

# Allocating Liability for Deficient Warnings on Generic Drugs: A Prescription for Change

## ABSTRACT

*Brand-name pharmaceutical companies create pioneer drugs that cure diseases around the world. However, because research and development costs are very high, brand-name drugs are expensive. In response to escalating costs, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman Act”) to promote generic competition. As generics become more prominent in the pharmaceutical marketplace, individuals injured by generic drugs are suing the manufacturers with more frequency. The cases often turn on which company should bear the liability for failing to warn—the brand-name manufacturer or the generic drug maker. Although the injured person took the generic drug, the generic company has much less control over the warning label than the pioneer company. Courts thus far have attempted to compensate injured plaintiffs by either holding the brand-name manufacturer liable for injuries caused by a competitor’s product, or holding the generic manufacturer liable for label deficiencies it did not create. This Note discusses alternatives to redress injured individuals: (1) clarifying the role of generic drug manufacturers in the label formation and amendment process by the FDA; (2) labeling of generic drugs by the FDA; and (3) creating a federal trust fund, similar to the Vaccine Injury Compensation Trust Fund, to compensate plaintiffs who prove deficiencies in generic drug labels.*

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Brand-name pharmaceutical companies create “pioneer” drugs that cure diseases around the world. However, because research and development costs are very high, brand-name drugs are expensive.<sup>1</sup> Between 1990 and 2005, United States consumer spending on prescription drugs increased fivefold to \$251.8 billion per year.<sup>2</sup> During that same time period, prescription drug expenditures grew at twice the rate of other health care spending and nearly five times that of the overall economy.<sup>3</sup> The average price per prescription also increased dramatically, from \$9.50 in 1981 to \$53.92 in 2004.<sup>4</sup> A large portion of the price increase can be attributed to the approval process of the Food and Drug Administration (FDA) for a new drug, which takes an average of twelve to fifteen years and costs more than \$800 million per drug.<sup>5</sup> Indeed, only 30% of FDA-approved pharmaceuticals recover the cost of their research and development.<sup>6</sup>

In response to these escalating costs, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984

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1. Wansheng Jerry Liu, *Balancing Accessibility and Sustainability: How to Achieve the Dual Objectives of the Hatch-Waxman Act While Resolving Antitrust Issues in Pharmaceutical Patent Settlement Cases*, 18 ALB. L.J. SCI. & TECH. 441, 443 (2008).

2. Christopher Lea Lockwood, Comment, *Biotechnology Industry Organization v. District of Columbia: A Preemptive Strike Against State Price Restrictions on Prescription Pharmaceuticals*, 19 ALB. L.J. SCI. & TECH. 143, 149 (2009).

3. *Id.*

4. *Id.*

5. *Id.* at 148.

6. *Id.*

(“Hatch-Waxman Act”) to promote generic competition.<sup>7</sup> Congress intended the Act to “strike a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.”<sup>8</sup> Before the Hatch-Waxman Act, the significant lag between patent issuance and FDA approval left the manufacturers of pioneer pharmaceuticals with relatively short effective patent terms during which to recoup their investment.<sup>9</sup> The Hatch-Waxman Act provides brand-name, or “innovator,” drug companies with limited patent term extensions to restore some of the market exclusivity lost during the lengthy drug development and approval processes.<sup>10</sup> In exchange for that benefit to pioneer manufacturers, the Act also includes a patent infringement exception that permits generic companies to conduct experiments to create generic versions of pioneer products.<sup>11</sup> Additionally, the Act substantially shortened the FDA approval process for generics by providing that the generic manufacturers need not independently test a generic drug for safety or efficacy, but need only demonstrate chemical equivalence to the approved pioneer drug.<sup>12</sup> Generic drug development now averages three to five years, and the FDA generally approves chemically identical versions.<sup>13</sup>

Because generic manufacturers expend no resources on innovative research or expensive clinical trials, they can sell their products at much lower prices.<sup>14</sup> The first generic manufacturer to enter the market discounts the price of the brand-name drug by an average of 5 to 25%,<sup>15</sup> and once a generic enters the market, the brand loses an average of 44% of its market.<sup>16</sup> In markets with ten or more generic competitors, the average generic price falls to less than half of what the brand-name commanded before the arrival of competition on

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7. Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15 U.S.C., 21 U.S.C., and 35 U.S.C.).

8. Lockwood, *supra* note 2, at 147 (internal quotation marks omitted).

9. *Id.*

10. *Id.*

11. *Id.*

12. *Id.*; see 21 U.S.C. § 355(j)(2)(A) (2006); Allergan, Inc., v. Alcon Labs., Inc., 324 F.3d 1322, 1325–26 (Fed. Cir. 2003).

13. Liu, *supra* note 1, at 484.

14. *Id.* at 447.

15. Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 50 (2009).

16. *Id.* at 49.

the market.<sup>17</sup> The Hatch-Waxman Act has effectively increased the development and availability of generic drugs.<sup>18</sup> Since 1984, the generic market share increased from less than 20% to 65% in 2008.<sup>19</sup> From 2000 to 2009, generic drugs saved the U.S. healthcare system over \$824 billion, and in 2009 alone, savings approached \$140 billion.<sup>20</sup>

To gain FDA approval under the Hatch-Waxman Act, a generic drug company must certify the bioequivalence of its product to an approved brand-name drug, and that the warnings and labeling match those for the brand-name, or “listed,” drug.<sup>21</sup> Because the generic drug is chemically identical to the brand-name drug, the FDA does not require generic companies to repeat the clinical trials and safety studies that pioneer manufactures conduct to generate the original warning labels.<sup>22</sup> Generic companies are not permitted to alter that labeling. Indeed, the generic drug system is economically efficient precisely because generic manufacturers do not study or test a drug beyond ensuring that its version is chemically identical to the brand-name version.

As generics become more prominent in the pharmaceutical marketplace, individuals injured by generic drugs are suing the manufacturers with more frequency.<sup>23</sup> The cases often turn on who should bear the liability for failing to warn—the brand-name manufacturer, or the generic drug maker. Although the injured person took the generic drug, the generic company has much less control over the warning label than the pioneer company.

In 2009, the California Supreme Court declined to review *Conte v. Wyeth*.<sup>24</sup> In that case, the California Court of Appeals held that when a doctor foreseeably relies on a brand-name drug’s label and warnings, the pioneer manufacturer’s duty to warn extends even to

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17. CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY xiii (1998), available at <http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf>.

18. See *id.* at 49–50.

19. *Id.* at 49.

20. GENERIC PHARMACEUTICAL ASSOCIATION, SAVINGS ACHIEVED THROUGH THE USE OF GENERIC PHARMACEUTICALS 1 (2009), available at [http://www.gphaonline.org/sites/default/files/GPhA%20Savings%20Study%20Book%20Updated%20Web%20FINAL%20Jul23%2010\\_0.pdf](http://www.gphaonline.org/sites/default/files/GPhA%20Savings%20Study%20Book%20Updated%20Web%20FINAL%20Jul23%2010_0.pdf).

21. 21 U.S.C. § 355(j)(2)(A) (2006).

22. Carrier, *supra* note 16, at 46; see 21 U.S.C. § 355(j)(2)(A).

23. Bridget M. Ahmann & Erin M. Verneris, *Name Brand Exposure for Generic Drug Use: Prescription for Liability*, 32 HAMLINE L. REV. 767, 769 (2009) (noting “a wave of recent cases” involving generic drugs and the potential for brand-name manufacturers to be held liable for injuries caused by generic drug use).

24. *Conte v. Wyeth, Inc.*, 85 Cal Rptr. 3d 299 (Cal. Ct. App. 2008), *appeal denied*, No. S169116, 2009 Cal. LEXIS 233 (Cal. Jan. 21, 2009).

the doctor's patients who take only the generic version.<sup>25</sup> That decision, holding one company liable for its *competitor's* product, sparked significant protest from brand-name drug companies.<sup>26</sup>

In late 2009 and early 2010, the United States Courts of Appeals for the Fifth and Eighth Circuits rejected the *Conte* approach.<sup>27</sup> They held that a brand manufacturer's duty of care does not extend to those who foreseeably rely on the listed drug's label despite only taking the generic version of the drug.<sup>28</sup> Rather, they ruled that generic manufacturers were liable for any labeling deficiencies on the theory that a generic manufacturer can change warning labels or send "Dear Doctor" letters if they discover an adverse drug event not found during the testing of the pioneer product.<sup>29</sup> In reality, however, the FDA makes it very difficult for generic manufacturers to amend listed drugs' warning labels which are based on studies and data generic companies cannot obtain.<sup>30</sup> The generic drug companies contended that, if required to conduct the research necessary to support a labeling change, the cost of generics would significantly increase, which would undermine the policies underlying the Hatch-Waxman Act.<sup>31</sup>

In February 2010, the generic manufacturers in the Eighth Circuit case, *Mensing*, filed a petition for certiorari,<sup>32</sup> which the Supreme Court granted on December 10, 2010, and consolidated with *Demahy*, the Fifth Circuit case.<sup>33</sup> The Court will likely rule one of

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25. *Id.* at 304–05.

26. *Cf.* Ahmann & Verneris, *supra* note 23, at 780–86, 788–89 (discussing brand-name manufacturers' concern over the possibility of being held liable when injured persons did not even take the product they manufactured).

27. *See* Demahy v. Actavis, Inc., 593 F.3d 428 (5th Cir. 2010); Mensing v. Wyeth, Inc., 588 F.3d 603 (8th Cir. 2009). A district court in the Fourth Circuit also rejected the California approach. *See* Couick v. Wyeth, Inc., No. 3:09-cv-210-RJC-DSC, 2009 U.S. Dist. LEXIS 113943 (W.D.N.C. Dec. 7, 2009).

28. *Mensing*, 588 F.3d at 613.

29. *Id.* at 609–10.

30. *Cf.* Ahmann & Verneris, *supra* note 23, at 773–74.

31. *Mensing*, 588 F.3d at 611.

32. *See* Petition for Writ of Certiorari, Actavis Elizabeth, L.L.C. v. Mensing, 130 S. Ct. 3349 (2010) (No. 09-1039); Petition for Writ of Certiorari, PLIVA, Inc. v. Mensing, 130 S. Ct. 3349 (2010) (No. 09-993).

33. Order Granting Writ of Certiorari, Actavis Elizabeth, LLC v. Mensing, No. 09-1039, 2010 WL 752387 (U.S. Dec 10, 2010); Order Granting Writ of Certiorari, PLIVA, Inc. v. Mensing, No. 09-993, 2010 WL 621400 (U.S. Dec. 10, 2010); Order Granting Writ of Certiorari, Actavis Inc v. Demahy, No. 09-1501, 010 WL 230053 (U.S. Dec. 10, 2010). The Supreme Court granted certiorari despite the fact that the Solicitor General for the United States recommended that the Court deny the petition. Brief for the United States as Amicus Curiae, *PLIVA, Inc.*, 130 S. Ct. 3349 (No. 09-993), *Actavis Elizabeth, L.L.C.*, 130 S. Ct. 3349 (No. 09-1039), 2010 WL 4339894 at \*10. The Solicitor General argued that the Court should deny certiorari because the Eighth Circuit correctly held that federal law did not preempt Ms. Mensing's claims, because no other

three ways: (1) hold the generic manufacturers liable, thus undermining the purposes of the Hatch-Waxman Act; (2) find the pioneer company liable, although it did not manufacture the ingested product; or (3) determine that an injured plaintiff has no recourse in the judicial system, thereby leaving Congress to remedy the situation. As this Note argues, only the last option, combined with legislative action, would be a satisfying result.

While courts thus far have attempted to compensate injured plaintiffs by either holding the brand-name manufacturer liable for injuries caused by a competitor's product, or holding the generic manufacturer liable for label deficiencies it did not create, this Note will discuss alternative ways in which to redress injured individuals. Part I will discuss the regulatory framework that governs approval of pioneer and generic drugs, provide an overview of the relevant tort principles, and address the federal preemption landscape after the Supreme Court's decision in *Wyeth v. Levine*.<sup>34</sup> Part II will analyze the impact of recent, conflicting court opinions on the pharmaceutical industry and tort law. Part III will propose three solutions: (1) clarifying the role of generic drug manufacturers in the label formation and amendment process by the FDA; (2) labeling of generic drugs by the FDA; and (3) creating a federal trust fund, similar to the Vaccine Injury Compensation Trust Fund,<sup>35</sup> to compensate plaintiffs who prove deficiencies in generic drug labels.

## I. GENERIC DRUG WARNINGS

### A. Regulatory Framework

Under the Food, Drug, and Cosmetic Act (FDCA), the FDA regulates the manufacture, sale, and labeling of prescription drugs.<sup>36</sup> Congress has charged the FDA with ensuring that prescription drugs are "safe and effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof,"<sup>37</sup> as well as properly branded.<sup>38</sup> Misbranding means labeling that is "false or misleading in any particular" way, or which contains inadequate warnings or directions for use.<sup>39</sup> The FDCA further defines "labeling"

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circuit had held otherwise, and because "the interlocutory posture of [the] case makes it unsuitable for review." *Id.* at 11, 22, 23.

34. *Wyeth v. Levine*, 129 S. Ct. 1187 (2009).

35. *See* 26 U.S.C. § 9510 (2006).

36. 21 U.S.C. §§ 301-95 (2006).

37. *Id.* § 355(d).

38. *Id.* § 355(b), (d).

39. *Id.* § 352(a), (f).

as “all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.”<sup>40</sup>

### 1. Pre-Approval Requirements for Brand-Name Drugs

To market a “new”<sup>41</sup> prescription drug, a brand-name pharmaceutical manufacturer must submit a New Drug Application (NDA), accompanied by extensive clinical and scientific studies verifying the drug’s safety and effectiveness.<sup>42</sup> NDAs must include, among other disclosures: full reports of safety and efficacy investigations; a complete list of the components of the drug; a full statement of the composition of the drug; “a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packaging of such drug;” samples of the drug and its components; and “specimens of the labeling.”<sup>43</sup> The drug label must include detailed directions for appropriate use, warnings, precautions, and adverse reactions.<sup>44</sup> If the FDA approves the NDA, the agency includes the drug on its published list of approved drugs and designates it a “listed drug.”<sup>45</sup> Thereafter, the innovator has the exclusive right to sell the drug for a limited period of time, depending on the expiration date of the patent.<sup>46</sup>

### 2. Post-Approval Requirements for Brand-Name Drugs

Even after receiving FDA approval, brand-name manufacturers must continue to monitor, assess, and report adverse effects associated with the drug.<sup>47</sup> Approved NDA applicants must review all published literature, send annual reports to the FDA detailing any new findings, and inform the FDA of any adverse effects reported with the drug’s use.<sup>48</sup> Manufacturers must also propose labeling changes based on

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40. *Id.* § 321(m).

41. The FDCA defines a “new drug” as one qualified experts at the time of the 1962 amendments to the Act do not generally recognize as safe and effective “for use under the condition prescribed, recommended, or suggested in the labeling thereof” or that has not been used to a “material extent or for a material time” under these conditions. *Id.* § 321(p). As a result, virtually all drugs approved over the last 50 years are “new.”

42. *Id.* 355(a)-(i).

43. *Id.* § 355(b)(1).

44. 21 C.F.R. § 201.56 (2010).

45. 21 U.S.C. § 355(j)(2)(A)(i), (j)(7).

46. *See id.* § 355(b)(1) (requiring a NDA to include the patent number and the expiration date of any patent).

47. *See id.* § 355(k); 21 C.F.R. §§ 314.80-.81.

48. *See* 21 C.F.R. §§ 314.80(a), 314.81.

newly acquired information,<sup>49</sup> as risks often appear only after the drug has been used by a larger patient population and for a longer duration than in the clinical trials.<sup>50</sup> Additionally, for certain drugs, the FDA may mandate that the pioneer manufacturer commit to conducting Phase IV clinical trials—post-marketing studies that collect additional information including a drug’s risks, benefits, and best uses—to ensure its safety after approval.<sup>51</sup> Whenever a manufacturer receives “reasonable evidence of an association of a serious hazard with a drug,” the label must be changed, even though “a causal relationship need not have been proved.”<sup>52</sup> To ensure that drugs which do not meet these standards are removed from the market, the FDCA also grants the FDA broad enforcement powers.<sup>53</sup>

For any drug labeling change, pioneer companies must obtain the permission of the FDA.<sup>54</sup> If the change is “major,” the manufacturer must obtain prior FDA approval by filing a “prior approval supplement.”<sup>55</sup> “Moderate changes,” however, can be implemented before the FDA formally approves them through a Changes Being Effectuated (CBE) supplement,<sup>56</sup> but still must ultimately pass FDA review.<sup>57</sup>

49. *Id.* § 314.70(c)(6)(iii).

50. *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 606 (8th Cir. 2009).

51. Vanessa Eng, Note, *Drug Safety: It’s a Learning Process*, 24 ST. JOHN’S J. LEGAL COMMENT. 159, 160 (2009). Phase IV trials are post-marketing studies, after a drug is approved, which determine additional information including a drug’s risks, benefits, and best uses. U.S. Nat’l Insts. of Health, *Glossary*, CLINICALTRIALS.GOV, <http://clinicaltrials.gov/ct2/info/glossary> (last visited Nov. 3, 2010). If such trials reveal harmful effects, the FDA may take a drug off the market or restrict its use. Matthew Avery, *Personalized Medicine and Rescuing “Unsafe” Drugs with Pharmacogenomics: A Regulatory Perspective*, 65 FOOD & DRUG L.J. 37, 60 (2010).

52. 21 C.F.R. § 201.80(e).

53. 21 U.S.C. § 331(b), (c), and (g) prohibit the misbranding of drugs sold in interstate commerce, as well as the receipt or manufacture of those misbranded drugs. 21 U.S.C. § 331(b), (c), (g) (2006). § 333 details the criminal and civil penalties for violating § 331. *Id.* § 333. § 355(e) describes the processes by which the FDA will withdraw approval for a drug application. *Id.* § 355(e). If the Secretary finds that an imminent public health hazard exists, he may withdraw approval immediately. *Id.* Barring immediate danger, the FDA may also withdraw approval, after giving the applicant due notice and opportunity for a hearing, if it finds:

that on the basis of new information before [the agency], evaluated together with the evidence available . . . when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

*Id.*

54. Ahmann & Verneris, *supra* note 23, at 771.

55. 21 C.F.R. § 314.70(b).

56. *Id.* § 314.70(c)(3), (6)(iii)(A)–(D).

57. *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 606 (8th Cir. 2009). Though not an exhaustive list, such major changes include alterations to the drug substance or production process with the significant possibility of adversely affecting the identity, strength, purity, or potency of a drug relating to safety or effectiveness and major label changes. 21 C.F.R. § 314.70(b). In contrast,



### 3. Pre- and Post-Approval Requirements for Generic Drugs

To foster prompt and effective competition, the Hatch-Waxman Act provides for FDA approval upon satisfaction of regulatory requirements significantly less costly and more expedient than the FDA demands of brand-name drugs.<sup>58</sup> Generic manufacturers must submit an Abbreviated New Drug Application (ANDA),<sup>59</sup> demonstrating bioequivalence to the listed drug,<sup>60</sup> but need not conduct any further safety studies.<sup>61</sup> To ensure uniformity, the ANDA must contain a side-by-side comparison of the proposed label with that of the approved brand-name drug.<sup>62</sup>

As a further incentive to manufacture generic drugs, the Act provides that the first approved ANDA filer to prove either invalidity or non-infringement of the pioneer patent receives a 180-day period during which only that filer can sell a generic version of the listed drug.<sup>63</sup> During that time, the first ANDA filer shares the market only with the brand-name manufacturer. Such limited competition can obviously benefit the generic drug company financially.<sup>64</sup> Following approval, the generic drug manufacturers must continue to monitor, analyze, and report adverse effects.<sup>65</sup>

Significantly, FDA regulations do not mention whether or how generic manufacturers should make labeling changes after approval.<sup>66</sup> In fact, the FDA has repeatedly declined to create a mechanism for generic drug manufacturers to offer additional warnings or safety-

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moderate changes include, but are not limited to, alterations to the drug substance or production process with a moderate possibility of adversely affecting the identity, strength, purity, or potency of a drug relating to safety or effectiveness and many label changes, such as strengthening warnings, deleting misleading or unsupported indications for use, or strengthening dosage or administration instructions. *Id.* § 314.70(c).

58. 21 U.S.C. § 355(j); see Carrier, *supra* note 16, at 41–43.

59. 21 U.S.C. § 355(j); U.S. Dep’t of Health & Human Servs., *Abbreviated New Drug Application (ANDA): Generics*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandagenerics/default.htm> (last visited Nov. 3, 2010).

60. “Bioequivalence means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.” 21 C.F.R. § 320.1(e).

61. See 21 U.S.C. § 355(j)(2)(A)(iv).

62. See 21 C.F.R. § 314.94(a)(8)(i), (iv).

63. Liu, *supra* note 1, at 449.

64. See *id.* at 450.

65. 21 U.S.C. § 355(k); 21 C.F.R. §§ 314.81, 314.98. Generic manufacturers must also review published literature about the drug. 21 C.F.R. §§ 314.80(b), (d), 314.81(b).

66. See Suchira Ghosh, *Federal Preemption and Labeling: Where Product Liability Collides with FDA*, FOOD & DRUG L. INS. UPDATE, July/Aug. 2010, at 10–13.

related information,<sup>67</sup> declaring that the generic drug's labeling "must be the same as the listed drug product's labeling because the listed drug product is the basis for ANDA approval."<sup>68</sup> As recently as 2006, the FDA, in revising its labeling requirements, reiterated that "[r]evised labeling for ANDA products depends on the labeling for the reference listed drug" and that "the labeling of a drug product submitted for approval under an ANDA must be the same as the labeling of the listed drug . . . ."<sup>69</sup> Furthermore, in 2008, the FDA confirmed, once again, that generic manufacturers cannot alter warning labels even under the Changes Being Effected process; even after approval, the "generic manufacturer is required to conform to the approved labeling for the listed [pioneer] drug."<sup>70</sup>

### *B. Products Liability*

While products liability law differs among jurisdictions, most state courts look to the Restatement (Second) of Torts for guidance.<sup>71</sup> Moreover, the modest differences among common-law principles governing alleged deficiencies in generic drug labels are far from dispositive. Because state courts focus on similar issues, this Note presents only a brief overview of the relevant principles.

The typical generic drug labeling case turns on failure-to-warn and misrepresentation claims sounding in negligence.<sup>72</sup> To recover on a failure-to-warn theory, the plaintiff must prove that a manufacturer "did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about."<sup>73</sup> A plaintiff may prevail on a misrepresentation claim by proving either negligent or intentional conduct.<sup>74</sup> For intentional misrepresentation, the

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67. See Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28,872, 28,884 (proposed July 10, 1989).

68. Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,961 (April 28, 1992) (to be codified at 21 C.F.R. pts. 2, 5, 10, 310, 314, 320, 433). The FDA stated that "[c]onsistent labeling will assure physicians, health professionals, and consumers that a generic drug is as safe and effective as its brand-name counterpart." *Id.*

69. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products—Final Rule, 71 Fed. Reg. 3922, 3961, 3963 (Jan. 24, 2006).

70. Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 3 Fed. Reg. 2848, 2848 n.1. (Jan. 16, 2008), issued as a Final Rule, 73 Fed. Reg. 49,603 (Aug. 22, 2008).

71. See, e.g., *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008).

72. See *id.*; see also *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010); *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009); *Couick v. Wyeth, Inc.*, 3:09-cv-210-RJC-DSC, 2009 U.S. Dist. LEXIS 113943 (W.D.N.C. Dec. 7, 2009).

73. *Conte*, 85 Cal. Rptr. 3d at 310.

74. See RESTATEMENT (SECOND) OF TORTS §§ 310, 311 (1965).

Restatement (Second) of Torts § 310 provides that one “who makes a misrepresentation is subject to liability to another for physical harm which results” from “reliance upon the truth of the representation, if the actor . . . intends his statement to induce or should realize that it is likely to induce action . . . which involves an unreasonable risk of physical harm to the other.”<sup>75</sup> For negligent misrepresentation, § 311 provides that an actor “who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results . . . to such third persons as the actor should expect to be put in peril by the action taken.”<sup>76</sup> Finally, where cases involve prescription drugs, the “learned-intermediary doctrine”<sup>77</sup> teaches that the duty to warn runs from the brand-name manufacturer to the prescribing physician—not the patient.<sup>78</sup>

### C. Federal Preemption

From the submission of an initial draft label in the ANDA to final approval of the drug and its label, the FDA controls every word, comma, and typeface employed.<sup>79</sup> Not surprisingly, drug companies often assert, while defending against failure-to-warn claims, that the FDA caused their allegedly tortious conduct.<sup>80</sup> In the 2009 case of *Wyeth v. Levine*, the Supreme Court grappled with the preemption issue—as it applied to a pioneer drug—but failed to clearly answer whether preemption provides a viable defense for generic manufacturers.<sup>81</sup> Even after *Levine*, defendants in similar cases

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75. *Id.* § 310.

76. *Id.* § 311.

77. With respect to medical prescriptions, the “learned-intermediary doctrine” provides that “if adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to [e]nsure that the warning reaches the doctor’s patient for whom the drug is prescribed.” *Conte*, 85 Cal. Rptr. 3d at 308 n.5 (citing *Stevens v. Parke, Davis & Co.*, 107 Cal. Rptr. 45 (1973) (internal quotation marks omitted)).

78. *Id.*

79. *See* 21 U.S.C. §§ 301–395 (2006).

80. *See, e.g., Wyeth v. Levine*, 129 S. Ct. 1187, 1199 (2009) (“Wyeth contends that the FDCA establishes both a floor and a ceiling for drug regulation: Once the FDA has approved a drug’s label, a state-law verdict may not deem the label inadequate, regardless of whether there is any evidence that the FDA has considered the stronger warning at issue.”); *Demahy v. Actavis, Inc.*, 593 F.3d 428, 436 (5th Cir. 2010) (“Here, Actavis urges that federal law requires that it maintain at all times a label that is the “same as” the name brand’s, thus preventing simultaneous compliance with a state law requiring additional warnings.”); *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 608 (8th Cir. 2009) (“[T]he generic manufacturers argue they are prohibited from implementing a unilateral label change without prior FDA approval through the CBE process.”).

81. *See Levine*, 129 S. Ct. at 1204.

continue to move for summary judgment, asserting that federal law preempts the plaintiffs' claims.<sup>82</sup>

The Court has recognized two kinds of preemption: express and implied.<sup>83</sup> Express preemption exists when Congress specifically states its intention for a statute to preempt conflicting state law.<sup>84</sup> Implied preemption occurs when Congress has not explicitly declared a desire to preempt, but its actions nonetheless effectively preempt state law. Implied preemption, in turn, further separates into conflict and field preemption.<sup>85</sup> Conflict preemption occurs "where it is impossible for a private party to comply with both state and federal law," or where a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."<sup>86</sup> Field preemption arises when a "scheme of federal regulation [is] so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it."<sup>87</sup>

In *Levine*, the Supreme Court held, as a general rule, that the FDCA does not preempt failure-to-warn claims against brand-name manufacturers. The Court found that petitioner had presented no "clear evidence" that the FDA had precluded—or would preclude—Wyeth from issuing a stronger warning.<sup>88</sup> The *Levine* plaintiff sued Wyeth after a nurse injected the drug Phenergan directly into her artery, causing gangrene and the eventual amputation of her arm, ending her career as a professional musician.<sup>89</sup> Ms. Levine alleged that the label failed to warn physicians of the foreseeable risks of gangrene likely to occur with the dangerous IV-push method.<sup>90</sup> Wyeth responded that federal law preempted this failure-to-warn claim because the FDA had approved the drug's label, which warned of the risk, but not as clearly as the plaintiff alleged that the law required.<sup>91</sup>

Specifically, Wyeth argued that it could not possibly "comply with the state-law duty to modify Phenergan's labeling without violating federal law" and that Levine's state tort action thus

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82. See, e.g., *Gaeta v. Perrigo Pharm.* No. 09-15001, 2011 WL 198420 (9th Cir. Jan. 24, 2011); *Demahy*, 593 F.3d 428; *Mensing*, 588 F.3d 603; *Couick v. Wyeth, Inc.*, 3:09-cv-210-RJC-DSC, 2009 U.S. Dist. LEXIS 113943 (W.D.N.C. Dec. 7, 2009); *Conte*, 85 Cal. Rptr. 3d 299.

83. JOHN C. P. GOLDBERG ET AL., *TORT LAW: RESPONSIBILITIES AND REDRESS* 1054 (2d ed. 2008).

84. *Id.*

85. *Id.*

86. Lockwood, *supra* note 2, at 150–51 (internal quotation marks omitted).

87. *Id.* at 150.

88. *Wyeth v. Levine*, 129 S. Ct. 1187, 1198 (2009).

89. *Id.* at 1191.

90. *Id.* at 1192.

91. *See id.*

frustrated “the full purposes and objectives of Congress.”<sup>92</sup> The Court, in rejecting both arguments, focused on the long-term coexistence of state tort remedies and federal regulation of prescription drugs.<sup>93</sup> The majority explained that if Congress had thought state law tort actions would encumber its purposes, “it surely would have enacted an express pre-emption provision at some point during the FDCA’s 70-year history.”<sup>94</sup> The Court further declared that Congress’s “silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.”<sup>95</sup>

Both before and after the *Levine* decision, generic and brand-name manufacturers have asserted conflict preemption as a defense to failure-to-warn claims, and a growing number of federal district courts have split on the issue.<sup>96</sup> Thus far, the circuit courts have generally followed *Levine* by rejecting generic manufacturers’ preemption claims, despite the fact that *Levine* dealt only with brand-name manufacturers.<sup>97</sup> For example, in *Mensing*, the Eighth Circuit pondered, “After *Levine*, we must view with a questioning mind the generic defendants’ argument that Congress silently intended to grant the manufacturers of most prescription drugs blanket immunity from state tort liability when they market inadequately labeled products.”<sup>98</sup> As a result of *Levine* and its rejection of the preemption defense, courts appear set on holding *someone* responsible when plaintiffs are

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92. *Id.* at 1193 (internal quotation marks omitted).

93. *Id.* at 1200.

94. *Id.*

95. *Id.*

96. District court cases finding state law preempted include: *Gaeta v. Perrigo Pharms. Co.*, 672 F. Supp. 2d 1017 (N.D. Cal. 2009) (denying plaintiffs’ motion for reconsideration); *Smith v. Wyeth, Inc.*, No. 5:07-CV-18-R, 2009 WL 425032 (W.D. Ky. Feb. 20, 2009); *Morris v. Wyeth, Inc.*, 642 F. Supp. 2d 677 (W.D. Ky. 2009); *Wilson v. Pliva, Inc.*, 640 F. Supp. 2d 879 (W.D. Ky. 2009); *Masterson v. Apotex, Corp.*, No. 07-61665-CIV, 2008 WL 3262690 (S.D. Fla. Aug. 7, 2008). District courts finding no preemption include: *Munroe v. Barr Labs., Inc.*, 670 F. Supp. 2d 1299 (N.D. Fla. 2009); *Bartlett v. Mutual Pharm. Co.*, 659 F. Supp. 2d 279 (D.N.H. 2009); *Stacel v. Teva Pharms.*, 620 F. Supp. 2d 899 (N.D. Ill. 2009); *Kellogg v. Wyeth*, 612 F. Supp. 2d 421 (D. Vt. 2008); *Tucker v. SmithKline Beecham Corp.*, 596 F. Supp. 2d 1225 (S.D. Ind. 2008) (reversing its earlier ruling dismissing the case on preemption grounds); *Barnhill v. Teva Pharms.*, No. 06-0282-CB-M, 2007 U.S. Dist. LEXIS 44718 (S.D. Ala. Apr. 24, 2007).

97. See, e.g., *Gaeta v. Perrigo Pharm.* No. 09-15001, 2011 WL 198420 (9th Cir. Jan. 24, 2011) (reversing the district court judgment that plaintiff’s claims were preempted); *Pustejovsky v. Pliva, Inc.*, No. 10-10983, slip op. at 5, 9 (5th Cir. Oct. 8, 2010) (finding plaintiff’s state law claims not preempted by the Hatch-Waxman Act and affirming district court grant of summary judgment in favor of Pliva.); *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010), *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009).

98. *Mensing*, 588 F.3d at 607.

injured by the prescription drugs they consume.<sup>99</sup> Which manufacturer the courts hold liable has important implications for tort law and the healthcare industry.

## II. ALLOCATION OF LIABILITY

### A. Conte: *Brand-Name Manufacturer Bears the Loss*

In *Conte*, the plaintiff alleged that she developed tardive dyskinesia, an irreversible neurological condition, as a result of taking metoclopramide, the chemical equivalent to Reglan.<sup>100</sup> Ms. Conte alleged that Wyeth, the pioneer manufacturer of the drug, had failed to warn her adequately of known adverse effects that could occur with long-term use.<sup>101</sup> The California trial court granted summary judgment for Wyeth.<sup>102</sup> It reasoned that Conte could not demonstrate that her physician had actually relied on the warnings drafted by Wyeth for Reglan and that an innovator manufacturer has no legal duty to patients who take the generic version of its drug.<sup>103</sup> The California Court of Appeals reversed, holding that a brand-name manufacturer's common-law duty to exercise due care when providing warnings extends beyond consumers of its own drug to patients whose doctors foreseeably rely on the innovator's warning when prescribing the generic version.<sup>104</sup>

Ms. Conte alleged that Wyeth misrepresented the risks of long-term use in its warning label and in the Reglan monograph it submitted to the Physician's Desk Reference (PDR), an annual publication containing pharmaceutical product information.<sup>105</sup> Although she never ingested Wyeth's product, she argued that Wyeth should be found liable because her doctor relied on Wyeth's warning when prescribing Reglan.<sup>106</sup> Wyeth countered that her doctor testified

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99. See *Demahy*, 593 F.3d 428; *Mensing*, 588 F.3d 603; *Couick v. Wyeth, Inc.*, No. 3:09-cv-210-RJC-DSC, 2009 U.S. Dist. LEXIS 113943 (W.D.N.C. Dec. 7, 2009); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Cal. App. 2009).

100. *Conte*, 85 Cal. Rptr. 3d at 304–05.

101. *Id.*

102. *Id.* at 306.

103. See *id.* at 305–06.

104. *Id.* at 304–05.

105. *Id.* at 307–08. Drug manufacturers provide information to the PDR, and the FDA approves it. *Id.* at 308 n.4. Licensed physicians in the United States and around the world receive the PDR for free each year. *Id.* An entry generally includes the trade and chemical names and description of a drug, indications and contraindications for use, warnings, adverse reactions, and dosage and administration information. *Id.*

106. *Id.* at 307–08.

he did not rely on its warnings.<sup>107</sup> The appellate court found a factual dispute sufficient to deny summary judgment because the doctor had often relied on the PDR during his residency and had “probably” read the entry for Reglan.<sup>108</sup>

Noting that the case presented an issue of first impression in California, the court of appeals rejected the trial court’s reasoning.<sup>109</sup> Wyeth argued that the products liability claim masqueraded as one of fraud and misrepresentation, and that Conte could not prevail on a theory of strict liability because Wyeth did not produce or market the product that caused her injury.<sup>110</sup> The court of appeals, however, noted that Ms. Conte had alleged a products liability—not a failure-to-warn—claim, namely that “that Wyeth failed to use due care when disseminating its product information.”<sup>111</sup> The court of appeals found it foreseeable that pharmacists would fill a prescription for Reglan, written in reliance on its label, with metoclopramide, which the statutes of California—as in most states—authorize pharmacists to do.<sup>112</sup> The court of appeals further reasoned that a physician could foreseeably prescribe metoclopramide in reliance on the Reglan label due to the chemical equivalence of the two drugs.<sup>113</sup>

Wyeth also made a number of policy arguments, all of which the court of appeals rejected.<sup>114</sup> The court disagreed with the contention that imposing liability “would chill innovation in the pharmaceutical industry.”<sup>115</sup> The court acknowledged, but refused to evaluate, the potentially unbounded liability that Wyeth might incur from an adverse holding: “as the foreseeable risk of physical harm runs to users of both Brand-name and generic drugs, so too runs the duty of care.”<sup>116</sup>

Finally, the court of appeals refused to follow the Fourth Circuit’s 1994 decision in *Foster v. American Home Products*,<sup>117</sup> which unequivocally found that innovator manufacturers could not be held

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107. *Id.* at 308–09.

108. *Id.*

109. *Id.* at 305, 309.

110. *Id.* at 309.

111. *Id.* at 310. Under strict products liability, the standard of due care or reasonableness of a manufacturer’s conduct is irrelevant. *Id.* A plaintiff need only prove “that the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.” *Id.*

112. *Id.* at 313.

113. *Id.*

114. *Id.* at 314.

115. *Id.*

116. *Id.* at 314–15.

117. *Id.* at 315.

liable for injuries from generic drug use under theories of misrepresentation.<sup>118</sup> *Foster* involved the death of an infant from promethazine, which Wyeth (then American Home Products) manufactured as Phenergan (coincidentally the same drug involved in *Levine*).<sup>119</sup> The Fourth Circuit rejected the plaintiffs' negligence claim against Wyeth based on its labeling because imposing such a duty would "stretch the concept of foreseeability too far."<sup>120</sup> The court concluded that Wyeth owed the Fosters no duty because Wyeth did not manufacture the product that caused the injury.<sup>121</sup>

The *Conte* trial court agreed with the *Foster* court's policy rationale: Because a generic manufacturer benefits by "riding the coattails" of the brand-name manufacturer, which expends immense resources to develop, test, and label an innovative drug, it would unfairly burden the pioneer to bear the liability for harm caused by the generic.<sup>122</sup> Indeed, the trial court deemed it unfair "to hold the pioneer manufacturer liable as insurer for not only its own production but also its generic competitors, especially when the latter enjoys the full financial benefits but no risk regarding the product."<sup>123</sup>

The *Conte* appellate court disagreed, however, finding the *Foster* reasoning "circular" and refusing to apply it.<sup>124</sup> The appellate court asked, "[W]hat is unfair about requiring a defendant to shoulder its share of responsibility for injuries caused, at least in part, by its negligent or intentional dissemination of inaccurate information?"<sup>125</sup> It added that the pioneer manufacturer "enjoys unique advantages, such as the initial period of patent protection from competition, the fiscal rewards of Brand-name recognition and the commensurate ability to charge a higher price for its product."<sup>126</sup> Declining to reach the preemption issue, the court of appeals found the risk of injury foreseeable, lest it "ignore the reality of the breadth and effect of Wyeth's representations in modern commerce and depart from firmly established principles of fault-based tort liability."<sup>127</sup>

The *Conte* decision sparked concern among commentators regarding the extent to which brand-name manufacturers could be exposed, at least in California, to liability for drugs produced by their

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118. *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 171 (4th Cir. 1994).

119. *Id.* at 167; *see also* *Wyeth v. Levine*, 129 S. Ct. 1187, 1191 (2009).

120. *Id.* at 170–71.

121. *Id.*

122. *Conte*, 85 Cal. Rptr. 3d at 316 (citing *Foster*, 29 F.3d at 170).

123. *Id.* at 316–17.

124. *Id.* at 316.

125. *Id.* at 317.

126. *Id.*

127. *Id.* at 320–21.



generic competitors.<sup>128</sup> Commentators found it especially troubling that the court's speculation that the prescribing doctor had "probably" read Reglan's monograph in the PDR was sufficient to defeat summary judgment.<sup>129</sup> More recently, however, the federal courts have criticized and declined to follow *Conte*, opting instead to hold generic manufacturers liable, despite their lack of control over the labels they copy from the original manufacturer.<sup>130</sup>

*B. Mensing: Brand-Name Manufacturer Does Not Bear the Loss*

On facts remarkably similar to those in *Conte*, Gladys Mensing sued Wyeth *and* generic manufacturers in federal court in 2009, claiming both failure to warn and misrepresentation, and alleging that she, too, had developed tardive dyskinesia as a result of taking metoclopramide.<sup>131</sup> The district court entered summary judgment, both for the generic manufacturers—holding the claims federally preempted—and for the brand-name manufacturers—because Ms. Mensing did not take Reglan.<sup>132</sup> Mensing appealed, and the Eighth Circuit affirmed summary judgment for the pioneer companies, but reversed as to their generic competitors.<sup>133</sup>

The Eighth Circuit rejected the generic defendants' preemption argument, relying on the *Levine* opinion, which was issued after the *Mensing* verdict. "After *Wyeth* [*v. Levine*], we must view with a questioning mind the generic defendants' argument that Congress silently intended to grant the manufacturers of most prescription drugs blanket immunity from state tort liability when they market inadequately labeled products."<sup>134</sup> After *Levine*, almost all courts faced with tort claims against generic manufacturers have refused to find preemption.<sup>135</sup>

Because generic labels must copy those of pioneers before and after FDA approval, generic companies argued that they could not implement a unilateral change to a drug's label without prior FDA

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128. See, e.g., Ahmann & Verneris, *supra* note 26, at 789.

129. See *id.*

130. See *infra* Part II.B–C.

131. *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 604 (8th Cir. 2009). On February 26, 2009, the FDA, acting on its own initiative under the Food and Drug Administration Amendments Act of 2007, ordered manufacturers of Reglan and generic metoclopramide to add a black box warning to labels about the increased risks of tardive dyskinesia from long-term metoclopramide use. *Id.* at 606 n.2.

132. *Id.* at 604.

133. *Id.*

134. *Id.* at 607.

135. *Id.* (citing *Stacel v. Teva Pharms.*, 620 F. Supp. 2d 899, 906–07 (N.D. Ill. 2009); *Schrock v. Wyeth, Inc.*, 601 F. Supp. 2d 1262, 1265–66 (W.D. Okla. 2009)).

approval through the CBE procedure.<sup>136</sup> The Eighth Circuit, however, declined to decide whether generic manufacturers could unilaterally change a label through the CBE process because they “could have at least *proposed* a label change that the FDA could receive and impose uniformly on all metoclopramide manufacturers if approved.”<sup>137</sup> The FDA does mandate that generic labels “shall be revised as soon as there is reasonable evidence of an association of a serious hazard with a drug.”<sup>138</sup> Generic manufacturers argue that they comply with federal regulations by ensuring their label exactly matches that of the brand-name drug.<sup>139</sup> Quoting *Levine*, the Eighth Circuit stated, “The FDA has limited resources to monitor the 11,000 drugs on the market . . . . [M]anufacturers, not the FDA, bear primary responsibility for their drug labeling.”<sup>140</sup> The FDA, in commentary published shortly after the enactment of the Hatch-Waxman Act, wrote that after FDA approval of an ANDA, when the generic company holding the application “believes that new safety information should be added, *it should provide adequate supporting information to FDA*, and FDA will determine whether the labeling for the generic and listed drugs should be revised.”<sup>141</sup>

The Eighth Circuit noted that generic manufacturers must record and report adverse drug events after approval just as brand-name manufacturers do, and the regulations stating this requirement mention the initiation of labeling changes.<sup>142</sup> “Implicit in these comments is the FDA’s expectation that generic manufacturers will initiate label changes other than those made to mirror changes to the brand-name label and that the agency will attempt to approve such proposals quickly.”<sup>143</sup> The Eighth Circuit also emphasized that nothing in the FDCA or the Hatch-Waxman Act “explicitly forbids [generics] from proposing a label change through the prior approval process.”<sup>144</sup>

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136. *Id.* at 608.

137. *Id.*

138. 21 C.F.R. § 201.57(e) (2010).

139. *Mensing*, 588 F.3d at 609.

140. *Id.* (citing *Wyeth v. Levine*, 129 S. Ct. 1187, 1202 (2009)).

141. *Id.* (citing Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,961 cmt.40 (Apr. 28, 1992) (to be codified at 21 C.F.R. pts. 2, 5, 10, 310, 320, 433) (emphasis added)).

142. *Id.* (citing Abbreviated New Drug Application Regulations, 57 Fed. Reg. at 17,965 cmt.53 (“ANDA applicants [must] submit a periodic report of adverse drug experiences even if the ANDA applicant has not received any adverse drug experience reports or initiated any labeling changes.”)).

143. *Id.*

144. *Id.*

The generic defendants had argued that the prior approval process under § 314.70 is for “major changes,” while the CBE procedure deals with merely enhanced warnings, but the court found this reading too limited.<sup>145</sup> Rather, the court declared that the section’s repeated use of “[t]hese changes include, but are not limited to,” to describe the kinds of changes that manufacturers can recommend suggests that the potential types of changes under each procedure may be quite broad and that neither Congress nor the FDA intended to prohibit generics from offering label changes for prior approval.<sup>146</sup> The Eighth Circuit also noted that generic companies could have recommended that the FDA send “Dear Doctor” letters to warn prescribing physicians of the risks of long-term Reglan use.<sup>147</sup>

The preemption issue in *Mensing* was whether generic manufacturers could comply with the state law duty to warn and the FDCA.<sup>148</sup> Because the district court did not know how the FDA would have responded had a generic manufacturer recommended a label change, it refrained from imposing liability.<sup>149</sup> The Eighth Circuit, however, guided by *Levine*, stated that ambiguity about the FDA’s reaction “makes federal preemption less likely.”<sup>150</sup> In this case, no clear evidence about the FDA’s potential response existed.<sup>151</sup> As in *Levine*, the Eighth Circuit doubted that “the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to the CBE regulation,”<sup>152</sup> and the generic manufacturers could not provide an example of the “FDA even threaten[ing] an enforcement action against a generic manufacturer for unilaterally enhancing its label warnings.”<sup>153</sup>

The Eighth Circuit also rejected the generic defendants’ policy argument concerning the expense of undertaking scientific studies required to make a label change.<sup>154</sup> The court first declared that if the generic companies realized that the label needed strengthening, but believed they lacked authority to do so, they could have simply stopped selling the drug.<sup>155</sup> The court also noted that no regulation

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145. *Id.*

146. *Id.* at 609–10 (citing 21 C.F.R. § 314.70(b)(2), (c)(2), (d)(2) (2010)).

147. *Id.* at 610.

148. *Id.*

149. *Id.*

150. *Id.* (citing *Wyeth v. Levine*, 129 S. Ct. 1187, 1198 (2009) (“[A]bsent clear evidence that the FDA would not have approved a change to [the drug’s] label, we will not conclude that it was impossible for [the manufacturer] to comply with both federal and state requirements.”)).

151. *Id.* at 611.

152. *Id.* at 610–11 n.6 (citing *Levine*, 129 S. Ct. at 1197).

153. *Id.*

154. *Id.* at 611–12.

155. *Id.* at 611.

mandates that manufacturers conduct expensive clinical studies.<sup>156</sup> Indeed, in *Levine*, the Supreme Court declared that even receiving multiple reports of an adverse drug reaction “provided the scientific substantiation to justify a manufacturer’s request to change a label.”<sup>157</sup> The Eighth Circuit found that because generic and brand-name manufacturers must track and report adverse drug events, they could change their labels based on those reports.<sup>158</sup>

Ultimately, the Eighth Circuit articulated its desire to hold someone responsible for Ms. Mensing’s injury, stating that “[the Hatch-Waxman Act] provided for cheaper, expedited approval of generic drugs, not relief from the fundamental requirement of the FDCA that all marketed drugs remain safe.”<sup>159</sup> The court added, “we decline to assume that Congress intended to shield from tort liability the manufacturers of the majority of the prescription drugs consumed in this country and leave injured parties like Mensing no legal remedy.”<sup>160</sup> However, the Eighth Circuit agreed with the *Foster* court that it could not hold the pioneer manufacturer liable for Ms. Mensing’s injury, and found that a “majority of courts considering this issue”<sup>161</sup> have ruled that “holding name brand manufacturers liable for harm caused by generic manufacturers ‘stretch[es] the concept of foreseeability too far.’”<sup>162</sup>

### C. Demahy: *Generic Manufacturer Bears the Loss*

In early 2010, the Fifth Circuit followed the reasoning of *Mensing* to decide a case on similar facts.<sup>163</sup> Julie Demahy sued Actavis, yet another generic manufacturer of metoclopramide, after

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156. *Id.* at 611–12.

157. *Id.* at 612 (citing *Levine*, 129 S. Ct. at 1197).

158. *Id.* (citing 21 C.F.R. §§ 314.80, 314.98 (2010)).

159. *Id.*

160. *Id.*

161. *Id.* at 613.

162. *Id.* (citing *Foster v. Am. Home Prods.*, 29 F.3d 165, 171 (4th Cir. 1994)). In late 2009, in *Couick v. Wyeth, Inc.*, another plaintiff sued both brand-name and generic manufacturers in district court for injuries resulting from her use of the generic form of Reglan. *Couick v. Wyeth, Inc.*, No. 3:09-cv-210-RJC-DSC, 2009 U.S. Dist. LEXIS 113943, at \*2 (W.D.N.C. Dec. 7, 2009). One of the defendants, generic manufacturer Actavis, made arguments similar to those by the generic defendants in *Mensing*, and the court, frequently citing *Mensing*, rejected these preemption arguments. *See id.* at \*6–10. After noting that “there are strong arguments on both sides regarding whether a generic drug manufacturer can use a CBE supplement to change its label,” the district court stated that Actavis could not show that federal law prevented it from making changes to its labels or warning physicians in some other way about the dangers of the drug. *Id.* at \*9–10. The district court did not reach the question whether generic manufacturers can avail themselves of the CBE procedure as a matter of law. *Id.* at \*13.

163. *See Demahy v. Actavis, Inc.*, 593 F.3d 428, 430 (5th Cir. 2010).

she, too, developed tardive dyskinesia as a result of taking the generic form of Reglan.<sup>164</sup> Actavis moved to dismiss, arguing that the claims were conflict preempted, but the district court denied the motion with respect to the failure-to-warn claims.<sup>165</sup> The Fifth Circuit affirmed, emphasizing the high bar required for preemption, which otherwise would “foreclose a remedy that was traditionally available and for which federal law provides no substitute.”<sup>166</sup>

The Fifth Circuit echoed the *Mensing* court’s reasoning that manufacturers, both generic and brand-name, bear responsibility for the accuracy of their warning labels and the safety of their products.<sup>167</sup> Agreeing with the expansive interpretation of generics’ power to change labels in *Mensing*, the Fifth Circuit noted that, at a minimum, the generic manufacturer should inform the FDA about new safety hazards associated with its product.<sup>168</sup> Actavis argued that if it changed the label on its own, it would risk FDA withdrawal of approval because its label would no longer mimic the brand-name label.<sup>169</sup> However, the court concluded that FDA regulations indicate that the threat of withdrawal of approval was meant to ensure that generic manufacturers continued to revise labels in accordance with changes brand-name manufacturers made, not to prevent generic manufacturers from strengthening their own labels.<sup>170</sup>

Demahy responded that Actavis could have complied with both FDA regulations and state warning laws by following the CBE process, the prior approval process, or by sending warnings directly to physicians.<sup>171</sup> On their face, neither the Hatch-Waxman Act nor the CBE regulation distinguishes generic from brand-name manufacturers or prohibits generic manufacturers from using the CBE procedure to change their labels unilaterally.<sup>172</sup> Ultimately, the FDA regulations are ambiguous because they do not discuss label changes post-approval.<sup>173</sup> The Fifth Circuit refused to read into the regulations a prohibition barring generic manufacturers from following the CBE process, which would indeed prevent generics from revising their labels.<sup>174</sup> Although Actavis contended that recent FDA

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164. *Id.*

165. *Id.*

166. *Id.* at 435, 449.

167. *Id.* at 437.

168. *Id.* at 438.

169. *Id.*

170. *Id.*

171. *Id.* at 439.

172. *Id.*

173. *Id.* at 441.

174. *Id.* at 444.

statements supported a preemption argument, the court responded, as had the *Mensing* court, that the FDA formally withdrew those statements after *Levine*.<sup>175</sup> The Fifth Circuit also refused to hold that the FDCA or the Hatch-Waxman Act prevented generics from participating in the prior approval process.<sup>176</sup> Finally, the court held that Actavis could have recommended that the FDA send “Dear Doctor” letters to prescribing physicians.<sup>177</sup> While manufacturers must receive prior approval from the FDA to send such letters, the FDA can send them “if it determines that they are a necessary part of a risk evaluation and mitigation strategy.”<sup>178</sup>

Actavis argued that conducting the studies necessary to justify a label change would subvert the purpose of the Hatch-Waxman Act, but the Fifth Circuit responded that no regulation mentions a requirement that drug manufacturers undertake such studies.<sup>179</sup> The court found that the FDA does not mandate a causal relationship before revising a label,<sup>180</sup> and, in fact, expects “reasonable evidence” to come from sources such as “new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses).”<sup>181</sup> Again following *Levine*, the *Demahy* court found insufficient evidence “to overcome the presumption against preemption; that is, there is no evidence sufficient for us to say that it was the ‘clear and manifest purpose’ of Congress to preempt state law, or to allow the FDA to do the same.”<sup>182</sup> The Fifth Circuit, raising the possibility of legislative action, concluded: “The preservation of our federalism requires Congress to do more than it—or the FDA—has chosen to do here . . . . The need for supplanting state duties here and the attendant calibration of costs and benefits are far beyond judicial ken . . . .”<sup>183</sup>

### III. PRESCRIPTION FOR CHANGE

As courts have now noted in many opinions, the label-change procedures available to generic manufacturers are ambiguous, leaving

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175. *Id.* at 443.

176. *Id.*

177. *Id.* at 444 (citing 21 U.S.C. § 355-1(i)(2) (2006)).

178. *Id.*

179. *Id.* at 447.

180. *Id.* (citing 21 C.F.R. §§ 201.80(e), 314.70(c)(6)(iii) (2010)).

181. *Id.* (citing Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biological and Medical Devices, 73 Fed. Reg. 49,603, 49,604 (Aug. 22, 2008) (to be codified at 21 C.F.R. pts. 314, 601, 814)).

182. *Id.* at 449.

183. *Id.*

courts to infer the intent of Congress and the FDA.<sup>184</sup> The California Court of Appeals has been rightly criticized for imposing, in *Conte*, liability on manufacturers for the deficient products of their generic competitors, and its holding raises questions about basic product liability principles.<sup>185</sup> The more recent opinions in the Fifth and Eighth Circuits<sup>186</sup> pose problems of their own by saddling liability on generic manufacturers that wield little or no control over label content, and by undermining the shortcuts Congress provided in the Hatch-Waxman Act.<sup>187</sup> The Supreme Court, after hearing argument in *Mensing* in March 2011,<sup>188</sup> could hold the generic manufacturers liable as the Fifth and Eighth Circuits have already done,<sup>189</sup> find the pioneer company liable as did the *Conte* court,<sup>190</sup> or determine that an injured plaintiff has no judicial recourse, thereby leaving Congress to remedy the situation.

Because the FDA requires many brand-name drug companies to conduct post-approval Phase IV studies to better quantify known problems and detect new risks not observed in the smaller-scale, pre-approval clinical trials,<sup>191</sup> generic manufacturers may possess less research data than the pioneer companies.<sup>192</sup> Generic drug companies cannot access brand-name Phase IV data when they begin selling their generic drugs<sup>193</sup> and they “never accumulate the universe of data regarding a particular drug product” that the FDA and the brand-name manufacturer possess.<sup>194</sup> Although generic drug companies keep records of adverse reactions reported to them after approval,<sup>195</sup> they possess far fewer resources than pioneer manufacturers.<sup>196</sup> Moreover, the high costs of litigation could increase the costs of generic medicines,<sup>197</sup> thus defeating an important purpose of the

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184. See discussion *supra* Part II.B–C.

185. See *supra* Part II.A.

186. See discussion *supra* Part II.B–C.

187. See *id.*

188. See *Activis Elizabeth, L.L.C. v Mensing*, SCOTUSBLOG, <http://www.scotusblog.com/case-files/cases/activis-elizabeth-v-mensing/> (last visited Jan. 29, 2011).

189. See discussion *supra* Part II.B–C.

190. See *supra* Part II.A.

191. 31 C.F.R. § 310.303.

192. Lars Noah, *Adding Insult to Injury: Paying for Harms Caused by a Competitor's Copycat Product*, 45 TORT TRIAL & INS. PRAC. L.J. 673, 682 (2010). See also Petition for Writ of Certiorari, *PLIVA, Inc. v. Mensing*, 130 S. Ct. 3349 (2010) (No. 09-993), 2010 WL 638478 at \*20–22 [hereinafter *PLIVA Petition for Writ*].

193. Noah, *supra* note 192, at 682.

194. *PLIVA Petition for Writ* at \*21.

195. *Id.* at \*20–21.

196. *Id.* at \*21.

197. See *id.*

Hatch-Waxman Act.<sup>198</sup> Given the reluctance by the judiciary to infer preemption in the absence of explicit congressional intent, Congress and the FDA should address these issues to provide fair and efficient compensation to those harmed by generic drugs, without undermining the intended benefits of the Hatch-Waxman Act.

Section A of this Part discusses how Congress and the FDA should authorize generic manufacturers to warn consumers of risks associated with their products. Section B of this Part proposes a novel solution to the dilemma of which manufacturer should shoulder liability for harm caused by generic drugs mimicking the brand-name label: a no-fault, government trust fund similar to the Vaccine Injury Compensation Fund.<sup>199</sup>

### A. Changing Procedures for Changing Labels

Judicial interpretations of various FDA statements reflect confusion over the extent to which generic manufacturers can amend warning labels on their own. Although the FDA had previously issued statements suggesting that generic manufacturers could not amend their warning labels on their own, the FDA withdrew them after *Levine*.<sup>200</sup> Because the FDA has not issued any clarification since *Levine*, generic manufacturers continue to argue preemption, leaving courts to divine the intent of Congress and the FDA from limited statutory and regulatory documents.<sup>201</sup>

Congress could follow one of two paths. First, Congress could expressly allow generic manufacturers to make labeling changes and provide explicit instructions for doing so. Second, Congress could

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198. Lockwood, *supra* note 2, at 147.

199. See 26 U.S.C. § 9510 (2006).

200. The FDA formally withdrew its amicus briefs in *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006), *aff'd in part, rev'd in part*, 521 F.3d 253 (3d Cir. 2008), *vacated*, 129 S. Ct. 1578 (2009). The other FDA statement was a footnote in the "Supplementary Information" section of a notice of proposed rulemaking for a regulation not pertaining to generic drugs, noting that "CBE changes are not available for generic drugs." Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2849 n.1 (proposed Jan. 16, 2008). The FDA likely withdrew these statements in response to a Presidential Memorandum entitled "Preemption" that President Obama sent to executive and department and agency heads on May 20, 2009. Lawrence S. Ebner, *President Obama's "Preemption Memo": Much to Do About Very Little*, LEGAL BACKGROUNDER, June 19, 2009. The memorandum was meant to ensure that any preemptive regulations, including those promulgated in the last decade, are "justified under legal principles governing preemption." *Id.* The memorandum also mandated that any intent to preempt state law must be issued in a "codified regulation" through notice-and-comment rulemaking, rather than in Federal Register regulations. *Id.*

201. See discussion *supra* Part II.



authorize the FDA to manage labeling and generate drug labels on its own.

### 1. Granting Generics More Control

Generic companies justify their reluctance to initiate label changes on their fear of liability for failure to warn, concern that FDA approval could be rescinded, and lack of complete information as to potential dangers of the drug.<sup>202</sup> To address these concerns, Congress could amend 21 C.F.R §§ 314.70 and 314.97 to explicitly allow generic manufacturers to initiate label changes through the prior approval process and the CBE procedure. A generic manufacturer who does not initiate a label change once a reasonably dangerous adverse reaction becomes known might then be held liable for a failure to warn.

This approach, however, is not ideal. As noted above, given their extensive pre- and post-approval clinical testing, brand-name manufacturers are better positioned to revise warning labels than generic drug companies, which must rely on sporadic adverse drug reports and meta-analyses of other clinical studies.<sup>203</sup> The potential for liability could also cause generics to initiate label changes for any remotely dangerous condition associated with the drug. This would lead to confusing differences in warning labels, not only between generics and brand-name drugs, but also among generics. As both the Hatch-Waxman Act and the longstanding FDA regulations recognize, all versions of the *same* drug should have the *same* label; different labels could cause doctor confusion.<sup>204</sup> Finally, these label changes require resources that might increase the costs of generic drugs, thus undermining the purpose behind making the drug approval process easier for generic drug companies.<sup>205</sup>

### 2. Granting Generics No Control

*Levine* appears to carve out an exception when the FDA compels a company to write a label a certain way, making it impossible for a company to deviate from that label, because Congress and the FDA endeavor to achieve an objective beyond an individual company.<sup>206</sup> Therefore, Congress could expressly delegate to the FDA the power to write all mandatory labels for generic drugs itself. The

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202. See generally Petition for Writ of Certiorari, *PLIVA, Inc.*, 130 S. Ct. 3349 (No. 09-993).

203. *Id.* at \*20–22.

204. See 21 U.S.C. § 355(j)(2)(A) (2006).

205. See Lockwood, *supra* note 2, at 147.

206. *Cf. Wyeth v. Levine*, 129 S. Ct. 1187, 1204 (2009).

FDA would consider all known information about the drug, including research done by the pioneer company and updates provided by generic manufacturers as they learn of adverse drug reactions. Committees within the FDA, as well as independent advisory committees, would monitor the updated information. The FDA would create a uniform label for all generic versions of a given drug. Using the FDA-mandated label would then preempt failure-to-warn claims.

Generic manufacturers would regularly report adverse reactions, the seriousness of which FDA advisory committees would evaluate and then determine the need for revisions. Although FDA administrative costs would increase somewhat, the improved safety of each generic drug label and the continued savings in generic prices would justify the added expense. The special case of generic drug labeling demands such a centralized approach.

### *B. Immunizing Manufacturers: The "Vaccine Trust Fund" Paradigm*

Because injured plaintiffs might lack a legal remedy if the FDA responds too slowly or otherwise fails to efficiently control all labeling, a trust fund similar to the Vaccine Injury Compensation Trust Fund<sup>207</sup> should complement the FDA-controlled labeling solution. This combination of approaches would allow injured plaintiffs to recover while maintaining the low costs of generic drugs and increasing the safety of drug labels.

In 1986, Congress responded to similar concerns about plaintiff compensation, where public health demanded quick drug development, by enacting the National Childhood Vaccine Injury Compensation Act ("Vaccine Act").<sup>208</sup> The Act responded to the decreasing supply of vaccines that resulted from increasing legal costs and the inability of vaccine manufacturers to acquire product liability insurance.<sup>209</sup> Congress intended the Vaccine Act to provide just compensation to those injured by vaccines while guaranteeing a steady supply of vaccines and protecting vaccine manufacturers from undue civil liability.<sup>210</sup> The Act created the National Vaccine Program, which allows federal officials to manage vaccine safety and research to increase the effectiveness of nationwide immunization.<sup>211</sup> Additionally, the Act established the National Childhood Vaccine

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207. 26 U.S.C. § 9510 (2006).

208. 42 U.S.C. § 300aa-1 to -34 (2006).

209. Gordon Shemin, Comment, *Mercury Rising: The Omnibus Autism Proceeding and What Families Should Know Before Rushing Out of Vaccine Court*, 58 AM. U. L. REV. 459, 470 (2008).

210. *Id.*

211. *Id.*

Injury Compensation Program, through which individuals injured by vaccines can obtain compensation.<sup>212</sup> The Act also established the Vaccine Adverse Event Reporting System (VAERS), implemented by the Centers for Disease Control and Prevention (CDC) and the FDA in 1990.<sup>213</sup> The VAERS is a “passive reporting system that allows the FDA and the CDC to monitor vaccines for possible new side effects, identify patient risk factors for side effects, and assess the safety of new vaccines.”<sup>214</sup>

If the vaccine alleged to have caused harm is in the Vaccine Injury Table, a plaintiff must start in Vaccine Court, the judicial body that determines whether an injured patient qualifies for compensation.<sup>215</sup> To succeed, a petitioner or his representative must demonstrate that he “received a vaccine set forth in the Vaccine Injury Table,”<sup>216</sup> that he received the vaccine in the United States;<sup>217</sup> and that he “suffered the residual effects or complications” from the injury for more than six months, “died from the administration of the vaccine,” or his injury resulted in “hospitalization and surgical intervention.”<sup>218</sup> Claimants must file an action within thirty-six months of “the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury.”<sup>219</sup> Most importantly, the Vaccine Act preempts state law claims against vaccine manufacturers for vaccine-related injuries “unless a petitioner has exhausted his remedies under the Vaccine Act.”<sup>220</sup> If a claimant later sues in civil court, the Act modifies state

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212. *Id.* at 470–71.

213. JAMES R. COPLAND & PAUL HOWARD, IN THE WAKE OF *WYETH V. LEVINE*: MAKING THE CASE FOR FDA PREEMPTION AND ADMINISTRATIVE COMPENSATION 12 (2009), available at [http://www.manhattan-institute.org/html/fda\\_01.htm](http://www.manhattan-institute.org/html/fda_01.htm).

214. *Id.* More than 30,000 VAERS reports are submitted each year. *Id.*

215. *Id.*

216. 42 U.S.C. § 300aa-11(c)(1)(A) (2006).

217. *Id.* § 300aa-11(c)(1)(B)(i)(I).

218. *Id.* § 300aa-11(c)(1)(D).

219. *Id.* § 300aa-16(a)(2). If the claim alleges that a vaccine caused death, the estate must bring the action within twenty-four months of death, and within forty-eight months of the onset of the original symptoms leading to death. *Id.* § 300aa-16(a)(3).

220. Shemin, *supra* note 209, at 472. The Vaccine Act provides: “No person may bring a civil action for damages in an amount greater than \$1,000 . . . against a vaccine administrator or a manufacturer in a State or Federal court for damages arising from a vaccine-related injury . . . unless a petition has been filed, in accordance with section 300aa-16 of this title . . .” and the United States Court of Federal Claims has issued a judgment under § 12 and the petitioner rejects the judgment under § 21(a). 42 U.S.C. § 300aa-11(a)(2)(A). If an injured individual files a civil action in federal or state court, under § 11(a)(2)(B) of the Vaccine Act, that court must dismiss the claim until the vaccinee exhausts his or her remedies under the Vaccine Program. *Id.* § 300aa-11(a)(2)(B) (instructing the receiving court to dismiss the petition).

tort law to create additional protection for defendant vaccine manufacturers.<sup>221</sup>

The Act allows for claims based on the Vaccine Injury Table,<sup>222</sup> as well as “off-table” claims.<sup>223</sup> The Vaccine Injury Table lists the vaccines that the Act explicitly covers, the injuries associated with each vaccine, and the time periods in which the first symptoms must occur.<sup>224</sup> Meeting the requirements in the Table entitles the claimants to a rebuttable presumption that the vaccine caused his injury.<sup>225</sup> If the injury does not fall within the Table, a claimant can bring suit “off-table” and recover if he demonstrates by a preponderance of the evidence that the vaccine actually caused the harm.<sup>226</sup> An off-table claimant does not enjoy the causation presumption, rendering his claim more speculative.<sup>227</sup> A successful claimant, whether on-table or off, can recover medical expenses, lost wages, future medical care costs, and up to \$250,000 in damages for pain and suffering.<sup>228</sup> However, plaintiffs cannot claim punitive damages and “[i]n the event of a vaccine-related death, [the Vaccine Act provides for] an award of \$250,000 for the estate of the deceased.”<sup>229</sup> Compensation comes from the Vaccine Injury Compensation Trust Fund, which the Treasury Department oversees and funds with a seventy-five cent tax on each dose of the covered vaccines.<sup>230</sup>

After the Vaccine Court enters a judgment, the claimant has ninety days to decide whether to accept or reject the determination.<sup>231</sup> If he accepts, the Act precludes him from bringing a civil lawsuit, and, in fact, few petitioners reject favorable judgments from the court.<sup>232</sup> If he rejects the judgment, or if the court fails to make a decision within

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221. *Id.* § 300aa-22(b)(1) prohibits awarding compensation for injuries from “unavoidable” side effects of vaccines; § 300aa-22(b)(2) establishes a presumption that the manufacturer complied with FDA requirements for appropriate directions and warnings, and § 300aa-22(c) forbids holding the manufacturer liable for failure to warn an injured claimant. 42 U.S.C. § 300aa-22. A compensation claim must include an affidavit and supporting documentation such as “maternal prenatal and delivery records, newborn hospital records . . . , vaccination records associated with the vaccine allegedly causing the injury, pre-and post-injury physician or clinic records . . . [and] if applicable, a death certificate, and . . . autopsy results.” *Id.* § 300aa-11(c).

222. 42 U.S.C. § 300aa-14; 42 C.F.R. § 100.3(a) (2010).

223. Shemin, *supra* note 209, at 475.

224. 42 C.F.R. § 100.3(a).

225. Shemin, *supra* note 209, at 475.

226. *Id.* at 475–76.

227. *Id.* at 476.

228. 42 U.S.C. § 300aa-15(a) (2006).

229. *Id.* § 300aa-15(a)(2), (d)(1).

230. Shemin, *supra* note 209, at 477.

231. 42 U.S.C. § 300aa-21(a).

232. Shemin, *supra* note 209, at 477.

240 days, he may bring a civil lawsuit.<sup>233</sup> After a judgment by the Vaccine Court, either the claimant or the government can appeal the decision to the U.S. Court of Federal Claims, and beyond that to the U.S. Court of Appeals for the Federal Circuit.<sup>234</sup>

Between 1990 and 2009, the compensation program paid out over \$913 million on 1,086 compensated claims, suggesting substantial awards (about \$900,000 on average) for a fairly small number of children with serious injuries.<sup>235</sup> Significantly, only 3% of the money paid was spent on attorneys' fees and 11% on administrative costs, resulting in a reduction in transaction costs by some 56% compared to the tort system.<sup>236</sup>

Commentators have suggested the wholesale substitution of a system similar to the Vaccine Act for tort liability involving prescription drugs, allowing for preemption of all claims against drug manufacturers.<sup>237</sup> Such an approach, however, unwisely and unnecessarily includes pioneer drug manufacturers who enjoy both a legal patent monopoly and exclusive access to clinical studies and post-marketing adverse drug reaction data. Once an innovator's patent expires, however, the responsibility fragments among many generic firms, as mandated by Congress and coordinated by the FDA. The policy of basing label changes on science and ensuring consistency among bioequivalent compounds suggests that the FDA should assume the role of "labeler-in-chief." In such a world, a compensation trust fund could provide a remedy for injured individuals while allowing generic manufacturers to continue producing cheap drugs as desired under the Act.

Following the template of the vaccine program, a compensation trust fund for individuals injured by drugs produced by generic manufacturers should carefully craft classes of covered individuals, compensate only unforeseen adverse reactions with minor taxes on generic drugs, cap compensation, bar punitive damages, and offer the right to accept or appeal judgments.

A government-run compensation fund could prove successful in the context of generic drugs because, in certain critical respects, generic drugs resemble vaccines. Both have great public health benefits; both are tested, developed, and marketed under thorough FDA regulation; and both benefit the public more when promptly

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233. Wendy N. Davis, *The Immune Response: The Supreme Court May Tell Families with Autistic Children Whether They Can Sue Vaccine Makers*, ABA JOURNAL, Oct. 2010, at 51.

234. 42 U.S.C. § 300aa-12(e), 12(f).

235. COPLAND & HOWARD, *supra* note 213, at 13.

236. *Id.* (internal quotation marks omitted).

237. See *id.* at i ("We recommend that Congress broadly preempt state tort lawsuits seeking to hold drugs and medical devices responsible for claimants' illnesses and injuries.").

approved and competitively priced. However, where vaccines typically prevent disease, drugs generally treat disease, rendering causation difficult to determine because many confounding factors could contribute to an adverse reaction. Legislators therefore need to carefully craft classes of covered plaintiffs and injuries. Overcompensation could cause pharmaceutical manufacturers to decide against researching treatment of certain diseases if the risk of injury and resulting compensation becomes too great.<sup>238</sup> Because these claims could be very complicated factually, legislators would also need to account for under-compensation in creating injury tables for plaintiffs.

The fund should only compensate individuals for unforeseen adverse reactions, which would encourage manufacturers to tell the FDA about side effects they discovered during normal use.<sup>239</sup> Conversely, the fund should not compensate patients harmed by foreseeable side effects that manufacturers had already warned about on the label.<sup>240</sup> To discourage manufacturers from adding too many warnings—and risking information overload—this system would best work in conjunction with the proposal above, whereby the FDA would issue a single mandatory label for all generic versions of the same drug, and that label would result from careful monitoring of adverse drug reactions submitted by generic manufacturers. The FDA would create and update an injury compensation table, taking into account the probability of such injuries given other confounding factors presented by an injured individual. Patients who ingested the drug before the side effect appeared on the label could file a claim for compensation.

Claimants would need to prove that the drug caused their injury, and a newly constituted Generic Drug Court would consider the risk factors of the drug in addition to confounding factors—such as age, weight, smoking history, and preexisting conditions—specific to that individual. Compensation for a successful claim would include medical expenses, lost wages, future medical care costs, and a maximum of \$250,000 in pain and suffering. In the event of death, the deceased's estate could recover a comparable sum. Small taxes per generic drug dose would fund the trust to compensate successful claimants. To avoid conflicts of interest, the adjudicative body determining compensation should not include any federal personnel who play a part in creating the original labeling.<sup>241</sup> As with the

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238. *Cf. id.*

239. *Id.* at 14.

240. *Id.*

241. *Id.* at 15.

Vaccine Fund, plaintiffs would elect to accept or reject a favorable judgment, and either party could appeal judgments to the U.S. Court of Federal Claims, and subsequently to the U.S. Court of Appeals for the Federal Circuit.

#### IV. CONCLUSION

Both brand-name and generic drug manufacturers provide important health benefits to society. Pioneer companies undertake the expensive research and clinical trials necessary to engineer new drugs, while generic companies provide inexpensive drugs to the American public. Because the Hatch-Waxman Act requires that generic drug applications include warning labels identical to that of the brand-name drug, plaintiffs injured by the generic version often sue both pioneer and generic drug manufacturers for damages.

*Mensing* and *Demahy*, however, recognized the injustice of holding a brand-name manufacturer liable for failing to warn a patient who, as in *Conte*, never consumed that manufacturer's product.<sup>242</sup> Assigning liability to the generic drug manufacturer for failure to warn also seems unjust, because the FDA mandates that labels of generics must match those of brand-name drugs. Moreover, forcing generic drug manufacturers to pay plaintiffs will increase the costs of generic drugs—contrary to the purpose of the Hatch-Waxman Act.

Congress could direct the FDA to explicitly allow generic drug manufacturers to initiate label changes, but generic drug companies do not enjoy the informational advantages pioneer companies possess.<sup>243</sup> Additionally, forcing generic drug manufacturers to defend against failure-to-warn claims, as well as any resulting judgments, could dramatically increase the cost of generic drugs. Instead, the FDA should control all generic labeling, combining clinical data from the brand-name drug manufacturers with adverse drug reaction reports from the generic companies to determine when side effects warrant a revised label. Using the label mandated by the FDA would then preempt failure-to-warn claims.

In conjunction with FDA-controlled labeling, a federal trust similar to the Vaccine Injury Compensation Trust Fund would allow injured plaintiffs to recover damages according to a compensation grid after agency review of other risk factors for the alleged injury. A compensation trust fund could provide a remedy for injured

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242. See *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010); *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009); *Conte v. Wyeth, Inc.*, 85 Cal Rptr. 3d 299 (Cal. Ct. App. 2008).

243. See *supra* text accompanying notes 192–197, 202–203.

individuals, vindicating the Fifth and Eighth Circuits' policy of providing for plaintiffs, while allowing generic manufacturers to continue generating inexpensive pharmaceuticals for the public. The special case of generic drug labeling demands a universal and comprehensive solution.

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