufacturers to request an expedited six-month review by the FDA.<sup>164</sup> The process is intended to facilitate timely approval of drugs developed for the "treatment of a serious or life threatening condition" that addresses "unmet medical needs."<sup>165</sup>

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158. See Marc Kaufman et al., *FDA Is Flexing Less Muscle: Some Question Its Relationship with Drugmakers*, WASH. POST, Nov. 18, 2004, at A1.

Concerns about the FDA's safety monitoring have been growing ever since Congress required in 1992 that the industry assume a significant share of the costs of evaluating new drugs. These "user fees" now pay for more than half of CDER's annual budget of almost \$500 million, and the percentage is growing steadily. . . . Those concerns have taken on new urgency since the calamitous withdrawal of Vioxx, a move that focused sharp attention on whether the agency has become lax in overseeing the drug supply and too cozy with the industry.

*Id.*; see also ANGELL, *supra* note 157, at 210.

159. ANGELL, *supra* note 157, at 209–10.

160. *Vioxx Recall Spurs FDA Overhaul*, CNN MONEY, Nov. 5, 2004, <http://money.cnn.com/2004/11/05/news/fortune500/fda/>.

161. Melissa Davis, *Merck Mess Shows FDA's Flaws*, THE STREET, Jan. 4, 2005, [http://www.thestreet.com/\\_tscs/stocks/melissadavid/10201457.html](http://www.thestreet.com/_tscs/stocks/melissadavid/10201457.html). By contrast, the traditional process of study and approval requires years.

162. See Kaufman et al., *supra* note 158, at A1 ("I think what we've seen in the United States is that the FDA and industry have gotten very successful at getting drugs to the market based on their efficacy. But that has come at a cost: We are discovering the safety problems here after the drug has been on the market and widely used. . . . This is why I say safety has become a stepchild to the agency and the process.") (quoting Curt Furberg, a member of the FDA's advisory panel on drug safety and risk management).

163. *Id.*

164. Food and Drug Administration Modernization Act, Pub. L. No. 105-115, 111 Stat. 2296 (1997) (codified at 21 U.S.C. § 310 (2000)).

165. See FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: FAST TRACK DRUG DEVELOPMENT PROGRAMS—DESIGNATION, DEVELOPMENT AND APPLICATION

The fast-track approval process was created to facilitate quick approval of pharmaceuticals used for treatment of cancer, AIDS, and other life-threatening conditions. It is doubtful that Congress intended the FDA to use this tool for a drug like Vioxx, which was developed to relieve pain caused by arthritis.<sup>166</sup> Congress provided that manufacturers taking advantage of fast-track approval must conduct “post-approval studies to validate the surrogate endpoint or otherwise confirm the effect on the clinical endpoint.”<sup>167</sup> Too often these studies are delayed, negating any opportunity to discover problems before large segments of the population are exposed to a new drug.<sup>168</sup>

Because the elevated cardiovascular risks of Vioxx occur only after long-term use—generally for a period greater than six months—fast-track evaluation did not reveal potentially deadly problems associated with the drug. The “fast-track” for prescription drugs is analogous to the § 510(k) substantial equivalence process available to manufacturers of medical devices to facilitate quick approval of new products.

In *Lohr*, the Supreme Court refused to apply an express preemption clause contained in the MDA for a pacemaker that was approved pursuant to the § 510(k) approval process.<sup>169</sup> Section 510(k) permits manufacturers to introduce medical devices rapidly if the device is substantially equivalent to another device already on the market.<sup>170</sup> The similarities between drug “fast-track” approval and the § 510(k) substantial equivalence test strongly suggest the Supreme Court would reject attempts to expand federal preemption to drugs—like Vioxx—that were approved under the FDA’s “fast-track” process.

#### c. FDA Was Slow To Respond

Many physicians and health care providers blame the FDA for failing to warn the public of serious risks as evidence of the harmful side effects of Vioxx began to accumulate. The FDA’s first Vioxx study found a seven-fold increase in the risk of heart attack in low doses.<sup>171</sup> A subsequent trial directed by Merck found

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REVIEW (July 2004), <http://www.fda.gov/cder/guidance/5645fnl.pdf> [hereinafter GUIDANCE FOR INDUSTRY].

166. Perhaps just as puzzling is the implied assumption that Vioxx met an “unmet medical need[.]” See *supra* text accompanying notes 164–65. Celebrex, another arthritis drug in the Cox-2 family, already had been approved by the FDA for the treatment of arthritis pain. See Food and Drug Admin., U.S. Dep’t of Health and Human Servs., *FDA Approves Celebrex for Arthritis*, Dec. 31, 1998, <http://www.fda.gov/bbs/topics/ANSWERS/ANS00932.html>.

167. See GUIDANCE FOR INDUSTRY at 2 (citing Food and Drug Administration Modernization Act § 505(c)).

168. See FDA to Drug Firms: You Promised (May 23, 2003), <http://www.cbsnews.com/stories/2003/05/23/health/main555299.shtml> (noting that 28% of post-marketing studies for fast-track drugs had not yet begun, and 1.6% were officially delayed).

169. See *infra* Part III.A.1.

170. *Medtronic v. Lohr*, 518 U.S. 470, 497 (1996).

171. *Merck, FDA Grilled at Senate Hearing*, *supra* note 10.

a five-fold increase.<sup>172</sup> These numbers are particularly alarming because the test subjects who participated in the trial generally were young, healthy people, not elderly people who would be more likely to use an arthritis drug.<sup>173</sup> The FDA largely ignored these and other warnings. Notwithstanding concerns among FDA officials that Vioxx posed significant heart-related risks, the agency sat idly by while Merck spent more than \$100 million annually in direct-to-consumer marketing of Vioxx.<sup>174</sup>

In the wake of the Vioxx recall, FDA officials promised to make changes that would more adequately protect consumers of prescription drugs. Lester Crawford, Acting Commissioner of the FDA, proposed what he called an “independent” board to oversee drug safety issues at the FDA.<sup>175</sup> That board would consist of FDA scientists and medical experts from other government agencies. These experts would be appointed by Crawford, a curious component of the plan because the board seemingly would lack any real independence from the FDA.

The FDA has rejected all calls for meaningful change. On February 18, 2005, a thirty-two-member advisory panel of the FDA recommended that Merck be permitted to resume sales of Vioxx.<sup>176</sup> Incredibly, the members unanimously agreed that Vioxx “significantly increases the risk of cardiovascular events”<sup>177</sup> yet, nonetheless, voted to allow the return of Vioxx to the market. The recommendation from the committee will be considered by officials with the FDA,<sup>178</sup> although it is unlikely the agency will permit Merck to continue selling the drug.<sup>179</sup>

Attempts by the FDA and drug manufacturers to persuade courts to recognize federal preemption in drug cases undoubtedly will be hampered by the highly publicized withdrawal of Vioxx. It is clear to most that the FDA presently lacks the ability or the will to adequately protect consumers from defective drugs. Granting drug manufacturers immunity from state tort claims removes one of the few remaining incentives for companies to act reasonably in ensuring the safety of prescription drugs and to behave responsibly when promoting them.

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172. *Id.*

173. *Id.*

174. Topol, *supra* note 5, at 1708.

175. *Nominee to Head FDA Rejects Claims Against Agency* (Mar. 18, 2005), <http://www.cnn.com/2005/ALLPOLITICS/03/17/fda.crawford.ap/>. Acting Commissioner Lester Crawford, at the helm during critical points in the Vioxx disaster, was nominated by President Bush to become the permanent commissioner of the agency. *Id.*

176. *Celebrex, Bextra, Vioxx Can Stay*, CNN MONEY, Feb. 18, 2005, [http://money.cnn.com/2005/02/18/news/fortune500/merck\\_drugs/](http://money.cnn.com/2005/02/18/news/fortune500/merck_drugs/).

177. *Id.*

178. *Id.*

179. *See supra* note 13 and accompanying text.

### III. STATE-SPONSORED PREEMPTION: STATE STATUTES THAT FORBID LAWSUITS AGAINST MANUFACTURERS OF FDA-APPROVED DRUGS

In 1995, the Michigan Legislature passed a statute that gave broad protections to manufacturers of prescription drugs. Michigan Compiled Laws section 600.2946(5) gives immunity to drug companies in products liability lawsuits if the medication was in compliance with FDA regulations at the time of sale.<sup>180</sup> An exception to the defense applies if the company fraudulently withheld information that would have led the FDA to recall the drug (or deny approval).<sup>181</sup> The statute was intended to protect Upjohn Company, a Michigan-based pharmaceutical manufacturer.<sup>182</sup> Upjohn later was purchased by Pfizer Inc., a drugmaker that continues to employ thousands of Michigan residents.<sup>183</sup>

Efforts to overturn the law as unconstitutional have been unsuccessful. In *Taylor v. Smithkline Beecham Corp.*,<sup>184</sup> the Michigan Supreme Court addressed

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180. The pertinent section provides:

In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the [FDA], and the drug and its labeling were in compliance with the [FDA]'s approval at the time the drug left the control of the manufacturer or seller.

MICH. COMP. LAWS ANN. § 600.2946(5) (West 2006).

181. The exception reads:

[T]his subsection does not apply to a drug that is sold in the United States after the effective date of an order of the [FDA] to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:

(a) Intentionally withholds from or misrepresents to the [FDA] information . . . that is required to be submitted under the federal food, drug, and cosmetic act, and the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted.

(b) Makes an illegal payment to an official or employee of the [FDA] for the purpose of securing or maintaining approval of the drug.

*Id.* (citation omitted).

In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), discussed *supra* Part II.A.2, the Supreme Court held that fraud-on-the-FDA claims are preempted. The Court recognized that the FDA possesses significant power in handling companies that attempt to deceive the agency. *Id.* at 349. A broad reading of this case may prevent Michigan plaintiffs from litigating the issue of whether a drug manufacturer defrauded the FDA. Therefore, even the most egregious actions by drug manufacturers may go unpunished by Michigan courts, and Michigan residents will be unable to recover for injuries caused by dangerous drugs.

182. David Eggert, *Michigan Law Makes Drug Suits Difficult*, DETROIT FREE PRESS, Jan. 4, 2005, [http://www.freep.com/news/mich/drugsuits4e\\_20050104.htm](http://www.freep.com/news/mich/drugsuits4e_20050104.htm).

183. *Id.*

184. 658 N.W.2d 127 (Mich. 2003).

whether the statute violated the state constitution. The case involved consolidated claims by two plaintiffs who suffered injuries from the diet drugs Fen-Phen and Redux.<sup>185</sup> The court upheld the validity of the statute, dismissing arguments by the plaintiffs that the statute violated provisions of the state constitution. Because the case rested on state constitutional grounds, the United States Supreme Court lacked authority to hear an appeal.<sup>186</sup>

The statute again was challenged in *Garcia v. Wyeth-Ayerst Laboratories*.<sup>187</sup> In that case, the plaintiff was prescribed Duract to treat persistent pain in her neck and shoulders.<sup>188</sup> The drug resulted in liver failure and forced Garcia to undergo a liver transplant.<sup>189</sup> The drug since has been withdrawn as a result of this risk.

Garcia challenged the Michigan statute on three grounds. First, she argued that the statute had been impliedly preempted by the FDCA. The argument was premised on the exception to the statute that permitted litigation of drug cases if the company committed fraud on the FDA. Because fraud-on-the-FDA claims are preempted following the *Buckman* decision, Garcia argued that the entire statute was invalid. The Court of Appeals for the Sixth Circuit dismissed the argument, finding that the portions not deemed preempted still could be given meaning.

[T]he law remaining after an invalid portion of the law is severed will be enforced independently “unless the invalid provisions are deemed so essential, and are so interwoven with others, that it cannot be presumed that the legislature intended the statute to operate otherwise than as a whole.”<sup>190</sup>

Garcia next argued that the statute interfered with the fundamental right of access to courts and the constitutional right to a jury trial.<sup>191</sup> The Sixth Circuit rejected this argument, finding that a statute that simply raises the burden of proof of a common law tort claim does not implicate either of these rights.<sup>192</sup>

The final argument posited by Garcia was that the statute violated her due process rights by depriving her of common law tort remedies to recover for injuries caused by a defective product.<sup>193</sup> The Sixth Circuit held that the Michigan legislature acted within its authority when it drafted a statute to give drug manufacturers immunity from products liability suits. The plaintiff in *Garcia* may

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185. *Id.* at 129.

186. *See generally* *Murdock v. City of Memphis*, 87 U.S. (20 Wall.) 590 (1874) (describing the general rule that the Supreme Court does not have jurisdiction to review a state court decision that is supported by an independent and adequate state ground).

187. 385 F.3d 961 (6th Cir. 2004).

188. *Id.* at 963.

189. *Id.*

190. *Id.* at 967 (quoting *Moore v. Fowinkle*, 512 F.2d 629, 632 (6th Cir. 1975)).

191. *Id.*

192. *Id.* at 968.

193. *Id.*

still appeal this decision to the U.S. Supreme Court to challenge the constitutionality of the statute.

Michigan legislators placed their state in the dubious position of being the only state in the nation to prohibit lawsuits against manufacturers of defective drugs.<sup>194</sup> The result is that Michigan residents injured by dangerous drugs like Vioxx are prevented from pursuing claims against the manufacturers.<sup>195</sup> Even assuming the exception to the Michigan statute would permit suits when it could be demonstrated that the pharmaceutical company withheld information that would have led the FDA to reject approval or order withdrawal of the drug, the burden on patients will be very nearly impossible to meet given the recent vote by an FDA committee that recommended allowing Merck to resume sales.<sup>196</sup> While the vote likely was symbolic and intended to undercut claims by Vioxx patients that the drug's risk outweighed the benefits, it will have especially harsh repercussions for Michigan plaintiffs seeking to recover for injuries resulting from Vioxx use.<sup>197</sup>

The Michigan statute is considered a model by drug companies pushing for similar laws in other states.<sup>198</sup> The prospect of other states passing similar laws is attractive for drug makers that may have privately conceded that preemption of drug claims at the federal level is unattainable. Should drug companies be unsuccessful in convincing our courts to accept a preemption defense, the manufacturers likely will turn to state legislatures, with lawmakers being urged to enact highly restrictive laws similar to Michigan's.

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194. See Kathy Barks Hoffman, *Group Formed to Limit Lawsuits*, OAKLAND PRESS, Jan. 26, 2005, available at [http://www.theoaklandpress.com/stories/012605/bus\\_20050126007.shtml](http://www.theoaklandpress.com/stories/012605/bus_20050126007.shtml).

195. See Eggert, *supra* note 182 (noting that “[c]ritics say the Michigan law harms patients who have no recourse in state courts and cannot trust the FDA to adequately protect them”).

196. See *supra* text accompanying notes 145–46.

197. It is likely that some Michigan residents harmed by Vioxx will bring suit and argue their claims are not barred as a result of the fraud-on-the-FDA exception to the statute. Those plaintiffs will argue that Merck withheld critical information about the drug prior to approval and data gleaned from clinical studies conducted shortly after the drug's introduction to the market. Perhaps the strongest available evidence demonstrating fraud involves a series of e-mails in 2000 among Merck researchers and executives. A Merck scientist overseeing a clinical trial notified executives that a study participant probably died of a heart attack. That scientist was encouraged to alter the cause of death so as not to “raise concerns” with the FDA. In its reports to the FDA, Merck characterized the cause of death as “unknown” for the patient. Alex Berenson, *Evidence in Vioxx Suits Shows Intervention by Merck Officials*, N.Y. TIMES, Apr. 24, 2005, at A1.

198. See, e.g., Jeff Mapes, *Mannix Backs Bill to Bar Liability Suits*, OREGONIAN, Apr. 21, 2005, at C7 (noting that Oregon's Republican Party Chairman is pushing a bill that “would bar lawsuits against pharmaceuticals and other medical devices approved by the Federal Drug Administration as long as the manufacturer fully disclosed any risks”); see also Eggert, *supra* note 182.

#### IV. FDA ATTEMPTS BACK-DOOR APPROACH TO FEDERAL PREEMPTION

Undeterred by its inability to persuade either the courts or Congress to adopt a preemption doctrine, the FDA in January 2006 unveiled new federal rules declaring that failure to warn claims were preempted by the agency's regulation of prescription drugs.<sup>199</sup> The FDA reasserted its position that "FDA approval of labeling under the act . . . preempts conflicting or contrary State law."<sup>200</sup> The rule is scheduled to go into effect on June 30, 2006, absent efforts to overturn the regulation.

The administrative process for adopting the new rules, which primarily address new labeling requirements, began in December 2000 when the agency issued notice of proposed changes to labeling requirements.<sup>201</sup> The notice specifically addressed federal preemption and declared that the "FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law."<sup>202</sup> Notwithstanding that assurance, the current version of the rule proposes significant changes to our civil justice system.

The new preemption rule largely was the result of pressure from the Bush Administration to grant immunity to drug manufacturers. This political component to the process explains the departure from the agency's December 2000 position that its new rules would not preempt state law. Rather than urging Congress to enact legislation supporting preemption, the Bush Administration has circumvented the political process and pressured the FDA to make the attempt. The *Wall Street Journal* described disputes between the FDA and Bush Administration officials regarding the new rule:

Inclusion of the new FDA policy in the long-awaited drug-labeling rule has sparked disagreements between FDA career officials and Bush Administration appointees, according to people with knowledge of the matter. Some FDA career staffers have argued internally that it isn't relevant to the rule's focus on drug-labeling reform, and may draw controversy to an important regulatory improvement that isn't itself politically divisive.<sup>203</sup>

Criticism of the new rule was swift. Steve Rauschenberger, president of the National Conference of State Legislatures, called the rule a "thinly-veiled attempt on the part of the FDA to confer upon itself authority it does not have by

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199. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 21 C.F.R. §§ 201, 314, 601 (2006).

200. *Id.* (preamble of final rule).

201. *See* Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Labels, 65 Fed. Reg. 81,082 (proposed Dec. 22, 2000).

202. *Id.*

203. Anna Wilde Mathews, *FDA Plan Would Aid Drug Makers in Liability Suits*, WALL ST. J., Jan. 14, 2006, at A1.

statute and does not have by way of judicial ruling.”<sup>204</sup> If the rule is successfully implemented, companies would escape accountability for marketing dangerous drugs.

## V. POLICY

### A. Public Health

The federal FDCA is intended to protect consumers from dangerous and ineffective medical devices and drugs. Products liability lawsuits to recover damages for injuries caused by prescription drugs and medical devices further the important goals of the FDCA. The Supreme Court recognized the critical role of courts in protecting the public from dangerous products: “Regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.”<sup>205</sup>

Rather than regarding lawsuits against medical device and drug manufacturers as frustrating the goals of the FDA, the Agency should value the added pressure on the companies it regulates to ensure products are safe and the public is warned of potential risks. Instead, the FDA contends that the threat of lawsuits harms the public by encouraging manufacturers to withdraw beneficial products<sup>206</sup> or issue warnings that overemphasize risks, leading to underutilization of medical devices and prescription drugs.<sup>207</sup> It seems counterintuitive to argue that Americans underutilize prescription drugs. The prescription drug industry earns global revenues of more than \$500 billion per year.<sup>208</sup> Americans are responsible for \$248 billion in all pharmaceutical sales, accounting for nearly 45% of all revenue.<sup>209</sup> In the previous ten years, the number of prescriptions issued annually has increased approximately 67%, undercutting the argument that products liability

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204. Press Release, National Conference of State Legislatures, Proposed FDA Rule Preempts State Product Liability Laws (Jan. 13, 2006), *available at* <http://www.ncsl.org/programs/press/2006/pr060113.htm>.

205. San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 247 (1959).

206. We suspect the FDA would be hard-pressed to provide examples of beneficial drugs that were voluntarily withdrawn by manufacturers because of the threat of products liability lawsuits.

207. See Pear, *supra* note 83, at A1. A study published in *The Journal of the American Medical Association* concluded that direct-to-consumer advertising promoted the overuse of antidepressant drugs. Richard L. Kravitz et al., *Influence of Patients' Requests for Direct-to-Consumer Advertised Antidepressants*, 293 JAMA 1995 (2005) (“Patients’ requests have a profound effect on physician prescribing in major depression and adjustment disorder. Direct-to-consumer advertising may have competing effects on quality, potentially both averting underuse and promoting overuse.”).

208. IMS Health, IMS Reports 2004 Global Pharmaceutical Sales Grew 7 Percent to \$550 Billion, Mar. 9, 2005, [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_3665\\_71496463,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_3665_71496463,00.html). Dr. Marcia Angell, former editor-in-chief of *The New England Journal of Medicine*, discussed the explosion of prescription drug use in the United States. “The increase in drug spending reflects . . . the fact[] that people are taking a lot more drugs than they used to.” ANGELL, *supra* note 157, at xii.

209. IMS Health, *supra* note 208.

lawsuits are leading to the underutilization of drugs.<sup>210</sup> One need only watch a little prime-time television to appreciate the eagerness of Americans to cure any perceived ailment with a pill, and the enthusiasm of drug makers to encourage them to do so.<sup>211</sup>

### **B. Federalism**

The strong presumption against preemption belies the stated rationale for legislative efforts to shield drug manufacturers from liability for drugs approved by the FDA. Our history is replete with efforts by courts to avoid impairing the legitimate role of states in protecting its citizens.<sup>212</sup> In addressing whether state tort claims are preempted by federal regulation, courts must assume that “Congress did not intend to displace state law.”<sup>213</sup> This general rule should be respected unless significant evidence supports an alternate intent by Congress.

In the instant discussion of the FDA defense, there is no indication that Congress intended the FDCA to preempt state tort claims for defective drugs. In fact, when drafting the FDCA, Congress specifically rejected a proposal to include a private right of action for damages caused by defective medical devices because the right already existed at common law.<sup>214</sup> Products liability lawsuits have been litigated against drug manufacturers for decades. Congress neither has amended the FDCA to include an express preemption clause for drugs nor has it adopted tort measures that would directly remove the right to recover damages against drug makers.

The Supreme Court could clarify the field of preemption by refusing to recognize implied preemption. When enacting legislation on product safety, Congress would be required to expressly state the effect of the legislation on product liability claims brought under state common law. Absent express

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210. Kaiser Network, *Associated Press Examines Effect of Increased Prescription Drug Use in United States*, Apr. 18, 2005, [http://www.kaisernetwork.org/daily\\_reports/rep\\_hpolicy\\_recent\\_rep.cfm?dr\\_DateTime=04-18-05&show=yes](http://www.kaisernetwork.org/daily_reports/rep_hpolicy_recent_rep.cfm?dr_DateTime=04-18-05&show=yes) (reporting that prescription drugs are the fourth-leading cause of death in the nation, behind heart disease, cancer and stroke).

211. For a discussion of the problems associated with direct-to-consumer advertising of prescription drugs, see Alan Zarembo, *TV Ads for Drugs Help Boost Prescriptions, Researchers Say*, L.A. TIMES, Apr. 27, 2005, at A10, available at <http://www.latimes.com/news/nationworld/nation/la-sci-drugads27apr27,1,5461674.story> (“Doctors are easily persuaded to prescribe antidepressants—often unnecessarily—when patients mention having seen them in television advertisements . . .”).

212. See, e.g., *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (“Because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly preempt state-law causes of action.”).

213. *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981).

214. *Food, Drugs & Cosmetics: Hearings on S. 1944 Before the Subcomm. of Senate Comm. on Commerce*, 73d Cong., 2d Sess. (1933); see also Robert S. Adler et al., *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 924 n.130 (1995) (“Congress rejected a provision in a draft of the original FD&C providing a federal cause of action for damages because ‘a common law right of action exists.’” (quoting legislative history)).

preemption, claims for damages should be preempted only when compliance with state common law would have made compliance with federal laws or regulations impossible.<sup>215</sup>

### CONCLUSION

Drug companies have long made a concerted effort to undercut the regulatory powers of the FDA in approving and monitoring prescription drugs. The pharmaceutical industry spent nearly \$478 million on lobbying activities between 1997 and 2002.<sup>216</sup> Much of this money supported initiatives to relax FDA regulations pertaining to approval of new drugs. It is considerably easier today to get a drug to market than it was in the 1960s, when the FDA was commended for refusing applications for drugs like Thalidomide.<sup>217</sup>

Notwithstanding the structural inability of the FDA to carefully investigate and monitor drug safety, drug makers assert a preemption defense premised on the notion that FDA approval of a drug indicates a validation of the drug's safety. This position shirks the responsibility of drug manufacturers to carefully monitor the adverse effects of their products. One could reasonably assume that Vioxx might still be on the market if Merck had not been concerned about its financial exposure in products liability lawsuits.

The availability of courts to redress injuries provides the public powerful leverage against negligent drug manufacturers. The threat of litigation reduces the risk of misconduct by drug makers, providing the public with necessary protections against the effects of dangerous pharmaceuticals. If courts extended federal preemption to drug claims, or states adopted restrictive measures similar to those in Michigan, manufacturers would have little incentive to conduct post-approval clinical studies to examine a drug's safety. The FDA also would lose one of its few bargaining chips in pressuring companies to amend labels to warn of newly discovered risks. If failure-to-warn claims were not actionable, drug companies could effectively resist all efforts by the FDA to expand warnings.

The FDA and state legislatures must recognize that litigation—and the threat of litigation—provides an important safeguard in America's healthcare system. Rather than frustrating the efforts of consumers to recover fair damages for injuries caused by defective drugs, the FDA should at least tacitly encourage individuals and their attorneys to hold drug makers responsible for placing profits ahead of public safety.

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215. For a discussion on a bright-line rule that would clarify the field of federal preemption, see Marin Scordato, *Federal Preemption of State Tort Claims*, 35 U.C. DAVIS L. REV. 1 (2001).

216. ANGELL, *supra* note 157, at 198.

217. *See supra* note 133.