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## Generic Pharmaceuticals and the "Unfortunate Hand" Dealt to Harmed Consumers: The Emerging State Court Resistance

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# Generic Pharmaceuticals and the “Unfortunate Hand” Dealt to Harmed Consumers: The Emerging State Court Resistance

Arlen W. Langvardt\*

## ABSTRACT

*Federal drug regulation law calls for United States Food and Drug Administration (FDA) approval of prescription medications but does not contain a provision expressly preempting tort claims by plaintiffs who claim to have been harmed by such medications. After three Supreme Court decisions during the past six years, whether a patient harmed by a prescription medication can pursue failure-to-warn and design-defect claims against the drug’s manufacturer depends largely on a happenstance: whether the pharmacist who filled the patient’s prescription dispensed a brand-name medication or, instead, its generic equivalent. Wyeth v. Levine (2009) established that such claims may go forward—in other words, they are not preempted by federal law—if the harm-causing medication used by the plaintiff was an FDA-approved brand name drug. But in PLIVA, Inc. v. Mensing (2011) and Mutual Pharmaceutical Co. v. Bartlett (2013), the Court ruled that federal law impliedly preempts such claims if the plaintiff’s harm stemmed from using an FDA-approved generic equivalent of the brand name drug.*

*The Court sought to shift blame for this odd state of affairs, lamenting that Congress had dealt an “unfortunate hand” to consumers harmed by generics. However, as this Article will reveal, the Court’s strained application of preemption principles served as the real culprit. Of course, lower federal and state courts, along with harmed consumers, are stuck with the*

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*Court's rulings. Congressional action that might remedy the Mensing-Bartlett "unfortunate hand" is extremely unlikely. A proposed FDA regulation that seemed promising has remained in limbo for a lengthy period of time and appears to have waning prospects of promulgation.*

*Interpreting Mensing and Bartlett broadly, the lower federal courts have ruled that almost all state-law-based claims by harmed consumers against generic manufacturers are preempted or otherwise ineligible to go forward. State courts, however, have shown a much stronger tendency to resist an overly broad reading of Mensing and Bartlett and to identify ways that respect those precedents but allow room for certain state-law-based claims against generic manufacturers to escape preemption. As this Article will explain, the state court resistance to the Mensing-Bartlett steamroller has produced sensible approaches applicable to certain claims against generic manufacturers, as well as others—such as permitting consumers harmed by generics to sue the relevant brand name manufacturer—that reflect laudable intentions but are inadvisable. This Article sorts out the responses that have made up the state court resistance and explores well-reasoned, justifiable approaches that can permit certain claims against generic manufacturers to escape Mensing-Bartlett's seemingly broad preemptive sweep. In the process, harmed consumers can be afforded partial relief from the "unfortunate hand."*

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## INTRODUCTION

After patents on brand-name medications expire, generic versions of those drugs may emerge and develop significant shares of the relevant market.<sup>1</sup> Generic versions (hereinafter “generics”) have proliferated in recent years and now account for roughly seventy-five percent of filled prescriptions.<sup>2</sup> Legislation designed to further drug-cost-reduction and enhancement-of-competition objectives has helped to bring about that development.<sup>3</sup>

Although federal law provides that new drugs cannot be placed on the market until they pass a rigorous safety-and-effectiveness review by the United States Food and Drug Administration (FDA),<sup>4</sup> Congress exempted generics from this time-consuming and expensive obligation in a 1984 enactment commonly known as the Hatch-Waxman Act.<sup>5</sup> Hatch-Waxman

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1. See 35 U.S.C. § 154 (2012) (establishing general principles regarding patent rights and duration). As will be seen, federal and state laws have played key roles in encouraging the marketplace presence of generic versions of brand-name drugs. See *infra* text accompanying notes 4–9, 58–66.

2. See, e.g., *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2583 (2011) (Sotomayor, J., dissenting).

3. See *id.* at 2574, 2581 (majority opinion); see also *id.* at 2583–84 (Sotomayor, J., dissenting) (discussing roles played by the Hatch-Waxman Act and state statutes in the proliferation of generics).

4. See 21 U.S.C. § 355(b)(1), (d) (2012). For further discussion of the new drug approval process, see *infra* text accompanying notes 38–57.

5. See *Mensing*, 131 S. Ct. at 2570.

specified that producers of generics need only show, as a precondition of sale, that their product is equivalent to the corresponding brand-name versions previously approved by the FDA.<sup>6</sup> This less burdensome pre-sale requirement has operated to increase the likelihood that generics are brought to market.<sup>7</sup>

State statutes, moreover, have been instrumental in helping generics gain market share once they arrive on the scene. State laws routinely permit, and sometimes even require, pharmacists to substitute generics for brand-name drugs prescribed by a physician unless the physician has specifically barred such a substitution.<sup>8</sup> Pharmacists often dispense generics because they tend to be less expensive than their brand-name counterparts (certainly less expensive than the brand-name drugs were when they were still under patent) and because they may be covered more advantageously by the patient's health insurance plan.<sup>9</sup>

For patients, then, one might say "so far, so good"—even if the brand-name-versus-generic choice tends to be made for them rather than by them.<sup>10</sup> If the generic is cheaper, choosing it would seem to be in the patient's interest. Presumably even better from a bang-for-the-buck perspective, the less expensive generic should be as safe and effective as the brand-name drug because, as noted earlier, federal law requires that generics be equivalent to the relevant brand-name versions that have already received FDA approval.<sup>11</sup>

What seems a rosy generics picture becomes far less so, however, for certain patients: those who experienced harm after using the generics they received when their prescriptions were filled. They have been dealt an "unfortunate hand,"

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6. Both chemical equivalence and bioequivalence are required. See 21 U.S.C. § 355(j)(2)(A) (2012). For further discussion of Hatch-Waxman and its provisions concerning generics, see *infra* text accompanying notes 61–66.

7. See *Mensing*, 131 S. Ct. at 2574, 2581; *id.* at 2583–84 (Sotomayor, J., dissenting).

8. See *id.* at 2583–84 (Sotomayor, J., dissenting); Stacey B. Lee, PLIVA v. Mensing, *Generic Consumers' Unfortunate Hand*, 12 YALE J. HEALTH POL'Y L. & ETHICS 209, 238 (2012).

9. See *Mensing*, 131 S. Ct. 2583–84.

10. Some states, but clearly not all, require patient consent in order for a generic to be dispensed. See *id.* at 2583. Saying that pharmacists "often" dispense a generic is probably an understatement. When a generic is available, pharmacists dispense it, rather than the brand name medication, approximately ninety percent of the time. *Id.* at 2584.

11. See 21 U.S.C. § 355(j)(2)(A).

according to the U.S. Supreme Court.<sup>12</sup> To understand why, one must consider a trilogy of Supreme Court decisions dealing with the extent to which federal drug regulation law preempts state-law-based tort claims.

The first of the three cases, *Wyeth v. Levine*,<sup>13</sup> turned out well for the plaintiff. In that 2009 decision, the Court rejected the drug manufacturer's preemption defense and permitted the plaintiff's failure-to-warn claim to proceed, even though the tort claim contemplated a supposed need for a stronger warning than the one set forth in the drug label approved by the FDA during the new-drug-approval process.<sup>14</sup> Importantly, however, *Levine* involved a brand-name drug, not a generic.<sup>15</sup>

Two years after *Levine*, the Court decided another case involving a failure-to-warn claim against a drug maker. In *PLIVA, Inc. v. Mensing*,<sup>16</sup> a five-justice majority held that federal law preempted the plaintiff's failure-to-warn claim despite its similarity to the claim in *Levine*.<sup>17</sup> The case involved a generic rather than a brand-name drug—a critical difference for the Court, which placed great emphasis on the duty of “sameness” imposed by the Hatch-Waxman Act.<sup>18</sup> That duty, the majority reasoned, prohibited the generic manufacturer from adding to or otherwise departing from the text of the drug label approved by the FDA for the brand-name version some years earlier.<sup>19</sup> The Court also stressed that generic manufacturers are not entitled to take an action that brand-name manufacturers such as the one in *Levine* can sometimes take: strengthening warnings in the FDA-approved label and then going back to the FDA for approval of the changed label.<sup>20</sup> Hence, in the *Mensing* majority's view, preemption applied because it was impossible for the defendant to provide what the plaintiff's state-law-based claim contemplated (a stronger warning) and remain in compliance with federal law, which barred the defendant from altering the FDA-approved label.<sup>21</sup>

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12. *Mensing*, 131 S. Ct. at 2581.

13. *Wyeth v. Levine*, 555 U.S. 555 (2009).

14. *Id.* at 568–71, 574–76, 578–81.

15. *Id.* at 558–59.

16. *Mensing*, 131 S. Ct. at 2567.

17. *Id.* at 2572, 2577–78, 2580–81.

18. *Id.* at 2572, 2574–75, 2582.

19. *Id.* at 2577–78.

20. *Id.* at 2575–76.

21. *Id.* at 2577–78.

The third case in the trilogy, *Mutual Pharmaceutical Co. v. Bartlett*,<sup>22</sup> also involved a generic. In that 2013 decision, the same five-justice majority that had decided *Mensing* again stressed the duty of sameness contemplated by federal law and held that the impossibility doctrine required preemption of the plaintiff's design-defect claim.<sup>23</sup> The Court reasoned that under federal law, the generic manufacturer could not depart from the FDA-approved formulation for the drug and, as in *Mensing*, could not change the content of the FDA-approved product label.<sup>24</sup>

After *Mensing* and *Bartlett*, therefore, whether a patient harmed by a prescription medication can seek to make out tort claims against the drug's manufacturer will depend largely upon the "happenstance" of whether the pharmacist filled the prescription with the brand-name medication or, instead, a generic.<sup>25</sup> If the former, tort claims are not preempted.<sup>26</sup> If the latter, preemption is triggered—causing the patient who often had no choice in the matter to lose certain potentially important rights.<sup>27</sup> Those who received generics, therefore, have been dealt what Justice Thomas, in his *Mensing* majority opinion, termed an "unfortunate hand."<sup>28</sup>

In *Mensing* and *Bartlett*, the Court sought to lay the blame on Congress.<sup>29</sup> Each majority opinion asserted that federal drug regulation law left the Court no choice but to issue its preemption rulings; each opinion reminded readers that Congress, or possibly the FDA, could decide to take action to ameliorate the preemption problem that the Court supposedly

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22. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

23. *Id.* at 2470, 2475, 2476–77, 2479.

24. *Id.* at 2475, 2479.

25. *Mensing*, 131 S. Ct. at 2583 (2011) (Sotomayor, J., dissenting). Justice Thomas conceded as much in his *Mensing* majority opinion, but emphasized that the federal drug regulation statutes contemplated such an outcome. *See id.* at 2581–82. He also acknowledged that the plaintiffs in *Mensing* and a case joined with it for decision purposes would see "little sense" in their cases' outcome, insofar as it hinged on their having received a generic rather than a brand name medication. *Id.* at 2581.

26. *Bartlett*, 133 S. Ct. at 2480. *Mensing*, 131 S. Ct. at 2581.

27. *Compare* *Wyeth v. Levine*, 555 U.S. 555, 558–59, 568–71, 574–76, 578–81 (2009) (failure-to-warn claim against brand-name manufacturer not preempted), *with* *Mensing*, 131 S. Ct. at 2581–82 (failure-to-warn claim against generic manufacturer preempted).

28. *Mensing*, 131 S. Ct. at 2581.

29. *Bartlett*, 133 S. Ct. at 2480; *see* *Mensing*, 131 S. Ct. at 2581–82.

was powerless to head off.<sup>30</sup> For the dissenters in *Mensing* and *Bartlett*, the majority's blame-it-on-Congress excuse rang hollow. They criticized the majority for adopting an overly broad version of the impossibility doctrine and for failing to consider whether the results reached in the two decisions were consistent with what Congress would have wanted.<sup>31</sup>

Whatever the relative merits of the competing arguments in *Mensing* and *Bartlett*, the prevalence of generics in the marketplace<sup>32</sup> means that the preemption holdings in those cases potentially affect far more would-be plaintiffs than does the plaintiff-friendly holding in *Levine*.<sup>33</sup> After *Mensing* and *Bartlett*, state tort law will have a significantly diminished role to play unless: (a) Congress or the FDA meaningfully changes the rules the Supreme Court interpreted in *Mensing* and *Bartlett* as having sweeping preemptive effect,<sup>34</sup> or (b) state courts interpret *Mensing* and *Bartlett* narrowly and recognize varieties of tort claims that can plausibly avoid preemption.<sup>35</sup>

Prospect (a) might occur if a proposed FDA regulation that has long remained stalled were to overcome objections from generic manufacturers, achieve final rule status, and be interpreted by the courts as an outcome-altering countermeasure to the *Mensing-Bartlett* rationale. As later discussion will reveal, however, those "ifs" pose significant obstacles that leave the proposed regulation's ultimate fate uncertain at best.<sup>36</sup> This Article, accordingly, places greater

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30. See *Bartlett*, 133 S. Ct. at 2480; *Mensing*, 131 S. Ct. at 2581.

31. See *Bartlett*, 133 S. Ct. at 2480–81, 2482 (Breyer, J., dissenting); *Bartlett*, 133 S. Ct. at 2483–84, 2485–86, 2494–95 (Sotomayor, J., dissenting); *Mensing*, 131 S. Ct. at 2582–83, 2586–87, 2589, 2592–93 (Sotomayor, J., dissenting).

32. See *supra* text accompanying notes 8–9; *supra* note 10.

33. See *Wyeth v. Levine*, 555 U.S. 555, 568–71, 574–76, 578–81 (2009). The *Levine* dissenters lost the brand-name medications battle over whether tort claims should be preempted, but they won the corresponding generics battle in the *Mensing-Bartlett* tandem and gained a clear advantage in the larger war over whether the federal regulatory role as to pharmaceuticals leaves room for regulation under state law. See *infra* text accompanying notes 211–14.

34. See *Bartlett*, 133 S. Ct. at 2480 (offering such an indication regarding action by Congress); see also *Mensing*, 131 S. Ct. at 2581 (indicating that action by Congress or the FDA might change the analysis).

35. Of course, state law could have a greater role to play if the Supreme Court were to overrule *Mensing* and *Bartlett*, but such a development seems unlikely.

36. See *infra* notes 234, 268.



emphasis on prospect (b) and the role state courts may play in responding appropriately, yet assertively, to *Mensing* and *Bartlett*, so that the “hand” dealt to patients harmed by generics is sometimes less “unfortunate” than the *Mensing-Bartlett* duo might suggest. As will be seen, state courts appear to be warming up to the task by not always giving *Mensing* and *Bartlett* the sweeping effect that lower federal courts have tended to give those decisions.<sup>37</sup>

Section II of the Article will furnish background on the statutes and regulations dealing with FDA oversight of pharmaceuticals. In addition, Section II will discuss relevant Supreme Court decisions, most notably the pharmaceuticals trilogy (*Levine*, *Mensing*, and *Bartlett*). Section III will analyze and assess the decisions in the trilogy and will summarize applications of those decisions by the federal courts of appeal. Section IV will examine cases in which state courts, seemingly not willing to succumb to *Mensing-Bartlett*’s potential steamrolling effect, have sought to carve out tort claims that would escape preemption. Section V will assess those efforts and consider the plausibility or implausibility of the legal theories they have offered. Section V will also offer recommendations for further action, in the wake of *Mensing-Bartlett*, to achieve a suitable balance between the federal and state roles in regulating pharmaceuticals and protecting consumers who experience harm as a result of using them.

## I. FDA REGULATION AND KEY SUPREME COURT DECISIONS

### A. THE NDA PROCESS AND RELATED ISSUES

The Federal Food, Drug, and Cosmetic Act (FDCA) bars manufacturers of pharmaceuticals from introducing any drug into the marketplace until the necessary approval has been obtained from the FDA.<sup>38</sup> Truly new drugs must clear the New Drug Approval (NDA) hurdle.<sup>39</sup> Because the brand-name medications referred to in the Article’s introduction fit within the new drugs category, this discussion will employ the terms

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37. See *infra* text accompanying notes 337–604.

38. 21 U.S.C. § 355(a) (2012).

39. *Id.* § 355(b).

“brand-name medications” (or “brand-name drugs”) and “new drugs” interchangeably.

The NDA process calls for rigorous FDA review and is both time-consuming and expensive for manufacturers of new drugs.<sup>40</sup> These manufacturers must compile and submit voluminous materials that include the results of extensive clinical studies and other information bearing upon the safety and effectiveness of the drug under review.<sup>41</sup> They must also submit the label they propose to use for their drug, because FDA approval of the label’s exact text is required.<sup>42</sup> If the FDA concludes that the new drug is “safe for use” for the purposes described in the NDA and under the conditions contemplated by the proposed label, approval of the NDA will be granted.<sup>43</sup>

Once a brand-name drug and its label have received the requisite approval, the manufacturer cannot change the drug formulation, including its active ingredients, in any meaningful way unless the FDA approves the change.<sup>44</sup> As a general rule, the manufacturer of the brand-name medication cannot modify the approved label without submitting a supplemental application to the FDA and receiving the agency’s prior approval.<sup>45</sup> However, if later-acquired information potentially bearing upon the drug’s safety causes the manufacturer to believe that a label with a stronger warning is necessary, the manufacturer may begin using the strengthened label and simultaneously request FDA approval for the change.<sup>46</sup> An FDA regulation known as the “changes being effected” (CBE) regulation authorizes the brand-name manufacturer to utilize this exception to the general rule that a label change requires prior FDA approval.<sup>47</sup>

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40. See, e.g., *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 (2011).

41. See 21 U.S.C. § 355(b).

42. *Id.* § 355(b)(1)(F).

43. *Id.* § 355(d).

44. 21 C.F.R. § 314.70(b)(2)(i) (2015); *Bartlett*, 133 S. Ct. at 2471.

45. 21 U.S.C. § 355(b)(1)(F) (2012); *Wyeth v. Levine*, 555 U.S. 555, 568 (2009).

46. *Levine*, 555 U.S. at 568.

47. 21 C.F.R. § 314.70(c)(6)(iii)(A) (2015). The option provided by the CBE regulation proved to be important in *Levine*. See *Levine*, 555 U.S. at 568–70. For discussion of *Levine*, see *infra* text accompanying notes 68–127. The FDA has taken the position that the CBE regulation permits only brand-name manufacturers, not manufacturers of generics, to strengthen the approved label’s warnings without the FDA’s prior approval. See *PLIVA, Inc. v.*

Even though a drug label has received FDA approval, drug makers have a continuing duty to make sure the label provides adequate warnings in the event that significant safety-related information becomes known after approval of the label.<sup>48</sup> This duty stems from the federal misbranding statute, which provides that a drug is “misbranded” if its label does not contain “adequate warnings” against unsafe dosages of the medication or unsafe methods or duration of administration.<sup>49</sup> Accordingly, the FDA has concluded, drug makers that acquire important safety-related information after the drug is on the market are obligated to petition the agency for approval of a strengthened label if the previously approved one is no longer adequate.<sup>50</sup> This petitioning of the FDA must take place before the drug manufacturer begins to use the revised label, unless the drug maker is a brand-name manufacturer and has chosen to pursue the CBE route referred to earlier.<sup>51</sup> Although the FDA takes the position that the existing CBE regulation cannot be invoked by manufacturers of generics,<sup>52</sup> it regards the duty stemming from the misbranding statute to apply to all drug makers, whether of brand-name medications or of generics.<sup>53</sup>

Until fairly recent years, the FDA could not actually order use of a particular strengthened label even when a proper request for a revised label had been made.<sup>54</sup> Rather, the FDA had to work with the brand-name manufacturer to reach an agreement on the text of a revised label.<sup>55</sup> A 2007 statutory amendment, however, granted the FDA greater authority.<sup>56</sup> Now, when later-acquired safety information warrants, the FDA may order the brand-name manufacturer to revise the label in accordance with FDA instructions regarding content,

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Mensing, 131 S. Ct. 2567, 2575 (2011). A proposed FDA regulation, if promulgated, would make the CBE option available to manufacturers of generics. For discussion of that proposed regulation, see *infra* notes 234, 268.

48. See 21 C.F.R. §§ 201.80(e), 314.80(b) (2015); *Levine*, 555 U.S. at 570–71.

49. 21 U.S.C. § 352(f)(2) (2012); *Mensing*, 131 S. Ct. at 2576.

50. 21 C.F.R. § 201.57(e) (2005); *Levine*, 555 U.S. at 570–71.

51. *Mensing*, 131 S. Ct. at 2575–76; *Levine*, 555 U.S. at 570–71.

52. *Mensing*, 131 S. Ct. at 2575.

53. *Id.* at 2576–77.

54. See *Levine*, 555 U.S. at 567.

55. *Id.* at 567, 571.

56. *Id.* at 567.

regardless of whether the manufacturer agrees with the specific textual changes.<sup>57</sup>

## B. THE ANDA PROCESS AND RELATED ISSUES

General principles of patent law establish that the expiration of a patent on a name-brand drug entitles competitors of the drug to enter the marketplace with generics—medications having the same formulation as the formerly patented medication.<sup>58</sup> Prior to 1984, however, the time-consuming and expensive FDA approval requirement described above applied to all drugs (generics included).<sup>59</sup> This requirement made the production of generics a less attractive venture than it might have been.<sup>60</sup>

The regulatory environment for generics changed in 1984, however. In that year's Hatch-Waxman Act, Congress sought to make the regulatory approval process less burdensome and less expensive for generics (and thereby increase the likelihood that generics would enter the marketplace and compete with brand-name drugs).<sup>61</sup> Hatch-Waxman exempted generics from the NDA review that truly new drugs must undergo.<sup>62</sup> Rather than requiring producers of generics to conduct extensive clinical trials of the sort necessary for initial approval of a drug, Hatch-Waxman provided that makers of generics need only demonstrate to the FDA, through the Abbreviated New Drug Approval (ANDA) process, that their versions of the medications are equivalent to the brand-name drug previously approved by the agency.<sup>63</sup> With its focus being on equivalence, as opposed to the safety and effectiveness issues already

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57. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823, 924–26 (2007) (codified at 21 U.S.C. § 355(o)(4) (2012)). See *Levine*, 555 U.S. at 567, 571.

58. See 35 U.S.C. §§ 154, 171 (2012).

59. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 (2011).

60. See *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013).

61. See *id.*; *Mensing*, 131 S. Ct. at 2574.

62. 21 U.S.C. § 355(j)(2)(A) (2012).

63. *Id.* The requisite equivalence has two mandatory components. First, the generic must be chemically equivalent to the brand name drug. This means that the generic must match the brand name drug in terms of active ingredients, methods of administration, dosage form, and strength. *Id.* § 355(j)(2)(A)(ii), (iii). Second, the generic must also be bioequivalent to the brand-name drug. *Id.* § 355(j)(2)(A)(iv). Bioequivalence is present if the generic has the same “rate and extent of absorption” as the brand-name medication. *Id.* § 355(j)(8)(B).

addressed by the FDA when it approved the relevant brand-name drug, ANDA review is significantly less rigorous, less time-consuming, and less expensive than the NDA process.<sup>64</sup>

Besides requiring that the generic must be equivalent to the brand-name drug, Hatch-Waxman mandated that the generic's label must also be the same as the FDA-approved label for the brand-name drug.<sup>65</sup> Accordingly, under what the Supreme Court has referred to as Hatch-Waxman's duty of "sameness," generics cannot depart from the brand-name drug in terms of drug design or product label.<sup>66</sup> This duty of sameness proved critical, as will be seen, to the second and third decisions in the Supreme Court's recent trilogy of cases dealing with whether federal law preempts tort claims against drug manufacturers.<sup>67</sup> This Article now considers the three decisions.

#### C. THE TRILOGY, PART 1: *WYETH V. LEVINE*

Ruling in pro-plaintiff fashion in the first of the three cases, *Wyeth v. Levine*,<sup>68</sup> the Supreme Court rejected drug manufacturer Wyeth's attempt to invoke a preemption defense against Levine's tort claims.<sup>69</sup> The claims pertained to Phenergan, a brand-name anti-nausea drug for which Wyeth received FDA approval in the 1950s.<sup>70</sup> During a medical clinic visit in which she sought treatment for migraine headaches, Levine was given Phenergan in addition to a potent pain medication.<sup>71</sup> The same treatment had been provided to Levine on previous occasions, though not via the Phenergan administration method used in the instance giving rise to her lawsuit.<sup>72</sup>

If Phenergan is exposed to arterial blood, gangrene results quickly and irreversibly.<sup>73</sup> Phenergan is typically given safely through use of an intravenous (IV) drip or through

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64. See *Bartlett*, 133 S. Ct. at 2471.

65. 21 U.S.C. § 355(j)(2)(A)(v); see *id.* § 355(j)(4)(G).

66. See *Bartlett*, 133 S. Ct. at 2475–76, 2481; *Mensing*, 131 S. Ct. at 2575.

67. See *infra* text accompanying notes 128–210.

68. *Wyeth v. Levine*, 555 U.S. 555 (2009).

69. *Id.* at 558–59, 571–73, 581.

70. *Id.* at 559, 561, 578 & n.11.

71. *Id.* at 559.

72. *Id.*

73. *Id.* at 559.

intramuscular injection.<sup>74</sup> In the instance at issue, however, a physician's assistant administered Phenergan to Levine by way of a third method, "IV-push."<sup>75</sup> This method, which involves injection directly into a vein, carries the benefit of quicker relief from nausea but presents significant risks if it is not carried out correctly.<sup>76</sup> In Levine's case, Phenergan entered an artery, either because the needle penetrated it directly or because the medication escaped from the vein, entered surrounding tissue, and came into contact with arterial blood.<sup>77</sup> Levine thereafter developed gangrene, necessitating amputation of her right hand and later her entire forearm.<sup>78</sup>

Over the years, the product label for Phenergan had undergone changes as a result of supplemental applications by Wyeth to the FDA regarding later-acquired evidence indicating the risks of inadvertent intra-arterial injection of the medication.<sup>79</sup> The most recent FDA-approved label warned about the gangrene danger following inadvertent intra-arterial injection and expressed a preference for use of the IV-drip method of administration. However, the label did not expressly warn that because of its risks, the IV-push method should never be used.<sup>80</sup>

In the negligence and strict liability claims she filed against Wyeth, Levine contended that given the severe risks posed by the IV-push method as compared with its lesser benefit, Wyeth's label should have warned that the method was simply too dangerous to use.<sup>81</sup> Evidence adduced at trial indicated that since the 1960s, there had been at least 20 reports of amputations similar to Levine's following inadvertent intra-arterial injections of Phenergan.<sup>82</sup> After a Vermont jury ruled in Levine's favor and awarded her several million dollars in damages,<sup>83</sup> the state's highest court upheld

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74. *Id.*

75. *Id.*

76. *Id.* at 559–60, 561.

77. *Id.* at 1191.

78. *Id.* at 559. She experienced considerable pain and suffering and incurred significant medical expenses. In addition, she lost her livelihood as a professional musician. *Id.*

79. *Id.* at 561.

80. *Id.* at 560, 561–62.

81. *Id.* at 559–60, 562, 564–65.

82. *Id.* at 562–63.

83. *Id.* at 562. The jury awarded \$7.4 million in damages, but the trial court reduced that amount to allow for funds Levine had received in

the verdict.<sup>84</sup> The United States Supreme Court granted certiorari in order to decide whether the FDA approvals granted to Wyeth preempted Levine's tort claims.<sup>85</sup>

Federal preemption of state regulation (including, sometimes, state-law-based tort claims) comes in two basic forms: *express preemption* and *implied preemption*.<sup>86</sup> Express preemption can apply when a provision in federal law expressly bars state regulation on the relevant subjects addressed in the law, and a court concludes that the state action at issue falls within the scope of the preemption provision.<sup>87</sup> Wyeth could not attempt to invoke express preemption, however, because there is no preemption clause in the previously discussed federal statutory provisions under which the FDA approves new drugs and their product labels.<sup>88</sup>

The relevant drug regulation sections in the Federal Food, Drug, and Cosmetics Act thus differ from the federal statutory regime under which the FDA is charged with deciding whether to approve medical devices for entry into the marketplace.<sup>89</sup> The latter regime, stemming from the Medical Device Amendments of 1976, contains a preemption clause<sup>90</sup> that proved critical to a Supreme Court decision handed down only a year before *Levine*.<sup>91</sup> In that decision, *Riegel v. Medtronic*,

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settlements of claims against the clinic where she had been treated and against the physician's assistant who attempted to use the IV-push method of administering Phenergan. *Id.*

84. *Id.* at 563.

85. *Id.*

86. *E.g., id.* at 563–64, 565 & n.3, 567. For background on the types of preemption, see Daniel J. Meltzer, *Preemption and Textualism*, 112 MICH. L. REV. 1 (2013); see also Ernest A. Young, "The Ordinary Diet of the Law": The Presumption Against Preemption in the Roberts Court, 2011 SUP. CT. REV. 253, 269–78 (2011).

87. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316, 321–22, 323–25 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484–85 (1996).

88. *Levine*, 555 U.S. at 574.

89. *Id.* at 566–569.

90. 21 U.S.C. § 360k(a) (2012). The clause reads as follows:  
[N]o 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.*

91. *Riegel*, 552 U.S. at 316.

*Inc.*,<sup>92</sup> an eight-justice majority held that if a medical device and its product label have received pre-market approval from the FDA, tort claims against the device manufacturer are preempted under the terms of the preemption clause.<sup>93</sup> However, tort claims against the device manufacturer are not preempted if, as is the case with many devices, the device at issue was required only to undergo a form of FDA review that is less rigorous than pre-market approval.<sup>94</sup>

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92. *Riegel*, 552 U.S. at 312.

93. *Id.* at 317–18, 322–23, 324–25, 326, 330. Under the Medical Device Amendments of 1976, the requirement of pre-market approval—the FDA’s highest level of review for safety and effectiveness—applies to truly new Class III medical devices first offered for sale following the effective date of the MDA. 21 U.S.C. § 360c(a)(1)(C)(ii) (2012). *See Riegel*, 552 U.S. at 316–17. The Class III category includes heart-related devices such as the FDA-approved balloon catheter at issue in *Riegel*. *Id.* at 317, 319. After characterizing pre-market approval as a rigorous process in which safety-related federal requirements specific to the relevant device are imposed, *id.* at 317, 322–23, the *Riegel* Court rejected the argument that the preemption section in the statute serves only to prohibit states from establishing separate FDA-like regulatory regimes. *See id.* at 324–25. The Court concluded instead that the plaintiff’s various tort claims, which focused on supposed design defects and failures to provide adequate warnings, were attempts under state law to have courts impose safety-oriented requirements “different from, or in addition to” the device-specific requirements associated with pre-market approval. *Id.* at 325–26; *see* 21 U.S.C. § 360k (2012). Therefore, the Court held that the conditions set forth in the statute’s preemption section were met and that the plaintiff’s claims were preempted. 552 U.S. at 323–28, 329. *Riegel*’s preemption holding does not apply, however, to many of the medical devices cleared for sale by the FDA. *See infra* note 94.

94. The Medical Device Amendments of 1976 (MDA) require pre-market approval for truly new devices first made available for sale after the MDA’s effective date. 21 U.S.C. § 360c(a)(1)(C)(ii) (2012). However, devices dating from prior to 1976, as well as devices substantially equivalent to pre-1976 devices, are grandfathered under the pre-1976 legal regime, which did not require pre-market approval by the FDA. *Id.*; 21 U.S.C. § 360c(f)(1) (2012). Although the FDA conducts a substantial equivalence review for many of the grandfathered devices, that review involves far less FDA scrutiny than the pre-market approval process does. *See id.* § 21 U.S.C. § 360c(f)(1)(A) (2012). This review is often called the § 510(k) process because of the relevant statutory section’s original number. *See Riegel*, 552 U.S. at 317. Far more medical devices that enter the market do so after completing the § 510(k) process than do so after having to complete pre-market review. *Id.* State law-based product liability claims are not considered preempted if they pertain to devices that have undergone only § 510(k) review, because that review, unlike the pre-market approval process, focuses on equivalence rather than safety. *See Riegel*, 552 U.S. at 322–23. This conclusion stems from another Supreme Court case to which Medtronic was a party, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). In *Lohr*, the Court concluded that the FDA’s substantial equivalence review of a grandfathered medical device did not involve the



Unlike the medical device manufacturer in *Riegel*, Wyeth could not point to a statutory preemption clause in an attempt to avoid liability in *Levine*.<sup>95</sup> With no express preemption argument being available, Wyeth sought to rely on implied preemption principles.<sup>96</sup> Implied preemption may take place if a court concludes that it would be impossible for a defendant to comply with conflicting federal and state duties.<sup>97</sup> In such a situation, the federal law will control and the state duties cannot be enforced against the defendant because they are preempted.<sup>98</sup> Implied preemption can also be found when the court concludes that the enforcement of duties under state law could interfere too seriously with the purposes and objectives of federal law.<sup>99</sup>

Wyeth made arguments based on implied preemption's impossibility variety as well as its purposes-and-objectives variety.<sup>100</sup> In a majority opinion authored by Justice Stevens, and joined by Justices Kennedy, Souter, Ginsburg, and Breyer, the Court rejected Wyeth's arguments and held that the plaintiff's failure-to-warn claims were not preempted.<sup>101</sup>

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imposition of federal device-specific "requirements" for purposes of the MDA's previously quoted preemption section, and that the same was true of basic labeling requirements applicable to medical devices generally. *Id.* at 492–94, 500–02. The Court went on to hold in *Lohr* that in the absence of the type of federal "requirements" contemplated by the preemption section, state law-based negligence claims could not be seen as imposing "different" or "addition[al] . . . requirement[s]" and thus were not preempted by the MDA. *Id.* For a comparison of preemption issues in the medical devices context with preemption issues in the pharmaceuticals context, see Marcia Boumil, *FDA Approval of Drugs and Devices: Preemption of State Laws for "Parallel" Tort Claims*, 18 J. HEALTH CARE L. & POL'Y 1, 30–33, 35–40 (2015).

95. *Wyeth v. Levine*, 555 U.S. 555, 593 (2009).

96. *Id.* at 563–64, 567, 574 (noting lack of preemption provision in federal drug regulation laws).

97. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577 (2011); *Levine*, 555 U.S. at 563, 568, 573, 581.

98. *Mensing*, 131 S. Ct. at 2577; *Levine*, 555 U.S. at 563, 568, 573, 581. Impossibility arguments serve as a variant of conflict preemption, which can occur when federal and state law are so greatly in conflict that the state law, or rights contemplated under it, must fall. *See Mensing*, 131 S. Ct. 2567 at 2577.

99. *Levine*, 555 U.S. at 563–64, 573. The purposes-and-objectives type of preemption is sometimes known as obstacles preemption. *See Meltzer, supra* note 86, at 3, 8, 14.

100. *Levine*, 555 U.S. at 563, 568.

101. *Levine*, 555 U.S. at 557, 558–59, 571–73, 581 (2009).

Concurring in the judgment, Justice Thomas provided a sixth vote for the outcome.<sup>102</sup>

Justice Stevens began the Court's analysis in *Levine* by noting two foundational principles established in previous decisions dealing with preemption: first, that congressional purpose is the "ultimate touchstone" in preemption analysis;<sup>103</sup> and second, that in any preemption case,

and particularly in those in which Congress has legislated . . . in a field which the States have traditionally occupied, [courts begin with the] assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.<sup>104</sup>

After tracing the history of federal regulation of pharmaceuticals, the Court observed that even as it enhanced the FDA's role, Congress "took care to preserve state law."<sup>105</sup> Tort lawsuits continued to be brought, notwithstanding the FDA's acquisition of a critical regulatory role regarding drugs.<sup>106</sup> Moreover, the Court emphasized, "when Congress enacted an express pre-emption provision for medical devices in 1976, . . . , it declined to enact such a provision for prescription drugs."<sup>107</sup>

The Court turned to Wyeth's impossibility argument. The drug maker contended that federal law commanded it to continue using the very product label the FDA had approved, but that the plaintiff's state-law-based tort claims effectively called for a changed label providing a stronger warning.<sup>108</sup> Thus, Wyeth maintained, it was impossible to comply with both

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102. *Id.* at 582 (Thomas, J., concurring).

103. *Id.* at 565 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

104. *Id.* at 565 (quoting *Lohr*, 518 U.S. at 485) (further internal citation omitted). The quoted language from *Lohr* included language from *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), a decision instrumental in the development of the so-called presumption against preemption. See Young, *supra* note 86, at 266–69. The presumption against preemption is designed to respect the states as independent sovereigns. See *Levine*, 555 U.S. at 565 n.3. Accordingly, courts assume that "Congress does not cavalierly pre-empt state-law causes of action." *Id.* (quoting *Lohr*, 518 U.S. at 485). For discussion of the usefulness of the presumption against preemption, see Meltzer, *supra* note 86, at 52–55. Among other things, the presumption against preemption can serve as, effectively, a tie-breaker. Young, *supra* note 86, at 271.

105. *Levine*, 555 U.S. at 567.

106. *Id.*

107. *Levine*, 555 U.S. at 567. For discussion of the express preemption provision in the federal statutes dealing with medical devices, see *supra* text accompanying notes 90–94.

108. *Id.* at 568.

federal law and state law.<sup>109</sup> The Court disagreed, pointing to the previously discussed CBE regulation.<sup>110</sup> Under that regulation, new or reanalyzed safety-related information entitles brand-name manufacturers, such as Wyeth, to depart from the approved label text and begin using a modified label that provides more rigorous warnings.<sup>111</sup> The manufacturer relying on the CBE regulation must apply to the FDA for a new approval at the time it begins using the altered label, but, importantly, it need not have received that approval before using the new label.<sup>112</sup>

Justice Stevens also emphasized that the misbranding section in the federal drug regulation laws established a continuing obligation on the part of drug manufacturers to ensure that the warnings on their product labels remain adequate.<sup>113</sup> This meant that “when the risk of gangrene from IV-push injection of Phenergan became apparent, Wyeth had a duty to provide a warning that adequately described that risk, and the CBE regulation permitted it to provide such a warning before receiving the FDA’s approval.”<sup>114</sup> The Court reasoned, therefore, that it was not impossible for Wyeth to remain in compliance with federal law while doing what state law

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109. *Id.*

110. *Id.*; see *supra* text accompanying notes 45–47; *supra* note 47 and accompanying text.

111. See *supra* text accompanying notes 45–47; *supra* note 47. Noting that the CBE regulation permits a label change if “newly acquired information” warrants the change, 21 C.F.R. § 314.70(c)(6)(iii)(A) (2015), Wyeth argued that the CBE avenue was unavailable to it because much of the information pertaining to the relevant safety issue had already been presented to the FDA and thus should not be seen as newly acquired information. *Levine*, 555 U.S. at 568–69. Justice Stevens pointed out, however, that in its notice regarding the final CBE rule, the FDA defined “newly acquired information” as including not only new data but also “new analyses of previously submitted data.” *Id.* at 569. See Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49604 (Aug. 22, 2008) (to be codified at 21 C.F.R. pt. 314, 601, 814). This definition, he continued, recognizes that “risk information accumulates over time” and that “the same data may take on a different meaning in light of subsequent developments.” *Levine*, 555 U.S. at 569. Hence, Wyeth could have employed the CBE route for implementing a revised label even if it was reanalyzing previously presented information. See *id.* at 569–70.

112. See *supra* text accompanying notes 45–47.

113. *Levine*, 555 U.S. at 570–71. The misbranding statute provides that a drug is misbranded if its label does not adequately warn about safety-related matters associated with the medication. 21 U.S.C. § 352(f)(2)(2012.) See *supra* text accompanying notes 48–49.

114. *Levine*, 555 U.S. at 571.

contemplated.<sup>115</sup> Concluding the Court's rejection of Wyeth's impossibility argument, Justice Stevens issued an important reminder: "Impossibility preemption is a demanding defense."<sup>116</sup>

The *Levine* Court then turned to Wyeth's other preemption argument: that expecting the drug maker to comply with a state-law-based duty to furnish a stronger warning would unduly interfere with the purposes and objectives of federal law regarding drug labeling.<sup>117</sup> Wyeth contended that federal law envisioned FDA approval as "setting both a floor and ceiling"—supposedly meaning that once FDA approval of a drug's label has taken place, there remains no regulatory room for a state-law-based claim that the label was inadequate.<sup>118</sup> "The most glaring problem with this argument," the Court explained, "is that all evidence of Congress' purposes is to the contrary."<sup>119</sup> Justice Stevens noted that in the several-decades-long history of the Food, Drug, and Cosmetics Act (FDCA), Congress had never provided a federal right of action to consumers harmed by unsafe drugs.<sup>120</sup> This inaction suggested likely congressional determinations that "widely available state rights of action provided appropriate relief for injured consumers" and that "state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings."<sup>121</sup>

Another bit of congressional inaction merited the Court's emphasis: "If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's

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115. *Id.* Even though prior approval by the FDA is not required when a manufacturer pursues the CBE route, FDA approval of the strengthened label will ultimately be necessary if the manufacturer is to be able to continue using that label over the long term. See 21 C.F.R. § 314.70(c)(6)(iii)(A); *Levine*, 555 U.S. at 571. It is conceivable, of course, that the FDA might decide to reject the strengthened label. Without more, however, that potential outcome would not change the analysis. "[A]bsent clear evidence that the FDA would not have approved a change to Phenergan's label," the Court stated, "we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements." *Id.* The Court noted that Wyeth had presented no such evidence. *Id.* at 572.

116. *Levine*, 555 U.S. at 573.

117. *Id.*

118. *Id.* at 573–74.

119. *Id.* at 574.

120. *Levine*, 555 U.S. at 574.

121. *Id.*

70-year history.”<sup>122</sup> But Congress had not done so, despite its inclusion of a preemption provision in the statutes dealing with FDA approval of medical devices.<sup>123</sup> The Court reasoned that the “silence” of Congress on the matter of preemption, “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>124</sup>

Summarizing its conclusions about congressional intent, the FDA’s previous expression of views, and the roles tort litigation may play, the Court stated:

In keeping with Congress’ decision not to preempt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation. The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge.

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122. *Id.*

123. *Id.* at 574. The express preemption provision in the federal statutes dealing with medical devices is discussed at *supra* text accompanying notes 90–94.

124. *Levine*, 555 U.S. at 575. Thus, this evidence also suggested that “Congress did not regard state tort litigation as an obstacle to achieving its purposes.” *Id.* Wyeth sought to bolster its argument for purposes-and-objectives preemption by pointing to an FDA assertion that the agency’s approval of a drug label should preempt state-law-based claims for failure to warn. *Id.* For three key reasons, the *Levine* majority ascribed no significance to this FDA statement. First, it was not a statement by Congress and was inconsistent with the previously noted indications of congressional purposes. *Id.*; see also *id.* at 576–78. Second, it appeared in the preamble to a 2006 FDA regulation dealing with the format and content of drug labels, not in the substantive provisions of any regulation. See *id.* at 575, 576–77, 578–79, 580. Third, it contradicted the FDA’s longstanding position that state tort law was not an obstacle to achievement of the FDA’s mission. *Id.* at 577–79. In addition, the Court expressed concern about a procedural irregularity. The relevant FDA notice of proposed rulemaking said that the proposed regulation, if promulgated, would not operate to preempt state law. However, the 2006 preamble to the finalized rule made its sweeping preemption assertion without the states or potentially affected parties having any opportunity to comment. *Id.* at 577. This “procedural failure” made the FDA’s supposed “views on state law . . . inherently suspect.” *Id.* The Court stated that the FDA’s “dramatic change in position” regarding state-law-based litigation, *id.* at 579, coming as it did in a mere preamble to a regulation and against a statutory backdrop in which Congress “has repeatedly declined to preempt state law,” *id.* at 581, did not merit the deference sometimes extended to agency interpretations. See *id.* at 576–81. Moreover, Justice Stevens stressed, the Court is loath to defer to an agency’s conclusions about federal preemption of state law, absent a clear indication from Congress that the agency should weigh in on that question. *Id.* at 576–77.

State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times.<sup>125</sup>

Having already rejected Wyeth's impossibility argument,<sup>126</sup> the Court held that the plaintiff's tort claims did not interfere with purposes underlying the federal drug regulation laws and thus were not subject to preemption on that basis.<sup>127</sup>

#### D. THE TRILOGY, PART 2: *PLIVA, INC. v. MENSING*

Two years after *Levine*, the Supreme Court decided *PLIVA, Inc. v. Mensing*.<sup>128</sup> This second decision in the Court's pharmaceuticals trilogy again presented the question whether federal drug regulation law preempts plaintiffs' state-law-based claims that a drug manufacturer failed to warn adequately about a danger associated with its medication.<sup>129</sup> But this time the Court answered the question differently, holding the claims to be preempted.<sup>130</sup> Whereas *Levine* was a case against the manufacturer of a brand-name drug, *Mensing* was a case against a manufacturer of a generic version of such a drug. For the five-justice majority, this distinction proved to be critical.<sup>131</sup>

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125. *Id.* at 578–79.

126. *See Levine*, 555 U.S. at 568–73. In his concurrence in the judgment, Justice Thomas agreed that it was not impossible for Wyeth to comply with both federal and state law, and that the plaintiff's tort claims therefore should not be preempted. *Id.* at 582–83 (Thomas, J., concurring). He declined to join the majority opinion, however, because of his objections to the form of implied preemption that focuses on congressional purposes and objectives. *See id.* at 583–604. For discussion and analysis of Justice Thomas's objection to this variety of preemption (which is sometimes known as obstacle preemption), see Meltzer, *supra* note 86, at 2–4, 8–9, 35. *See also* Young, *supra* note 86, at 327–28 (discussing Justice Thomas's objections to obstacle preemption).

127. *Levine*, 555 U.S. at 581. Justice Alito authored a dissenting opinion that Chief Justice Roberts and Justice Scalia joined. *Id.* at 604 (Alito, J., dissenting). Regarding the case as an example of “tragic facts mak[ing] bad law,” the dissenters interpreted the federal drug regulation statutes as setting up a regime in which FDA approval is authoritative and the agency's judgments are not to be second-guessed by juries in tort cases. *See id.* at 606–26.

128. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2567 (2011).

129. *Id.*

130. *Id.* at 2572.

131. *See id.* at 2581–82. Justice Thomas authored the majority opinion, which Chief Justice Roberts and Justices Kennedy, Scalia, and Alito joined.

Reglan, a brand-name drug used in treatment of digestive tract problems, was approved by the FDA in 1980. Generic versions of the drug, whose common name is metoclopramide, later entered the marketplace.<sup>132</sup> Evidence gathered over the years indicated that long-term use of metoclopramide (whether the brand-name drug or a generic equivalent) can cause tardive dyskinesia, a severe neurological disorder.<sup>133</sup> Of patients who take the drug for several years, up to twenty-nine percent develop tardive dyskinesia.<sup>134</sup> In light of this information, the labels for Reglan and the generics have changed since the original approval in 1980. Stronger FDA-approved warnings about the tardive dyskinesia risk associated with long-term use were added to the labels in 1985 and 2004.<sup>135</sup>

In 2001 and 2002, physicians prescribed Reglan for the plaintiffs in *Mensing* and a case consolidated with it for decision purposes.<sup>136</sup> Relying on state laws of the sort described earlier in the Article,<sup>137</sup> pharmacists dispensed generics, rather than Reglan, to the plaintiffs. Both plaintiffs took the drug for several years, and both developed tardive dyskinesia.<sup>138</sup> In later tort actions against the generic manufacturers whose medications they used, the plaintiffs contended that given the accumulating evidence about the tardive dyskinesia risk presented by long-term use of metoclopramide, the manufacturers had failed to employ adequate warning labels.<sup>139</sup> After lower courts rejected the manufacturers' preemption defenses, the Supreme Court granted certiorari to determine whether federal drug regulation law preempts tort

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*Id.* at 2571. Of the five justices in the majority, only Justice Kennedy had also been part of the *Levine* majority, though Justice Thomas had concurred in the judgment in that case. *See supra* text accompanying notes 101–02. The Chief Justice and Justices Scalia and Alito had been in the minority in *Levine*. *See supra* note 127 and accompanying text.

132. *Mensing*, 131 S. Ct. at 2572.

133. *Id.*

134. *Id.*

135. *Id.* For instance, the label change the FDA approved in 2004 warned that Reglan use “should not exceed 12 weeks in duration.” *Id.* The warning was made even stronger in an FDA-ordered change in 2009, though that change in the label came after the events giving rise to *Mensing*. *See id.* at 2573, 2574 n.1.

136. *Mensing*, 131 S. Ct. at 2573.

137. *See supra* text accompanying notes 8–9.

138. *Mensing*, 131 S. Ct. at 2573.

139. *Id.*

claims premised on the contention that generic manufacturers failed to include stronger warnings on their drug labels.<sup>140</sup>

Justice Thomas began the analysis in *Mensing* by noting that under the Hatch-Waxman Act, a generic drug must have the same composition as the corresponding brand-name drug and must bear labeling identical to the labeling approved by the FDA for the brand-name drug.<sup>141</sup> Hatch-Waxman, therefore, sets up a duty of “sameness.”<sup>142</sup> According to the *Mensing* majority, that duty tied the generic manufacturers’ hands regarding label content and thus related directly to the defendants’ preemption argument.<sup>143</sup> The generic manufacturers contended that they could not do what the plaintiffs’ state-law-based tort claims called for them to do—use a modified label with even stronger warnings—and remain in compliance with the federal requirement that they use the same label previously approved for the relevant brand-name drug.<sup>144</sup> Hence, they contended, preemption on the ground of impossibility should apply.<sup>145</sup>

En route to agreeing with the generic manufacturers’ impossibility argument,<sup>146</sup> the Court rejected three key arguments by the plaintiffs. First, the plaintiffs contended that despite the general duty of sameness noted above, the previously discussed CBE regulation would have permitted the generic makers to use a modified label with strengthened warnings before receiving FDA approval.<sup>147</sup> The plaintiffs maintained, therefore, that it was not impossible for the defendants to do what the tort claims against them contemplated and still act in accordance with federal law.<sup>148</sup> Deferring to an FDA interpretation that regarded the CBE option as available only to brand-name manufacturers, not to generic manufacturers, the Court concluded that the plaintiffs’ first anti-impossibility argument failed.<sup>149</sup>

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140. *Id.* at 2772, 2573.

141. *See* 21 U.S.C. §§ 355(j)(2)(A) (2012); *Mensing*, 131 S. Ct. at 2574.

142. *Mensing*, 131 S. Ct. at 2575.

143. *See id.* at 2574–75, 2577–78.

144. *Id.* at 2577–78.

145. *Id.*

146. *Id.*; *see also id.* at 2581–82.

147. *Id.* at 2575.

148. *Id.* For discussion of the CBE regulation, see *supra* text accompanying notes 45–47.

149. *Mensing*, 131 S. Ct. at 2575–76. Recall that in *Wyeth v. Levine*, 555 U.S. 555 (2009), the brand-name manufacturer’s ability to pursue the CBE



Second, the plaintiffs opposed the generic manufacturers' impossibility argument by contending that the defendants could have sent "Dear Doctor" letters to prescribing physicians in an effort to communicate safety related information that went beyond the approved label's content.<sup>150</sup> The Court cited an FDA interpretation that treated Dear Doctor letters as "labeling" for purposes of Hatch-Waxman's requirement that generics only employ the "approved...labeling." In this interpretation, the FDA concluded that a generic maker's use of Dear Doctor letters containing additional warnings would amount to unlawful use of unapproved labeling.<sup>151</sup> Again deferring to the FDA, the Court rejected the plaintiffs' argument that the defendants could have employed Dear Doctor letters.<sup>152</sup>

Third, the plaintiffs argued—this time with an FDA interpretation seemingly in their favor—that all drug makers (brand-name and generic) have a continuing duty stemming from the federal misbranding statute to ensure that their product labels contain adequate safety-related warnings.<sup>153</sup> According to the plaintiffs and the FDA, the generic manufacturers were obligated to propose a strengthened warning label to the FDA, which could then have tried to work with the manufacturer to seek agreement on the text of a revised label.<sup>154</sup> The plaintiffs contended, therefore, that impossibility preemption should not apply because the defendants were obligated to set in motion a process that could have led to a strengthened warning label of the sort contemplated by the tort claims at issue.<sup>155</sup>

After noting that the generic manufacturers disputed whether they actually had an obligation under federal law to propose a stronger warning label, the Court stopped short of

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avenue was a key reason why the Court rejected the argument that impossibility preemption should apply. *See id.* at 568–70. The FDA has since proposed a regulation under which the CBE option would be made available to generic manufacturers, but the proposed regulation is long-stalled and remains unpromulgated. Its ultimate fate is uncertain. *See infra* notes 234, 268.

150. *Mensing*, 131 S. Ct. at 2576.

151. *Id.*

152. *Id.*

153. *Id.*

154. *Id.* For discussion of the misbranding statute, see *supra* text accompanying notes 48–53.

155. *See Mensing*, 131 S. Ct. at 2576, 2578–79.

deferring to the FDA and adopting its position.<sup>156</sup> The Court indicated instead that it would assume, without deciding the issue, that the FDA was correct in concluding that the generic makers had such a duty.<sup>157</sup> Justice Thomas observed, however, that even if the FDA was correct on that point, the plaintiffs still did not have an adequate answer to the defendants' impossibility argument.<sup>158</sup>

Although he conceded that the plaintiffs had made a "fair argument" when they contended that the manufactures should not be deemed to have carried their burden of proving impossibility when they had not even attempted to launch a process that might have led to a stronger label, Justice Thomas declined to accept the argument.<sup>159</sup> An application by the generic manufacturers for a strengthened label would not have guaranteed that such a label would come about, because the law in effect at the relevant time indicated that such an application would only have justified FDA attempts to seek an agreement with the brand-name manufacturer on revised language for the label.<sup>160</sup> Complying with a supposed federal duty to *request* a stronger label would not have satisfied a state-law duty to *use* a stronger label, the Court indicated.<sup>161</sup>

Therefore, according to the *Mensing* majority, it was impossible for generic manufacturers to fulfill their federal and state duties on their own.<sup>162</sup> They could not "independently"

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156. *See id.* at 2576–77, 2578 (2011).

157. *Id.*

158. *See id.* at 2577–78.

159. *Id.* at 2579.

160. *Id.* at 2578–79, 2580–81. Prior to 2007, the FDA could not order the use of a particular strengthened label even if it concluded that an application for such a label was meritorious. Rather, in such a situation, the FDA was limited to working with the brand-name manufacturer in an effort to reach an agreement on revised text for the label. *See supra* text accompanying notes 55–57. A 2007 enactment granted the FDA the authority to order use of a particular label in such a situation. *See id.* In deciding *Mensing*, however, the Court did not consider whether the 2007 grant of this authority to the FDA would have any effect on the case. Justice Thomas noted that because the relevant events in *Mensing* preceded the 2007 action by Congress, the pre-2007 statutes would control the case. *Mensing*, 131 S. Ct. at 2574 n.1. He stated that the Court was "express[ing] no view on the impact of the 2007 Act." *Id.*

161. *See Mensing*, 131 S. Ct. at 2578, 2580–81.

162. *Id.* at 2577–79, 2580–81. The focus on impossibility in light of the statutory rules regarding generics was consistent with Justice Thomas's preferred approach to preemption: textualism, as opposed to conducting a purposes-and-objectives (or obstacles) inquiry. Meltzer, *supra* note 86, at 2–3.

satisfy their federal and state obligations because, under federal law, further actions by the FDA would have been necessary in order for a stronger warning label to have come into being.<sup>163</sup> The possibility that a stronger warning label might have resulted from an application for such a label was not enough to eliminate the impossibility problem.<sup>164</sup> Hence, the Court concluded, preemption of the plaintiffs' tort claims was warranted.<sup>165</sup>

Justice Thomas acknowledged that the plaintiffs would see "little sense" in the Court's decision, given that their claims would not have been preempted if the pharmacists who filled their prescriptions had dispensed the relevant brand-name drug rather than a generic.<sup>166</sup> But the outcome, he noted, was simply the product of the "unfortunate hand" that Congress had dealt consumers of generics in the federal drug regulation laws.<sup>167</sup>

Justice Sotomayor issued a vigorous dissent in which Justices Ginsburg, Breyer, and Kagan joined.<sup>168</sup> Accusing the *Mensing* majority of "effectively rewrit[ing]" the *Levine* decision of only two years earlier,<sup>169</sup> Justice Sotomayor criticized the majority for not applying the presumption against preemption that had been recognized in prior decisions.<sup>170</sup> She also contended that through his focus on whether the generic manufacturers could "independently" satisfy their state and federal obligations, Justice Thomas had unjustifiably expanded the impossibility doctrine and had weakened the demanding

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For discussion of the problems with an exclusively textualist approach, see *id.* at 4–5, 8–9, 35, 46–52.

163. *Mensing*, 131 S. Ct. at 2580. In referring to acting "independently," the Court meant acting unilaterally, without having to depend upon further action by the FDA. See *id.* at 2578–79, 2580–81. The Court mentioned acting "independently" at least four times in *Mensing*. See *id.* at 2579, 2580, 2581, 2581 n.8.

164. See *Mensing*, 131 S. Ct. at 2578–79.

165. *Id.* at 2577–78, 2580–81.

166. *Id.* at 2581.

167. *Id.*; see *id.* at 2582. Suggesting that Congress had left the Court no choice but to rule as it did, the majority noted that "Congress and the FDA retain the authority to change the law and regulations if they so desire." *Id.*

168. *Id.* (Sotomayor, J., dissenting).

169. *Id.* at 2582. For discussion of *Levine*, see *supra* text accompanying notes 68–127.

170. *Mensing*, 131 S. Ct. at 2583 (Sotomayor, J., dissenting); see *id.* at 2589.

burden that defendants asserting impossibility had historically been obligated to carry.<sup>171</sup>

Reminding readers that “the purpose of Congress is the ultimate touchstone” in determinations of whether preemption is warranted,<sup>172</sup> the dissenters stressed that given the lack of an express preemption provision in the relevant federal statute and the long tradition of allowing room for tort actions as a complement to federal regulation of pharmaceuticals, the Court’s preemption ruling was not what Congress would have had in mind.<sup>173</sup> For the dissenters, the majority’s analysis hit the mark only in the acknowledgment that the Court’s ruling would make “little sense” to the plaintiffs.<sup>174</sup> It indeed made little sense, Justice Sotomayor remarked, to have harmed consumers’ rights hinge on the “happenstance” of whether the pharmacist dispensed a brand-name medication or, instead, a generic version of it.<sup>175</sup>

E. THE TRILOGY, PART 3: *MUTUAL PHARMACEUTICAL CO. V. BARTLETT*

The Supreme Court treated the third case in the pharmaceuticals trilogy, *Mutual Pharmaceutical Co. v. Bartlett*,<sup>176</sup> as if it were *Mensing II*. With the same five justices who formed the *Mensing* majority again constituting the majority in *Bartlett*,<sup>177</sup> the Court held that federal law preempted tort claims in which the plaintiff contended that the generic she took was defectively designed and inadequately

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171. See *id.* at 2582, 2586, 2587–88, 2589–90.

172. *Id.* at 2586 (quoting *Wyeth v. Levine*, 555 U.S. 555, 565 (2009)) (further internal citation omitted).

173. *Id.* at 2586–87; see *id.* at 2583–85, 2591, 2592–93. The dissenters would have rejected the defendants’ impossibility argument on the ground that the defendants could have approached the FDA with a request for a strengthened label and thus were able to launch a process by which a modified label of the sort contemplated by the plaintiffs’ tort claims might have resulted. See *id.* at 2587–88. Justice Sotomayor reasoned that such an approach to the impossibility issue would have been more in keeping with the presumption against preemption and with the demanding nature of the impossibility defense. See *id.* at 2589–90, 2590–91, 2593.

174. *Id.* at 2583; see *id.* at 2582.

175. *Id.* at 2583 (Sotomayor, J., dissenting).

176. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

177. The five were Justice Alito (who wrote for the majority), Chief Justice Roberts, and Justices Kennedy, Scalia, and Thomas. *Id.* at 2469. For the matching *Mensing* lineup, see *supra* note 131 and accompanying text.

labeled.<sup>178</sup> The drug at issue was an anti-inflammatory pain reliever commonly known as sulindac, the brand-name version of which had received FDA approval in 1978. The plaintiff (Bartlett) had been prescribed the brand-name medication, but the pharmacist filled the prescription with Mutual Pharmaceutical's generic version.<sup>179</sup>

Bartlett claimed that the drug was defectively designed because of the risk that users of it would develop toxic epidermal necrolysis.<sup>180</sup> She developed this disorder and suffered "horrific" consequences.<sup>181</sup> Initially, Bartlett brought a negligent-failure-to-warn claim in addition to her strict liability claim for defective design.<sup>182</sup> A federal district court dismissed the failure-to-warn claim but permitted the design-defect claim to go to the jury, which returned a verdict in Bartlett's favor.<sup>183</sup> The U.S. Court of Appeals for the First Circuit affirmed.<sup>184</sup>

Writing for the Supreme Court, Justice Alito wasted little time in concluding that *Mensing* foreclosed any failure-to-warn claim in *Bartlett*. Even if the FDA-approved labels for sulindac said little about the toxic epidermal necrolysis risk until after Bartlett had already developed the disorder, her failure-to-warn claim would have to be considered preempted on the ground of impossibility.<sup>185</sup> Then Justice Alito turned to consideration of Bartlett's design-defect claim under New Hampshire law—a claim the Court characterized as serving not only compensatory purposes but also regulatory functions.<sup>186</sup> The Court concluded that rather than simply furnishing a basis for an award of damages, the design-defect claim effectively imposed a duty on drug makers to change the design of the drug.<sup>187</sup> However, the majority stressed, changing the medication's composition was not an option for Mutual

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178. *Bartlett*, 133 S. Ct. at 2470, 2473, 2475–78.

179. *Id.* at 2470, 2471–72.

180. *Id.* at 2472.

181. *Id.* Much of her body deteriorated because of severe burns and open wounds. She also lapsed into a coma for a number of months, underwent a dozen eye surgeries, received tube feedings for approximately a year, and experienced various physical disabilities. *Id.*

182. *Id.*

183. *Id.*

184. *Id.*

185. *Bartlett*, 133 S. Ct. at 2472–73, 2476. See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574–81 (2011).

186. *Bartlett*, 133 S. Ct. at 2473–74.

187. *Id.*

Pharmaceutical because the Hatch-Waxman Act requires generics to have the same composition as the relevant brand-name versions approved earlier by the FDA.<sup>188</sup> The Court held, therefore, that it was impossible for the defendant to comply with Hatch-Waxman and with a supposed duty under New Hampshire strict liability principles to change the drug's makeup.<sup>189</sup>

Justice Alito then noted that a drug's allegedly flawed composition was not the only basis on which tort liability might be based.<sup>190</sup> Alternatively, state law contemplated that the medication could be treated as defectively designed and unreasonably dangerous if its manufacturer did not provide adequate safety warnings.<sup>191</sup> The Court reasoned that with federal law barring the generic manufacturer from altering the drug's makeup, the inadequate warnings avenue to liability merited attention.<sup>192</sup> However, assuming that the plaintiff's strict liability claim would have obligated the generic manufacturer to provide a stronger safety warning than it provided, Hatch-Waxman's duty of sameness regarding generic labels again became relevant.<sup>193</sup> That duty barred Mutual Pharmaceutical from modifying the FDA-approved label.<sup>194</sup> The *Mensing* rationale, therefore, controlled—meaning that Bartlett's defective-design claim, insofar as it contemplated a strengthened warning regarding the medication, was preempted on impossibility grounds.<sup>195</sup>

When the First Circuit upheld the jury verdict in Bartlett's favor, it rejected the defendant's preemption defense by stating that the supposed problem of impossibility could have been avoided if Mutual Pharmaceutical had simply chosen not to produce sulindac at all.<sup>196</sup> The *Bartlett* majority rejected this reasoning, calling the “stop-selling” rationale “incompatible with our preemption [decisions, which] presume that an actor seeking to satisfy both his federal- and state-law obligations is

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188. 21 U.S.C. § 355(j)(2)(A) (2012); *Bartlett*, 133 S. Ct. at 2475.

189. *Bartlett*, 133 S. Ct. at 2475.

190. *Id.* at 2475–76.

191. *Id.*

192. *Id.* at 2476.

193. *Id.*

194. 21 U.S.C. § 355(j)(2)(A); *Bartlett*, 133 S. Ct. at 2476 (2013).

195. *Bartlett*, 133 S. Ct. at 2576–77, 2578; *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574–81 (2011).

196. *Bartlett*, 133 S. Ct. at 2472, 2477.

not required to cease acting altogether in order to avoid liability.”<sup>197</sup> Offering concluding comments similar to those of Justice Thomas in *Mensing*,<sup>198</sup> Justice Alito acknowledged that the plaintiff’s situation “is tragic and evokes deep sympathy.”<sup>199</sup> However, the *Bartlett* majority concluded, Congress had left the Court no choice but to conclude that state-law-based tort claims contemplating actions forbidden by federal law were preempted.<sup>200</sup> In addition, Justice Alito noted that “the Court would welcome Congress’ ‘explicit’ resolution of the difficult preemption questions that arise in the prescription drug context,” because such questions had “repeatedly vexed the Court—and produced widely divergent views—in recent years.”<sup>201</sup>

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197. *Id.* at 2477. The Court suggested, however, that the stop-selling argument might be treated differently if state law banned the sale of a product (a situation not before the Court in *Bartlett*). According to the Court, “[a]t least where a State imposes liability based on a balancing of a product’s harms and benefits in light of its labeling—rather than directly prohibiting the product’s sale—the mere fact that a manufacturer may avoid liability by leaving the market does not defeat a claim of impossibility.” *Id.* at 2478 n.5 (emphasis added).

198. *See Mensing*, 131 S. Ct. at 2581–82.

199. *Bartlett*, 133 S. Ct. at 2480.

200. *Bartlett*, 133 S. Ct. at 2480. The court observed, however, that it was “not address[ing] state design-defect claims that parallel the federal misbranding statute.” *Id.* at 2477 n.4. Under that statute, a drug is considered misbranded if its label does not contain adequate warnings about unsafe dosages of the medication or about unsafe methods or duration of administration of it. 21 U.S.C. § 352(f)(2) (2012). As interpreted by the FDA, the misbranding statute obligates drug makers, even after they receive FDA approval for their drug, to inform the FDA about newly acquired safety-related information of a significant nature and to request FDA approval of a strengthened label. *See* 21 C.F.R. §§ 201.57(e), 201.80(e), 314.80(b); *see also Mensing*, 131 S. Ct. at 2576–77 (discussing this FDA interpretation). The misbranding law can also obligate a manufacturer to remove its drug from the market if newly acquired information indicate that the medication is dangerous to consumers’ health even when prescribed as indicated on the label. *See* 21 U.S.C. § 352(j); *Bartlett*, 133 S. Ct. at 2577 n.4. The misbranding statute did not apply in *Bartlett*, the Court noted, because the evidence presented regarding sulindac was not newly acquired information that had not been made available to the FDA. However, in commenting that it was not addressing state law tort claims that parallel the federal misbranding statute, the Court may have left an opening for states to recognize such parallel claims and potentially enable plaintiffs to argue against preemption. This issue will receive further treatment later in the article. *See infra* text accompanying notes 359–61, 407–11, 418, 547–58.

201. *Bartlett*, 133 S. Ct. at 2480.

In a dissent that Justice Kagan joined, Justice Breyer observed that complying with both federal and state duties was not literally impossible for the defendant because it could have either stopped selling the drug in New Hampshire or continued to sell it, but pay money damages to plaintiffs such as Bartlett.<sup>202</sup> He asserted that the exercise of either option by the defendant would not pose an impermissible obstacle to the purposes underlying the federal drug regulation law—especially given the lack of an express preemption provision in the federal statutory scheme.<sup>203</sup>

As she did in *Mensing*,<sup>204</sup> Justice Sotomayor vehemently dissented.<sup>205</sup> In an opinion to which Justice Ginsburg also subscribed, Justice Sotomayor asserted that the majority adopted *Mensing*'s already too expansive view of impossibility and unjustifiably extended that decision's holding to justify a conclusion that the plaintiff's design-defect claim was preempted.<sup>206</sup> The Court did so, she continued, by determining that "Mutual Pharmaceutical was held liable for a failure-to-warn claim in disguise, even though the District Court clearly rejected such a claim and instead allowed liability on a distinct theory."<sup>207</sup> The majority's attempt to lay the blame for the outcome on Congress did not sit well with Justice Sotomayor, who stressed that "responsibility for the fact that Karen Bartlett has been deprived of a remedy for her injuries rests with this Court."<sup>208</sup> She maintained that if the majority had properly applied preemption principles<sup>209</sup> and had correctly

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202. *Id.* at 2480–82 (Breyer, J., dissenting).

203. *Id.* at 2482.

204. *See supra* text accompanying notes 170–75.

205. *Bartlett*, 133 S. Ct. at 2482 (Sotomayor, J., dissenting).

206. *Id.*

207. *Bartlett*, 133 S. Ct. at 2482. Commenting on what she regarded as a strained attempt by the majority to turn a design-defect claim into a failure-to-warn claim and then point to *Mensing* as a controlling precedent, Justice Sotomayor characterized *Bartlett* as relying on an unwarranted and incorrect, though unspoken, "assumption that federal law gives pharmaceutical companies a right to sell a federally approved drug free from common-law liability." *Id.* at 2483; *see id.* at 2491. She maintained that given the lack of an express preemption provision in the federal drug regulation laws and the presence of other indications that Congress did not intend to remove state-law-based tort claims from the regulatory picture, *Bartlett*'s preemption holding was unsound. *Id.* at 2484–85.

208. *Id.* at 2483; *see id.* at 2496.

209. *Id.* at 2483, 2485–86, 2494–95. In particular, Justice Sotomayor noted that the Court failed to take into account the usual presumption against



interpreted New Hampshire law, Bartlett's design-defect claim would have escaped preemption.<sup>210</sup>

## II. THE PHARMACEUTICALS TRILOGY: ANALYSIS AND FEDERAL REACTIONS

### A. ASSESSING THE THREE SUPREME COURT DECISIONS

The three decisions discussed above reveal a Court deeply divided over whether juries in tort cases should be able to second-guess the FDA after the agency has approved a drug. The dissenters in *Wyeth v. Levine* lost the initial battle, as the Court held that the plaintiff's failure-to-warn claim against the manufacturer of a brand-name drug approved by the FDA was not preempted.<sup>211</sup> But in the next two battles (*Mensing* and *Bartlett*), the *Levine* dissenters helped to form a majority for rulings that held tort claims against manufacturers of generics to be preempted.<sup>212</sup> As a practical matter, the justices in the *Mensing-Bartlett* majority made significant strides toward winning the larger war over whether tort claims against drug makers should be permitted at all.<sup>213</sup> Because pharmacists fill prescriptions with generics far more often than with brand-

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preemption, the lack of an express preemption provision in the relevant federal drug regulation laws, and indications that Congress envisioned state-law-based tort actions as playing a complementary drug-regulation role. *Id.* at 2483–85, 2491–96.

210. See *id.* at 2486–92. Justice Sotomayor contended that the majority misinterpreted New Hampshire law regarding strict liability claims of the design-defect variety by concluding that such claims would effectively require the generic manufacturer to change the drug's composition or label. No such requirement stemmed from the relevant state tort law, she argued. *Id.* at 2486–87, 2488–89. She observed that a tort claim of the sort at issue in the case "creates an incentive for drug manufacturers to make changes to its product . . . to try to avoid liability," but such an incentive and the possible exposure to liability for damages do not amount to a "legal mandate" to change the drug's composition or label. *Id.* at 2488. In Justice Sotomayor's view, "[t]his difference is significant one: A mandate leaves no choice for a party that wishes to comply with the law, whereas an incentive may only influence a choice." *Id.* Without such a mandate under state law, the Court's argument for impossibility preemption "does not get off the ground." *Id.* at 2489.

211. *Wyeth v. Levine*, 555 U.S. 555, 558–59, 571–73, 581 (2009).

212. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572 (2011); *Bartlett*, 133 S. Ct. at 2470, 2473, 2475–78.

213. See John H. Beisner et al., "Supreme Court's *Bartlett* Decision Reaffirms Broad Scope of Generic Drug Preemption," SKADDEN (June 24, 2013), <https://www.skadden.com/insights/supreme-courts-bartlett-decision-reaffirms-broad-scope-generic-drug-preemption>.

name drugs, the outcomes in *Mensing* and *Bartlett* mean that for most harmed consumers, a tort claim is likely to be prohibited.<sup>214</sup>

The *Mensing-Bartlett* tandem clearly signals that consumers who are harmed by a prescription medication and want to pursue a legal remedy must hope that they received a brand-name drug rather than a generic. As Justice Sotomayor put it in her *Mensing* dissent, the “happenstance” of what the pharmacist dispensed now has a potentially determinative effect on the harmed patient’s ability to obtain legal recourse.<sup>215</sup> Her accurate observation suggests that analytical soundness became a casualty as the war over the fate of tort claims progressed. How could it be likely that Congress would envision a legal regime in which a patient’s rights would hinge on a pharmacist’s decision on which one of two identical drugs to dispense? Before further exploration of what Congress presumably would or would not have wanted regarding generics, however, it is necessary to trace how the “happenstance” factor acquired such significance.

In *Levine*, the five justices in the majority invoked familiar principles of preemption analysis in concluding that federal law—in particular, the fact of FDA approval—did not preempt the plaintiff’s failure-to-warn claim against the brand-name manufacturer.<sup>216</sup> They provided a reminder that the purpose of Congress is the “ultimate touchstone” in deciding whether preemption is warranted.<sup>217</sup> They applied the presumption against preemption, in light of the absence of a clear indication of congressional intent that preemption would be appropriate.<sup>218</sup> Moreover, they ascribed considerable significance to the lack of an express preemption provision in the relevant federal drug regulation laws and contrasted that absence with the presence of such a provision in the statutes dealing with medical devices.<sup>219</sup> Finally, they highlighted longstanding indications that Congress regarded tort claims under state law as complementary to FDA regulation of

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214. *Mensing*, 131 S. Ct. at 2580–82; see *supra* text accompanying notes 8–9.

215. *Mensing*, 131 S. Ct. at 2583 (Sotomayor, J., dissenting).

216. See *Levine*, 555 U.S. at 565–69, 571–74.

217. *Levine*, 555 U.S. at 565 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

218. *Id.*; see *supra* note 104 (discussing presumption against preemption).

219. *Levine*, 555 U.S. at 563–64, 567, 574.

drugs.<sup>220</sup> All of these considerations pertained to the purposes-and-objectives form of preemption, which the defendant sought but the Court declined to apply.<sup>221</sup>

The *Levine* majority also addressed impossibility preemption, an appropriate subject of analysis because the defendant had argued in the alternative for preemption on that basis. As noted earlier, the Court rejected the defendant's impossibility argument because the changes-being-effected (CBE) regulation enabled brand-name manufacturers such as the defendant to begin using, without prior FDA approval, a revised label with a stronger warning if later-acquired information indicated a need for it.<sup>222</sup> Justice Thomas declined to join the majority opinion because it discussed purposes-and-objectives preemption—a preemption basis of which he categorically disapproves because he sees it as potentially leading to judicial flights of fancy.<sup>223</sup> However, he concurred in the judgment, agreeing with the basic point that the defendant could not succeed with its impossibility argument.<sup>224</sup> The three dissenters, of course, regarded preemption as appropriate and objected to the notion that a jury in a tort case might effectively second-guess the FDA.<sup>225</sup>

The attention paid in *Levine* to the impossibility argument was both appropriate and understandable, but it provided an opening that led to the contrary preemption holdings in *Mensing* and *Bartlett*. Having unsuccessfully argued for preemption of the plaintiff's failure-to-warn claim against the brand-name manufacturer in *Levine*, the dissenters in that case (Chief Justice Roberts and Justices Scalia and Alito)<sup>226</sup> could hardly have been expected to oppose preemption of the same type of claim against a generic manufacturer. In *Mensing*, therefore, they found the impossibility rationale appealing and

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220. *Id.* at 567, 574–75, 578–79.

221. *Id.* at 573–79.

222. *Id.* at 568–70. For discussion of the CBE regulation and its relevance to *Levine*, see *supra* text accompanying notes 45–47, 109–12; see also *supra* note 111 and accompanying text.

223. See *Levine*, 555 U.S. at 583 (Thomas, J., concurring).

224. *Id.* at 582–83.

225. See *id.* at 604, 606–26 (Alito, J., dissenting).

226. See *id.*

saw the Hatch-Waxman Act's duty of "sameness" as a convenient path to a conclusion of impossibility.<sup>227</sup>

Justice Thomas, who had concurred in the judgment in *Levine* but wrote the majority opinion in *Mensing*, no doubt regarded the impossibility rationale as desirable because focusing on it drew attention away from issues associated with the purposes-and-objectives form of preemption.<sup>228</sup> He opposes most inquiries into whether preemption should or should not take place based on what Congress intended, because he sees too much potential that courts would not remain tethered to actual statutory language in deciding on supposed congressional purposes. In Justice Thomas's view, courts conducting preemption analyses should determine congressional purposes purely from consideration of the statutory language.<sup>229</sup> Insofar as it set up a duty of sameness regarding generics, Hatch-Waxman's language enabled Justice Thomas to answer the impossibility question with a "yes" in *Mensing* even though he provided a "no" answer in *Levine*.<sup>230</sup> The emphasis on supposed impossibility in light of the duty of sameness evidently was enough to convince Justice Kennedy, who had been part of the *Levine* majority, to add a fifth vote for preemption in *Mensing*.<sup>231</sup> The same majority then held together in *Bartlett*.<sup>232</sup>

The FDA helped the *Mensing* majority reach its impossibility conclusion by taking the position that generic manufacturers could not use the CBE regulation's avenue to use of a strengthened label. The Court could then conveniently defer to this FDA interpretation<sup>233</sup> and maintain that the holding in *Mensing* was not inconsistent with *Levine* despite the two decisions' different outcomes.<sup>234</sup>

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227. See 21 U.S.C. § 355(j)(2)(A) (2012); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2575 (2011).

228. See *Levine*, 555 U.S. at 583 (Thomas, J. concurring).

229. See *Levine*, 555 U.S. at 588, 595, 598–601; see also Meltzer, *supra* note 86, at 2–5, 35 (analyzing Justice Thomas's textualist approach to preemption).

230. *Mensing*, 131 S. Ct. at 2574–75, 2577–79, 2580–81; see *Levine*, 555 U.S. at 582–83 (Thomas, J., concurring).

231. *Mensing*, 131 S. Ct. at 2572; see *Levine*, 555 U.S. at 557.

232. See *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2469 (2013).

233. *Mensing*, 131 S. Ct. at 2575–76.

234. See *id.* at 2581. The brand-name manufacturer's ability to utilize the CBE avenue had been among the reasons why, in *Levine*, the plaintiff's failure-to-warn claim was not preempted. See *Levine*, 555 U.S. at 568–70. In a November 2013 proposed regulation, the FDA outlined a proposal to allow

However, the route to finding impossibility in *Mensing* was not otherwise smooth or clear-cut. In another position advanced by the FDA—one that was potentially more favorable to plaintiffs wishing to pursue tort claims—the agency asserted that all drug manufacturers (generic manufacturers included) have an ongoing safety duty to propose strengthened warnings to the FDA if they acquire important safety-related information after the relevant drug label received FDA approval.<sup>235</sup> The Court declined to defer to this FDA interpretation but went on to note that even if it were assumed to be correct, it would not make a difference in the impossibility analysis.<sup>236</sup> The plaintiffs and the FDA contended that the defendant should not be able to argue impossibility because, in failing to fulfill a supposed federal duty to request FDA approval of an enhanced label, the defendant had not even tried to launch a proceeding that could have led to a stronger label of the sort contemplated by the tort claim at issue.<sup>237</sup> This was a “fair argument,” the Court

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generic manufacturers to rely on the CBE regulation. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985–87 (Nov. 13, 2013) (to be codified at 21 C.F.R. pt. 314, 601). Under the current CBE regulation, as interpreted by the FDA, brand-name manufacturers may begin using a strengthened warning label without the FDA’s prior approval if later-acquired safety information warrants using such a revised label. *See supra* text accompanying notes 45–47. Although FDA approval of the revised label would ultimately be necessary, the approval could come after the revised label has been put into use. *See id.* The proposed FDA regulation would open up the CBE avenue to generic manufacturers as well. 78 Fed. Reg. 67985, 67986–87. If the proposed regulation were to become a final rule, it presumably would undercut the stated impossibility rationale in *Mensing*, *see Mensing*, 131 S. Ct. at 2574–75, 2577–79, 2580–81, and would help support arguments that a failure-to-warn case against a generic manufacturer should escape preemption under a *Levine*-like rationale. *See Levine*, 555 U.S. at 568–70. If the proposed FDA regulation were promulgated and the Court again had to decide a failure-to-warn case against a generic manufacturer, a ruling of preemption seemingly would not result unless the Court put a questionable gloss on its *Mensing* reasoning, overruled *Levine* or recast its reasoning, or ruled that the regulation unreasonably interpreted governing statutes. Moreover, if *Mensing*’s rationale took a hit, the reasoning in *Bartlett* would be significantly undermined as well. It is important to note, however, that the proposed regulation has remained just that—proposed—for a significant length of time and that its ultimate status is uncertain. *See infra* note 268.

235. *Mensing*, 131 S. Ct. at 2576, 2578–79. The FDA based this supposed duty on the federal misbranding statute. *See supra* text accompanying notes 48–53.

236. *Mensing*, 131 S. Ct. at 2577–79.

237. *Id.* at 2579.

conceded,<sup>238</sup> but it failed because the mere filing of a request for authority to use a modified label would not have guaranteed that a stronger label would in fact result.<sup>239</sup> According to the Court, the fact that FDA approval would be necessary meant that the generic manufacturer could not “independently”—i.e., by acting purely on its own—satisfy both its federal duty to use the previously approved label and its state-law obligation to use a stronger label.<sup>240</sup>

In order to dispose of the plaintiffs’ “fair argument” that impossibility was not present, the *Mensing* majority added the independent action element to the analysis and thereby broadened the impossibility doctrine in a pro-defendant way.<sup>241</sup> As the four dissenters pointed out, this action by the Court softened the demanding nature of the impossibility defense.<sup>242</sup> The Court also ignored the familiar presumption against preemption and paid little attention to the traditional notion that Congress regarded common law tort actions as a complement to the federal drug regulation regime.<sup>243</sup> These almost certainly deliberate omissions appear consistent with Justice Thomas’s desire to keep the focus on impossibility issues and avoid a foray into anything that might resemble a purposes-and-objectives inquiry.<sup>244</sup>

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238. *Id.*

239. *Id.* at 2578.

240. *Id.* at 2580; *see id.* at 2579, 2580–81.

241. *See id.* at 2589–90 (Sotomayor, J., dissenting).

242. *See id.* at 2582, 2586–90.

243. *See id.* at 2586–87. In an apparent effort to eliminate the traditional presumption against preemption, Justice Thomas devoted a section of his opinion to an argument subscribed to by only four justices (himself included). According to this argument, the Supremacy Clause in the U.S. Constitution amounts to a *non obstante* provision that “impliedly repeals” state laws if they conflict with federal law. *Id.* at 2579–80. Because of this supposed *non obstante* provision, he continued, courts “should not strain to find ways to reconcile federal law with seemingly conflicting state law.” *Id.* at 2580. Justice Kennedy did not join this section of the opinion. *See id.* at 2572. Justice Thomas’s *non obstante* trial balloon, therefore, did not command a majority of the Court. For discussion of problems with the *non obstante* argument and the effects it could produce if it were to be adopted by the Supreme Court, see Meltzer, *supra* note 86, at 4–5, 8–9, 35, 45–52. *See also* Young, *supra* note 86, at 310–20, 325–28 (examining problems with *non obstante* argument).

244. *See Mensing*, 131 S. Ct. at 2577–79, 2581–82. For discussion of Justice Thomas’s opposition to the types of inquiries associated with purposes-and-objectives preemption (obstacle preemption), *see supra* text accompanying notes 223–24, 228–29.

The omissions from the *Mensing* analysis also suggest that Justice Sotomayor offered a partially valid criticism when, in her dissent, she charged the majority with seeking to “rewrite” the decision in *Levine*.<sup>245</sup> Because *Levine* involved a brand-name manufacturer and *Mensing* involved a generic manufacturer subject to a special set of statutes, the *Mensing* majority did not literally rewrite *Levine*.<sup>246</sup> But to the extent that the majority opinion in *Mensing* ignored or paid little attention to key features of the decision issued only two years earlier, *Mensing* made certain that *Levine*’s lessons about purposes-and-objectives analysis would not be heeded.<sup>247</sup> In a practical sense, moreover, *Mensing* effectively rewrote the tort liability rules for most harmed consumers, because far more receive generics than receive brand-name drugs when their prescriptions are filled.<sup>248</sup>

After *Mensing*’s preemption ruling, the same five-justice majority took what it regarded as the next logical step: holding, in *Bartlett*, that the duty of sameness applicable to generics necessitated preemption of the plaintiff’s design-defect claim against the generic manufacturer.<sup>249</sup> The *Bartlett* outcome should not have been seen as foreordained by *Mensing*, however. To shoehorn *Bartlett* into the impossibility rationale applied in *Mensing*, the Court misconstrued the nature and effects of New Hampshire tort law.

Justice Alito, writing for the *Bartlett* majority, launched the misconstruction by characterizing the plaintiff’s design-defect claim as contemplating a requirement that the defendant change the composition of the drug at issue.<sup>250</sup> Changing the drug’s composition, however, was not something the defendant, as a generic manufacturer, could do without violating the Hatch-Waxman Act.<sup>251</sup> Justice Alito then reasoned that impossibility preemption barred the design-defect claim insofar as it would necessitate an altered design for the drug.<sup>252</sup>

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245. *Mensing*, 131 S. Ct. at 2582 (Sotomayor, J., dissenting).

246. *Cf. Mensing*, 131 S. Ct. at 2582–83.

247. *See Wyeth v. Levine*, 555 U.S. 555, 563–69, 574–79 (2009).

248. *See supra* text accompanying notes 8–9; *see also supra* note 10 and accompanying text.

249. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2475–78 (2013).

250. *See id.* at 2573–75.

251. *See id.* at 2471.

252. *Id.* at 2575; *see id.* at 2471.

However, in asserting that the design-defect claim effectively required a change in the drug's makeup, the Court ascribed a false effect to the claim and overlooked the important compensatory function of tort actions. Such claims are meant to allow compensation for plaintiffs who have experienced harm as a result of defendants' violations of legal duties.<sup>253</sup> Until *Mensing* and *Bartlett*, that function had been seen as compatible with FDA regulation of pharmaceuticals.<sup>254</sup> Of course, a defendant held liable in a design-defect case may have an incentive to change the drug's composition—something a generic manufacturer could not do and something the name-brand manufacturer could do only with FDA approval. As Justice Sotomayor pointed out in her *Bartlett* dissent, however, an incentive furnished by state law does not amount to a requirement under state law.<sup>255</sup> Only when state law requires what federal law prohibits should impossibility apply.<sup>256</sup>

The *Bartlett* majority's misinterpretation of the design-defect claim's effect also led the Court to identify two alternative but problematic steps that state law was calling upon the generic manufacturer to take. According to the Court, the generic manufacturer either would have to change the drug's composition (as supposedly required by state tort law) or stop selling the drug.<sup>257</sup> The Court reasoned that the former was barred by the Hatch-Waxman Act—thus calling impossibility into play—and that the latter, as a matter of public policy, was not a route generic manufacturer should be expected to take in order to avoid running afoul of conflicting federal and state requirements.<sup>258</sup> This either-or, however, amounted to a false alternative because changing the drug's makeup was not required by state common law (as noted

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253. See *id.* at 2481–82 (Breyer, J., dissenting); *id.* at 2484–85 (Sotomayor, J., dissenting).

254. See *Bartlett*, 133 S. Ct. at 2482 (Breyer, J., dissenting); *id.* at 2484–85 (Sotomayor, J., dissenting); *Wyeth v. Levine*, 555 U.S. 555, 574–75 (2009). Tort law has the ability to “fill the gaps in federal regulation by [helping to] identify previously unknown drug dangers.” *Bartlett*, 133 S. Ct. at 2485. Moreover, preserving an appropriate role for such common law claims may be especially important because the federal drug regulation laws do not include a provision granting a private right of action to consumers harmed by unsafe drugs. See *Levine*, 555 U.S. at 574.

255. *Bartlett*, 133 S. Ct. at 2488 (Sotomayor, J., dissenting).

256. *Id.* at 2489.

257. *Id.* at 2474–75, 2477 (majority opinion).

258. *Id.* at 2475, 2477–78.



above) and because there was another option the Court did not identify. Under that option, the generic manufacturer could continue to sell the drug as designed but pay damages to harmed plaintiffs who could prove the elements of their tort claims. As Justice Breyer noted and Justice Sotomayor suggested in their respective dissents in *Bartlett*, that option would not call for the defendant to violate the Hatch-Waxman Act and would respect the compensatory role that tort lawsuits have traditionally played.<sup>259</sup> The *Bartlett* majority's failure to consider this middle-ground option led Justice Sotomayor to observe derisively, but not without foundation, that the majority appeared to regard generic manufacturers as being entitled to an unfettered right to sell their products without any risk of tort liability.<sup>260</sup>

Continuing the shoehorning of *Bartlett* into the impossibility rationale of *Mensing*, Justice Alito again examined New Hampshire tort law and concluded that it would permit strict liability claims of the design-defect variety when unreasonable dangerousness stemmed from the product itself or from the absence of adequate warnings.<sup>261</sup> Because it had already concluded that a design-defect claim premised on the drug's composition and harmful side-effects would require the generic manufacturer to change the drug's makeup and thus could not go forward in light of Hatch-Waxman,<sup>262</sup> the Court reasoned that only the inadequate-warnings avenue to design-defect liability remained. This meant, as Justice Alito explained, that the plaintiff's claim had to be treated as a failure-to-warn claim.<sup>263</sup> Enter *Mensing* and, again, Hatch-Waxman, this time its provision requiring generic drugs to bear the same label approved by the FDA for the relevant brand-name version. The Court concluded, therefore, that the impossibility rationale applied and that the plaintiff's claim in *Bartlett*, treated as if it were a failure-to warn claim, was every bit as preempted as the actual failure-to-warn claim in *Mensing*.<sup>264</sup>

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259. *Id.* at 2480–81, 2482 (Breyer, J., dissenting); *see id.* at 2484–85, 2486–87, 2492–94 (Sotomayor, J., dissenting).

260. *Id.* at 2491, 2494.

261. *Bartlett*, 133 S. Ct. at 2474–75.

262. *Id.* at 2473–75.

263. *Id.* at 2474, 2475–76.

264. *Id.* at 2476–77, 2478, 2479–80. In her dissent, Justice Sotomayor criticized the majority for “unwisely extend[ing]” its preemption holding in

As noted earlier, the Court expressed sympathy for the severely harmed plaintiffs in both *Mensing* and *Bartlett*, acknowledging in *Mensing* that Congress had dealt them an “unfortunate hand,” and offering comments of a similar nature in *Bartlett*.<sup>265</sup> In emphasizing that Congress supposedly had dictated the outcome through the provisions contained in Hatch-Waxman, the Court suggested that congressional or FDA action to change the governing legal rules might lead to different outcomes in future cases against generic manufacturers.<sup>266</sup> But such congressional action seems highly unlikely,<sup>267</sup> and the prospects of corrective action by FDA remain uncertain at best.<sup>268</sup> The Court’s blame-it-on-Congress

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*Mensing* through the questionable device of concluding that the defendant had been held liable “for a failure-to-warn claim in disguise, even though the [trial court] clearly rejected such a claim and instead allowed liability on a distinct theory.” *Id.* at 2482 (Sotomayor, J., dissenting).

265. See *Bartlett*, 133 S. Ct. at 2478, 2480; *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2581 (2011).

266. *Bartlett*, 133 S. Ct. at 2480; *Mensing*, 131 S. Ct. at 2581–82.

267. In the current political environment, attempts to overturn *Mensing* and *Bartlett* legislatively would seem doomed to failure. Bills meant to have such an effect have died amid opposition in Congress. See Jordan Paradise, *FDA’s Proposed Changes to Generic Drug Label Rules Questioned by Members of Congress*, HEALTH REFORM WATCH (Jan. 29, 2014), <http://www.healthreformwatch.com/2014/01/29/fdas-proposed-changes-to-generic-drug-label-rules-questioned-by-members-of-congress/>. Moreover, it is a rare occasion when Congress enacts a statute that overturns a Supreme Court decision in which the Court ruled in favor of preemption. Meltzer, *supra* note 86, at 18, 40. Commentators have proposed new statutory frameworks that are interesting, see, e.g., Lee, *supra* note 8, at 245–58, but the odds that Congress would scuttle or rework the existing laws seem remote.

268. Although they may be somewhat greater than the chances of congressional action, the chances of FDA action that would negate *Mensing* and *Bartlett* fall far short of a sure thing. In November 2013, the FDA announced a proposed regulation that, if promulgated, would allow generic manufacturers to rely on the CBE regulation—a regulation currently available only to brand-name manufacturers. See *supra* text accompanying notes 45–47; *supra* note 234 and accompanying text. For discussion of the proposed regulation and of other rulemaking avenues that might be promising, see Marie Boyd, *Unequal Protection Under the Law: Why FDA Should Use Negotiated Rulemaking to Reform the Regulation of Generic Drugs*, 35 CARDOZO L. REV. 1525, 1527–28, 1541–54 (2014). If the proposed regulation were to become a final rule, it could have a significant effect on generic manufacturers’ tort liability. The proposed regulation remains stalled, however. The usual comment period, originally set to run through mid-January, 2014, expired long ago. See Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985, 67985 (Nov. 13, 2013) (to be codified at 21 C.F.R. pt. 314, 601). Eventually the FDA reopened the comment period and extended it to April 27,

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2015. See Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products; Public Meeting; Request for Comments; Reopening of the Comment Period, 80 Fed. Reg. 8577 (proposed Feb. 18, 2015) (to be codified at 21 C.F.R. pt. 314, 601). In addition, the FDA announced and then conducted a March 2015 public meeting at which comments on the proposed regulation and alternatives to it could be offered. See *id.* No further developments have occurred as of this writing. As would be expected, harmed consumers and interest groups aligned with them have offered comments favoring the proposed regulation. See Alliance for Justice et al., *Comments to FDA on Generic Drugs and Industry Proposal*, CTR. FOR JUST. & DEMOCRACY (Apr. 20, 2015), <https://centerjd.org/content/comments-fda-generic-drugs-and-industry-proposal> (including comments of Alliance for Justice, Center for Justice & Democracy, Connecticut Center for Patient Safety, Mothers Against Medical Error, New Yorkers for Patient & Family Empowerment, Public Justice, and Texas Watch); Sabriya Rice, *Generic drug makers await FDA decision on labeling regulation*, MOD. HEALTHCARE (Mar. 14, 2014), <http://www.modernhealthcare.com/article/20140314/NEWS/303149917>. Some members of Congress have also expressed their support for the FDA's proposed action. *Id.*; Kurt R. Karst, *Generic Drug Labeling Preemption: The Flavor of the Day*, FDA L. BLOG (Mar. 10, 2014), [http://www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/2014/03/generic-drug-labeling-preemption-the-flavor-of-the-day.html](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2014/03/generic-drug-labeling-preemption-the-flavor-of-the-day.html). As would also be expected, however, generic manufacturers, having received largely a free pass from the *Mensing-Bartlett* tandem in regard to potential tort liability, have objected to the proposed regulation and have advocated alternative proposals. See Paradise, *supra* note 267; Scott Gottlieb, Alex Brill & Robert W. Pollock, *Proposed FDA Generic Drug Regulation: Higher Prices, No Public Health Benefit*, AM. ENTER. INST. (Mar. 12, 2014), <https://www.aei.org/publication/proposed-fda-generic-drug-regulation-higher-prices-no-public-health-benefit/>. They have also signaled that they would oppose the proposed regulation in other ways if it were promulgated in the proposed version's form. For instance, some generic manufacturers have said they would challenge any such final rule in court, on the ground that the rule would go beyond the FDA's statutory authority. Alexander Gaffney, *Generic Drug Industry Threatens FDA With Lawsuit Over Drug Labeling Proposal*, REG. AFF. PROF. SOC'Y (Oct. 7, 2014), <http://www.raps.org/Regulatory-Focus/News/2014/10/07/20497/Generic-Drug-Industry-Threatens-FDA-With-Lawsuit-Over-Drug-Labeling-Proposal/>. Moreover, some in Congress have expressed concern about the whether such a rule would fall within the FDA's authority. Paradise, *supra* note 267; Alexander Gaffney, *FDA Reopens Debate Over Major Generic Drug Labeling Rule*, REG. AFF. PROF. SOC'Y (Feb. 17, 2015), <http://raps.org/Regulatory-Focus/News/2015/02/17/21361/FDA-Reopens-Debate-Over-Major-Generic-Drug-Labeling-Rule/> [hereinafter *FDA Reopens Debate*]. Given the opposition in influential quarters to the proposed rule, the legal challenges that could follow its promulgation, and the FDA's solicitation of further comments regarding not only the proposed rule but also possible alternatives, the proposed regulation, at least in its original form, may no longer be as high a priority for the FDA as it was when it was announced. See *FDA Reopens Debate*. In its portion of the legally required announcement of regulatory agendas that federal agencies released in December 2015, the FDA still listed the proposed regulation on its agenda. See Introduction to the Unified Agenda of Federal Regulatory and Deregulatory Actions, 80 Fed. Reg.

observations, moreover, had a forced tone. Given the analytical gymnastics employed in *Bartlett* in order to bring the case within *Mensing*—which itself involved a pro-defendant broadening of the impossibility doctrine—the Court reached conclusions not compelled by anything Congress had done.<sup>269</sup>

In issuing its preemption rulings in *Mensing* and *Bartlett*, the Court paid heed to the language of Hatch-Waxman and to the majority justices' supposed understanding of what state tort law contemplated.<sup>270</sup> But with the purpose of Congress being the “ultimate touchstone” in determinations of whether preemption is warranted,<sup>271</sup> the Court needed to pay attention not only to what Congress said in substantive Hatch-Waxman provisions but also to what Congress *did not say*. In addition, proper consideration should have been given to the context in which Congress added Hatch-Waxman to the federal drug regulation laws.

Regarding what Congress did not say, the most important thing to note is the absence of an express preemption provision in the federal statutes pertaining to brand-name and generic drugs.<sup>272</sup> The fact that Congress did not include such a provision was appropriately a point of emphasis in *Levine* as the Court rejected the defendant's preemption arguments,<sup>273</sup> but was essentially glossed over in *Mensing* and *Bartlett* as the Court strained to justify its preemption holdings.<sup>274</sup> Of course,

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77709 (Dec. 15, 2015); Introduction to the 2015 U.S. Regulatory Plan, HHS-FDA 40 Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 80 Fed. Reg. 77770 (Dec. 15, 2015). However, the FDA noted that it was considering “several alternatives described in comments submitted to the public docket established for the proposed rule.” *Id.* at 77771. The FDA's regulatory agenda also mentioned July 2016 as a target date for a final rule, *id.*, but the agency's slow pace thus far suggest that there may be further delays beyond July 2016. It also seems fair to assume that if an alternative version of the proposed regulation would ultimately achieve final rule status, the alternative version probably would have far less effect on preemption analysis than the proposed regulation might have had.

269. See *supra* text accompanying notes 157–75, 185–210.

270. See *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470–71, 2473–76 (2013); *Mensing*, 131 S. Ct. at 2574–75, 2577–78.

271. See *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (internal citation omitted).

272. *Id.* at 563.

273. *Id.* at 563, 567, 574.

274. See *Bartlett*, 133 S. Ct. 2466, 2480 (2013). See generally *Mensing*, 131 S. Ct. at 2582–83 (2011) (Sotomayor, J., dissenting) (“a plurality of the Court

the Court was correct when it observed that an express preemption clause is not essential in order for preemption to be held appropriate,<sup>275</sup> but the lack of such a provision should be a strong indicator of a lack of preemptive purpose on the part of Congress when the context suggests that the omission was deliberate.

Congress has included an express preemption provision in certain statutes dealing with medical matters, most notably in the laws under which the FDA regulates and approves medical devices.<sup>276</sup> It has also included an express preemption clause in a special set of statutes dealing with FDA-approved vaccines and setting up a compensation fund for vaccine recipients who experienced harm.<sup>277</sup> Given these related settings in which Congress has put an express preemption clause in the relevant statutes, the lack of such a clause in the drug regulation laws suggests a deliberate decision by Congress to leave it out. Under the circumstances, the absence of an express preemption clause should have been treated, as it was in *Levine*, as a strong indicator of a congressional purpose that there should be room in the regulatory picture for state-law-based tort actions.<sup>278</sup>

After the *Mensing-Bartlett* tandem, however, a preemption-either-way message has emerged. There seems little doubt that if there had been an express preemption provision in the drug regulation laws, the Court would have found the tort claims preempted, as it did in a leading case dealing with tort claims against the manufacturer of an FDA-

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tosses aside our repeated admonition that courts should hesitate to conclude that Congress intended to pre-empt state laws governing health and safety.”).

275. *Bartlett*, 133 S. Ct. at 2480; *Mensing*, 131 S. Ct. at 2577 n.5.

276. 21 U.S.C. § 360k (2012). For discussion of the medical device statutes and the Supreme Court’s key decisions on whether FDA approval of a device preempts tort claims pertaining to it, see *supra* notes 93–94 and accompanying text.

277. See 42 U.S.C. § 300aa-22(b)(1) (2012). In *Bruesewitz v. Wyeth LLC*, parents of a child allegedly harmed by a vaccine rejected what they could have recovered under the no-fault compensation program set up by the National Childhood Vaccine Injury Act (NCVIA). *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1070–76 (2011). Instead, they brought a design-defect tort claim against the vaccine’s manufacturer. A six-justice majority of the Supreme Court held that although the NCVIA’s above-cited express preemption clause did not preempt all tort claims, it preempted the plaintiffs’ design-defect claim. *Id.* at 1075–82.

278. See *Wyeth v. Levine*, 555 U.S. 555, 563, 567, 574 (2009).

approved medical device.<sup>279</sup> In *Mensing* and *Bartlett*, the Court opted for preemption despite the conspicuous absence of an express preemption clause.<sup>280</sup> The resulting lesson has a “heads, I win; tails, you lose” feel to it.

In its *Mensing-Bartlett* focus on the Hatch-Waxman Act’s requirements regarding generics, the Court did not address three key questions that should have been important in the preemption analysis. First, in Hatch-Waxman, did Congress really intend to deprive harmed consumers of the ability to bring tort actions if they happened to receive a generic version of a drug rather than the brand-name version? Second, if Congress had such an intent (which seems unlikely), wouldn’t it have said something to that effect rather than relying on the hope that courts at some later point would say such claims are impliedly preempted? Third, would Congress have wanted Hatch-Waxman’s duty of sameness to be interpreted as the Court did in construing the statute to require sameness regarding drug composition and drug label,<sup>281</sup> but not regarding potential liability for harm caused? These overlapping questions merit attention here.

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279. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317–18, 322–26, 330 (2008). As noted previously, the Court held in *Riegel* that the medical device statute’s express preemption clause bars tort claims against the maker of an FDA-approved device if the device underwent the FDA’s highest level of review for safety and effectiveness. *Id.* at 327–28. *See supra* note 93 and accompanying text. However, if the device underwent only the lower-level review for substantial equivalence to a pre-1976 device, the express preemption clause does not preempt tort claims against the device’s manufacturer. *Riegel*, 552 U.S. at 322–23; *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 492–94, 500–01 (1996); *see supra* note 94 and accompanying text.

280. In so holding, the Court created an interesting inconsistency regarding the rights of certain consumers who experienced harm as a result of taking or using a product regulated by the FDA. If the harm-causing product was a medical device and the device only had to undergo the lower-level substantial equivalence review rather than the rigorous safety-and-effectiveness review contemplated by the pre-market approval process, the plaintiffs’ tort claims are not preempted. *Riegel*, 552 U.S. at 322–23; *Lohr*, 518 U.S. at 492–94, 500–01. However, if the harm-causing product was a generic drug, whose manufacturer only has to demonstrate equivalence to a brand-name drug (as opposed to completing the rigorous safety-and-effectiveness review contemplated by the new drug approval process), the plaintiffs’ tort claims face preemption. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470, 2471, 2473, 2475–78 (2013); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572, 2574–75, 2577–79, 2581–82 (2011).

281. *Bartlett*, 133 S. Ct. at 2471; *Mensing*, 131 S. Ct. at 2574–75, 2577.

Hatch-Waxman appears to have been prompted by pro-consumer and promotion-of-competition concerns.<sup>282</sup> By exempting generics from the time-consuming, extensive, and expensive showings required for safety and effectiveness purposes in the new drug approval process, Congress could enhance the likelihood that generics would in fact be brought to market and would be lower-priced than brand-name drugs.<sup>283</sup> That state of affairs presumably would be good for consumers. In addition, competition would be enhanced and brand-name manufacturers would be less likely to have de facto monopoly positions in the market even after their patents expired.<sup>284</sup> By requiring a showing of equivalence to the relevant brand-name medications and by requiring generics to have the same label as the brand-name label previously approved by the FDA, Congress could instill public confidence in generics and lessen consumers' possible concerns that generics might not be as safe or effective as brand-name drugs.<sup>285</sup> Again, consumers presumably would benefit.

With Hatch-Waxman being a pro-consumer enactment in the senses noted above, it seems unlikely that Congress would have intended the anti-consumer results reached through the *Mensing* and *Bartlett* holdings that barred harmed consumers' tort claims. Neither does it seem likely that Congress would use Hatch-Waxman to promote broader use of generics but stealthily seek to deny consumers access to the courts if they experienced harm as a result of such use. *Mensing* and *Bartlett*, however, achieved results consistent with that unlikely scenario.

From a promotion-of-competition perspective, Hatch-Waxman bears the mark of a Congress willing to ease a costly regulatory burden on generic manufacturers in order to enable them to compete more effectively with brand-name manufacturers.<sup>286</sup> It does not seem likely, however, that Congress had in mind a state of affairs under which generic manufacturers not only would have their regulatory approval costs slashed in comparison with those of brand-name

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282. See, e.g., *FTC v. Actavis Inc.*, 133 S.Ct. 2223, 2225–26 (2013) (noting the Hatch-Waxman Act's "general procompetitive thrust").

283. See *Bartlett*, 133 S. Ct. at 2471; *Mensing*, 131 S. Ct. at 2574.

284. *Bartlett*, 133 S. Ct. at 2471; *Mensing*, 131 S. Ct. at 2574.

285. See *Mensing*, 131 S. Ct. at 2574.

286. See, e.g., *FTC v. Actavis Inc.*, 133 S.Ct. 2223, 2225–26 (2013).

manufacturers, but would also receive the benefit of an exemption from the tort liability that brand-name manufacturers could still face. Even a Congress inclined to improve the competitive prospects of generics would not have been inclined to give generic manufacturers such a double benefit, whose effect could tilt the competitive playing field markedly against brand-name manufacturers. Again, however, the interpretations of Hatch-Waxman in *Mensing* and *Bartlett* are consistent with that unlikely prospect.<sup>287</sup> Then there is the “happenstance” problem.<sup>288</sup> Whatever one thinks of Congress generally or of the wisdom (or lack thereof) underlying particular enactments, it is hard to believe that in an extensive and detailed statutory treatment of drugs subject to federal regulation, Congress would have envisioned hinging important consumer rights on whether the harm-causing drug was a brand-name medication or its generic twin. But after *Mensing-Bartlett*, an arbitrary factor—which one did the pharmacist choose?—effectively controls.<sup>289</sup>

Despite the analytical flaws in *Mensing* and *Bartlett*, lower courts by and large are stuck with the two decisions, which appear to contemplate broad preemptive effect regarding tort claims against generic manufacturers.<sup>290</sup> Interestingly, however, *Mensing* and *Bartlett* offer possible hints that lower courts could try to seize upon in an effort to justify rulings that certain claims should survive preemption. In *Mensing*, Justice Thomas’s majority opinion noted that because the events in the case pre-dated 2007, the Court was not considering the effect, if any, of certain 2007 statutory amendments.<sup>291</sup> Those amendments gave the FDA the authority to order the use of a particular revised warning label if later-acquired safety information warranted such a label.<sup>292</sup> The pre-2007 legal rule applicable to such a situation only permitted the FDA to seek

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287. See *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574–75, 2577 (2011).

288. *Mensing*, 131 S. Ct. at 2583, 2592 (Sotomayor, J., dissenting).

289. See *id.* at 2581–82.

290. This is especially true of *Bartlett*, in which the Court did not hesitate to re-mold the design-defect claim into a failure-to-warn claim that would more readily fit within the rationale articulated in *Mensing*. See *supra* text accompanying notes 185–210.

291. *Mensing*, 131 S. Ct. at 2574 n.1. The 2007 amendments presumably did not play a role in the *Bartlett* analysis, because that case’s events also predated 2007. See *Bartlett*, 133 S. Ct. at 2472.

292. See 21 U.S.C. § 355(o)(4) (2012).



the brand-name manufacturer's agreement on the text of a particular revised label.<sup>293</sup> What, if anything, to make of that possible hint is uncertain, but it affords possibilities.

The *Bartlett* majority opinion also contained a possible hint, as Justice Alito observed in a footnote that the Court was not expressing any view on whether state-law-based tort claims that "parallel" the federal misbranding statute should escape preemption.<sup>294</sup> As noted earlier, that statute sets up a post-approval duty on the part of drug makers to make certain that their drugs bear adequate warnings about important safety concerns.<sup>295</sup> Justice Alito thus suggested, without further elaboration and clearly without committing the Court, that certain appropriately crafted tort claims might not be preempted. He was quick to note, however, that *Bartlett* did not involve any such parallel claim.<sup>296</sup>

As the following subsection will reveal, lower federal courts have tended to interpret *Mensing* and *Bartlett* as calling for sweeping preemption rulings regarding harmed consumers' tort claims against generic manufacturers. For the most part, the federal courts have not been inclined to pursue possible leads that the above-mentioned hints might suggest.<sup>297</sup> Various state courts, however, have interpreted *Mensing* and *Bartlett* somewhat less broadly. In addition, state courts have been more inclined than the federal courts to exploit the previously noted hints and other possible avenues for limiting the applicability of *Mensing* and *Bartlett* and allowing some tort claims against generic manufacturers to go forward. The state court decisions will be discussed and analyzed in Sections IV and V of the Article.<sup>298</sup>

## B. FEDERAL COURTS' APPLICATIONS OF THE SUPREME COURT'S PHARMACEUTICALS DECISIONS

Soundly reasoned or not, *Mensing* and *Bartlett* must be respected, of course, by lower federal courts and state courts. In federal courts, that respect has consistently led to decisions in

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293. See *Wyeth v. Levine*, 555 U.S. 555, 567, 571 (2009).

294. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2477 n.4 (2013).

295. See *supra* text accompanying notes 48–53.

296. *Bartlett*, 133 S. Ct. at 2477 n.4. For discussion of possible parallel claims, see Catherine M. Sharkey, *Tort-Agency Partnerships in an Age of Preemption*, 15 THEORETICAL INQ. L. 359, 363–68 (2014).

297. See *infra* text accompanying notes 321–24.

298. See *infra* text accompanying notes 337–604.

which plaintiffs' tort claims against generic manufacturers were held preempted. If the gist of the plaintiffs' claims is that the generic maker should have provided a stronger warning than the approved label furnished, the federal courts of appeal have invoked *Mensing* as controlling and have held the claims to be preempted on the ground of impossibility.<sup>299</sup> This has been so regardless of how the claims were denominated. If a claim styled as a negligence, strict liability, or breach of implied warranty claim had a failure-to-warn essence, it could not go forward.<sup>300</sup> Similarly, the courts of appeal have consistently held that claims amounting to design-defect claims—regardless of the label given to them by the plaintiffs—are preempted under the *Bartlett* reasoning.<sup>301</sup>

*Strayhorn v. Wyeth Pharmaceuticals, Inc.*<sup>302</sup> serves as a useful example. There, the Sixth Circuit observed that various circuits “have interpreted *Mensing* to broadly preempt claims that are, at their core, claims that the generic manufacturer failed to provide additional warnings beyond that which was required by federal law of the brand-name manufacturers.”<sup>303</sup> The Sixth Circuit concluded that the plaintiff's various claims, including negligence, breach of implied warranty, and other supposed causes of action under Tennessee law, were effectively failure-to-warn claims that could not survive *Mensing*.<sup>304</sup> The *Strayhorn* court also concluded that, just as in *Bartlett*, the plaintiff's variously pleaded design-defect claims contemplated a need for a strengthened warning by the generic

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299. See *infra* text accompanying notes 302–24; cases cited *infra* notes 302–20.

300. *Id.*

301. *Id.*

302. *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378 (6th Cir. 2013).

303. *Id.* at 391.

304. *Id.* at 393–95. As in *Mensing*, the drug at issue in *Strayhorn* was metoclopramide, the generic equivalent of the brand-name drug known as Reglan. *Id.* at 391. See also *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572–73 (2011). The plaintiffs in *Strayhorn* developed tardive dyskinesia, the same disorder developed by the plaintiffs in *Mensing*. *Strayhorn*, 737 F.3d at 383; *Mensing*, 131 S. Ct. at 2572–73. Most of the federal circuit courts' decisions applying *Mensing* and *Bartlett* have involved metoclopramide and plaintiffs who developed tardive dyskinesia. See cases cited *infra* notes 314–19. The same is true of most of the state court decisions to be discussed later in the article. See *infra* text accompanying notes 337–484.

manufacturers.<sup>305</sup> *Bartlett*, therefore, mandated preemption of those claims.<sup>306</sup>

No doubt concerned that their claims against the generic manufacturers might not be permitted to go forward, the plaintiffs in *Strayhorn* also sued the manufacturer of the brand-name version of the drug on what amounted to failure-to-warn grounds.<sup>307</sup> They alleged that in deciding whether to prescribe generic metoclopramide, physicians would foreseeably rely on information provided by the brand-name version's manufacturer.<sup>308</sup> The Sixth Circuit rejected that claim, however, because Tennessee product liability law would not permit such a claim in the absence of a showing that the plaintiffs ingested the brand-name version.<sup>309</sup> The facts revealed that they ingested only generics.<sup>310</sup> Writing for the *Strayhorn* panel, Judge Gillman observed that the court felt "compelled . . . [by the] controlling caselaw" to rule as it did, but that note should be taken of "the basic unfairness" of the case's outcome.<sup>311</sup> Judge Gillman went on to note that the plaintiffs were "caught in a classic 'Catch 22,' barred from all claims against the Generic Manufacturers whose drugs they ingested (due to federal preemption) and from all claims against the Brand-Name Manufacturer" because they did not use the brand-name version.<sup>312</sup>

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305. *Strayhorn*, 737 F.3d at 395–96 ("[T]he plaintiffs do not allege that the generic metoclopramide they took was ineffective . . . only that it was unsafe when used long-term because of the drug's dangerous side effects . . . In order to escape liability for such an alleged defect, the Generic Manufacturers would have had to give a stronger warning than they were permitted to give under federal law.").

306. *Id.* at 396–97. The court did recognize that a "failure-to-update" claim—a claim to be examined later in the article—could survive preemption under the right set of facts. *Id.* at 395–97. In *Fulgenzi v. PLIVA, Inc.*, the Sixth Circuit had held that such a claim would not be preempted. *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 584 (6th Cir. 2013). In *Strayhorn*, however, the court concluded that the plaintiffs had failed to plead such a claim properly and had waited until far too late in the proceedings to seek leave to amend their complaints. See *Strayhorn*, 737 F.3d at 399–400. For discussion of *Fulgenzi* and failure-to-update claims, see *infra* text accompanying notes 362–67 and *infra* note 369.

307. *Strayhorn*, 737 F.3d at 394–95.

308. *Id.* at 404.

309. *Id.* at 401.

310. *Id.* at 403–06.

311. *Id.* at 407.

312. *Id.* The Sixth Circuit noted the *Mensing* and *Bartlett* statements to the effect that Congress has the power to resolve the "dilemma" faced by

Another Sixth Circuit panel followed *Strayhorn*'s lead and held that various tort claims against generic manufacturers were preempted under *Mensing* and *Bartlett*.<sup>313</sup> Similar decisions interpreting *Mensing* and *Bartlett* as having a sweeping preemptive effect on tort claims have come from the Third,<sup>314</sup> Fourth,<sup>315</sup> Fifth,<sup>316</sup> Eighth,<sup>317</sup> Ninth,<sup>318</sup> Tenth,<sup>319</sup> and Eleventh Circuits.<sup>320</sup>

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plaintiffs such as those in *Strayhorn*. *Id.* The court added that the Tennessee legislature might provide relief by changing the state's product liability statute to "allow claims against brand-name manufacturers whose labels control the warnings that the generic manufacturers are compelled by federal law to duplicate." *Id.* But in the absence of such a change in controlling principles, the plaintiffs would remain "caught in [the] 'Catch 22.'" *Id.*

313. *Germain v. Teva Pharms., USA, Inc.*, 756 F.3d 917, 932–36 (6th Cir. 2014). As in *Strayhorn*, the *Germain* panel noted that a failure-to-update claim might be actionable under the right set of facts. *Id.* at 931–32. *See also supra* note 304 and accompanying text. However, the court concluded that any such claim had not properly been pleaded. *Germain*, 756 F.3d at 931–32 (finding that Plaintiffs failed to plead facts creating a plausible inference that the Generic Manufacturers failed to implement the required black box warning). For a discussion of failure-to-update claims, see *infra* text accompanying notes 363–69 and *infra* note 369. In addition, the court discussed the *Bartlett* footnote hinting that parallel misbranding claims might survive preemption. *Germain*, 756 F.3d at 928–29; *see Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2477 n.4 (2013). However, the court concluded that even if a parallel misbranding claim could survive preemption, the plaintiffs had not properly pleaded such a claim. *Germain*, 756 F.3d at 929–30.

314. *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 751 F.3d 150, 153, 156–58, 160–65 (3d Cir. 2014).

315. *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 475–79 (4th Cir. 2014).

316. *Johnson v. TEVA Pharms. USA, Inc.*, 758 F.3d 605, 609, 610–14 (5th Cir. 2014); *Eckhardt v. Qualitest Pharm., Inc.*, 751 F.3d 674, 678–80 (5th Cir. 2014); *Lashley v. Pfizer, Inc.*, 2014 U.S. App. LEXIS 7126, at \*8–16 (5th Cir. Feb. 21, 2014); *Morris v. PLIVA, Inc.*, 713 F.3d 774, 776–78 (5th Cir. 2013).

317. *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1139–41 (8th Cir. 2014); *Fullington v. Pfizer, Inc.*, 720 F.3d 739, 744–46 (8th Cir. 2013); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1094–95 (8th Cir. 2013) (post-*Mensing* but pre-*Bartlett* decision holding that claims premised on failure to warn were preempted).

318. *Moretti v. Wyeth, Inc.*, No. 12-16334, 2014 U.S. App. LEXIS 11333, at \*4–6 (9th Cir. June 17, 2014).

319. *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1286–90 (10th Cir. 2013). Besides holding that the plaintiffs' tort claims against the generic manufacturer defendants were preempted, the Tenth Circuit rejected the plaintiffs' tort claims against a brand-name manufacturer defendant. *See id.* at 1281–90. Because the plaintiffs had ingested generics rather than the brand-name medication, the Tenth Circuit concluded that Oklahoma law would not be likely to treat the brand-name manufacturer as owing legal duties to the plaintiffs. *Id.* at 1281–86. Employing language similar to the Sixth Circuit's in *Strayhorn*, the court noted "the catch-22 situation" in which the plaintiffs and other consumers of generic drugs find themselves: "They

In these decisions, the courts of appeal have devoted little attention to the Supreme Court's previously noted hints that there might be small openings in the *Mensing-Bartlett* preemption barrier.<sup>321</sup> Preemption has been held appropriate

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cannot obtain relief from brand-name drug manufacturers because, as we predict, [state law] would not impose a duty on the brand-name manufacturers that flows to consumers of generic drugs. Yet the [plaintiffs'] claims against generic manufacturers are preempted" under *Mensing* and *Bartlett*. *Id.* at 1290. After noting that as a federal court, it had "limited authority to correct this potential injustice," the Tenth Circuit provided an interesting suggestion about the role state courts might play: "It is for the state courts, rather than this panel, to engage in the delicate policy considerations predicate to the expansion of the scope of state tort law." *Id.* As later discussion and analysis will reveal, some state courts appear to have picked up on this suggestion. See *infra* text accompanying notes 336–603. The Tenth Circuit also acknowledged the Supreme Court's "unfortunate hand" remark in *Mensing*. *Id.* "If consumers of generic drugs are to obtain federal relief," the court concluded, "it must come from Congress." *Id.* at 1290.

320. See *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1248–50 (11th Cir. 2013). In *Guarino*, the Eleventh Circuit invoked *Mensing*, but not *Bartlett*—an understandable omission because *Bartlett* was decided only one day before *Guarino* was released. See *id.* at 1245, 1247. In addition to the circuits referred to in the text, the First Circuit has applied *Mensing* in holding that tort claims against a drug manufacturer were preempted. See *Marcus v. Forest Laboratories, Inc.*, 779 F.3d 34 (1st Cir. 2015). The First Circuit's decision was unique, however, because the defendant was a brand-name manufacturer and the plaintiffs had taken the brand-name medication. *Id.* at 37–38. As explained in earlier discussion, the Supreme Court concluded in *Wyeth v. Levine* that failure-to-warn claims against brand-name manufacturers are not preempted on the ground of impossibility because such manufacturers can rely on the CBE regulation as a basis for starting to use a strengthened warning label without prior FDA approval. *Wyeth v. Levine*, 555 U.S. 555, 569–70 (2009). See *supra* text accompanying notes 109–16; *supra* note 111 and accompanying text. However, the First Circuit concluded in *Marcus* that *Mensing* was the relevant precedent even though it involved claims against a generic manufacturer. *Marcus*, 779 F.3d at 40–41. According to the First Circuit, the CBE regulation was not an option for the brand-name manufacturer under the particular facts in the case, because there was no "newly acquired [safety] information" of the sort necessary to support a revised label under the CBE. *Id.* at 41–43. Rather, all of the potentially relevant information bearing on the drug's safety presumably had been evaluated by the FDA prior to the agency's approval of the drug's label. *Id.* at 42–43. Therefore, the *Marcus* court reasoned, *Mensing*'s impossibility rationale controlled because the defendant could not act independently—i.e., on its own—to provide a strengthened label. *Id.* at 43. See also *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2581 (2011). Besides providing an interesting take on *Mensing*, the First Circuit's decision serves to illustrate not only *Mensing*'s probable broadening of the impossibility doctrine but also that decision's undermining of *Levine*. See *supra* text accompanying notes 168–71, 245–48.

321. See *Mensing*, 131 S. Ct. at 2574 n.1; *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2477 n.4 (2013).

regardless of whether the relevant facts occurred prior to or after 2007.<sup>322</sup> No circuit court addressed the *Mensing* footnote in which the Court stated that because the case's facts arose prior to 2007, it was not considering whether the 2007 statutory amendments might affect the analysis.<sup>323</sup> As will be seen, some state courts have ascribed significance to that footnote.<sup>324</sup>

In a small number of cases, the federal courts of appeal have picked up on the possibility, noted in a *Bartlett* footnote, that state law-based claims paralleling the federal duty under the misbranding statute might not be preempted.<sup>325</sup> One Sixth Circuit panel suggested that such parallel claims should escape preemption.<sup>326</sup> Another Sixth Circuit panel discussed the possibility but ultimately took no position on the matter.<sup>327</sup> In a Fifth Circuit decision, the court spoke disapprovingly of parallel claims and flatly rejected the notion that they should escape *Mensing-Bartlett* preemption.<sup>328</sup> As later discussion will reveal, the parallel claims notion has taken hold in some of the state court decisions.<sup>329</sup>

Two other features of the decisions of the federal courts of appeal bear mentioning. First, several of them recognize that a certain type of tort action known as a failure-to-update claim

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322. See cases cited at *supra* notes 302–20.

323. See *Mensing*, 131 S. Ct. at 2574 n.1. For explanation of the 2007 change in the law, see *supra* text accompanying notes 55–57. The absence of such discussion suggests either that the plaintiffs did not attempt to argue that the 2007 amendments should make a difference in the analysis or that if such an argument was made, the courts did not consider it substantial enough to warrant discussion.

324. See *infra* text accompanying notes 375–85, 436–38, 565–74.

325. See *Bartlett*, 133 S. Ct. at 2477 n.4. The small number of decisions in which the courts of appeal have discussed the *Bartlett* footnote about parallel claims presumably means that plaintiffs in the federal court cases have seldom attempted to make out such claims.

326. *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 586–87 (6th Cir. 2013). *Fulgenzi* actually preceded the Supreme Court's decision in *Bartlett*, but the Sixth Circuit's discussion of possible parallel claims anticipated what the Court hinted at in the *Bartlett* footnote. See *id.*; *Bartlett*, 133 S. Ct. at 2477 n.4.

327. *Germain v. Teva Pharms., USA, Inc.*, 756 F.3d 917, 928–30 (6th Cir. 2014). The court concluded that even if it were assumed that a parallel claim would escape preemption, the plaintiffs had not properly pleaded such a claim. *Id.* at 929–30.

328. *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 476 (5th Cir. 2014).

329. See *infra* text accompanying notes 360–62, 408–11.

should not be considered preempted under *Mensing-Bartlett*.<sup>330</sup> Because this type of claim has become especially important in the state court decisions issued in response to the relevant Supreme Court decisions, discussion of the federal courts' treatment of failure-to-update claims will be reserved for a later portion of the Article.<sup>331</sup> Suffice it to say for now that even though most of the federal courts of appeal that have considered failure-to-update claims have said they are not preempted, those courts generally have held that the claims failed on other grounds.<sup>332</sup>

Second, various cases decided by the federal courts of appeal have involved not only tort claims against generic manufacturers, but also failure-to-warn claims against the relevant brand-name manufacturers.<sup>333</sup> In the previously discussed *Strayhorn* decision, the Sixth Circuit held that tort claims against a brand-name manufacturer could not be pursued under the relevant state's statutes or common law where the plaintiffs ingested only the generic equivalent and not the brand-name drug.<sup>334</sup> On the same or similar grounds, other circuits have unanimously rejected such claims in the absence of a showing that the plaintiffs used the brand-name medication.<sup>335</sup> Some state courts, as will be seen, have been more inclined to give traction to failure-to-warn claims against

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330. See, e.g., *Germain*, 756 F.3d at 931–32; *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 399 (6th Cir. 2013); *Fulgenzi*, 711 F.3d at 581–89. Other circuits have so concluded. See *infra* note 369.

331. See *infra* text accompanying notes 363–69 and *infra* note 369.

332. E.g., *Germain*, 756 F.3d at 931–32; *Strayhorn*, 737 F.3d at 399–400. Other circuits have ruled similarly. See *infra* note 369.

333. See *Johnson v. TEVA Pharms. USA, Inc.*, 758 F.3d 605 (5th Cir. 2014); *Germain v. Teva Pharms., USA, Inc.*, 756 F.3d 917 (6th Cir. 2014); *Moretti v. Wyeth, Inc.*, 2014 U.S. App. LEXIS 11333 (9th Cir., June 17, 2014); *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674 (5th Cir. 2014); *Lashley*, 750 F.3d at 476; *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378 (6th Cir. 2013); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273 (10th Cir. 2013); *Fullington v. Pfizer, Inc.*, 720 F.3d 739 (8th Cir. 2013); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1247 (11th Cir. 2013); *Bell v. Pfizer, Inc.*, 716 F.3d 1087 (8th Cir. 2013).

334. *Strayhorn*, 737 F.3d at 403–06. The Sixth Circuit reached the same conclusion in *Germain*. *Germain*, 756 F.3d at 936–39.

335. *Johnson*, 758 F.3d at 614–16; *Moretti*, 2014 U.S. App. LEXIS 11333, at \*3–\*4; *Eckhardt*, 751 F.3d at 680–82; *Lashley*, 750 F.3d at 476; *Fullington*, 720 F.3d at 743–44; *Schrock*, 727 F.3d at 1281–86; *Guarino*, 719 F.3d at 1250–53; *Bell*, 716 F.3d at 1092–94. As the Sixth Circuit did in *Strayhorn*, the *Guarino* court observed that either Congress or the relevant state legislature could provide relief to harmed consumers by altering the controlling legal rules. See *Strayhorn*, 737 F.3d at 407; see also *Guarino*, 719 F.3d at 1253.

a brand-name manufacturer even though the plaintiff ingested only the generic version of the drug.<sup>336</sup>

### III. STATE COURT RESPONSES TO THE “UNFORTUNATE HAND”

The Article now considers decisions issued by state courts in the wake of *Mensing* and *Bartlett*. As this section reveals, state courts have been more inclined than federal courts to seek ways around *Mensing-Bartlett* preemption and thereby preserve the prospect of tort remedies for harmed consumers. State courts’ treatment of tort claims against generic manufacturers will be discussed first, followed by examination of state courts’ decisions dealing with claims against brand-name manufacturers by plaintiffs who consumed generics.

#### A. FAILURE-TO-UPDATE AND PARALLEL CLAIMS AGAINST GENERIC MANUFACTURERS: THE *HUCK* APPROACH

*Huck v. Wyeth, Inc.*<sup>337</sup> provides a helpful starting point for discussion. The 2014 decision of the Supreme Court of Iowa illustrates a tendency of various state courts to scrutinize the holdings and rationales in *Mensing* and *Bartlett* in order to determine whether there may be a plausible basis on which certain tort claims could escape preemption, as opposed to assuming that the Supreme Court’s decisions must be given a vast sweep.<sup>338</sup> Most notably, *Huck* illustrates state courts’ receptivity to a type of claim known as a failure-to-update claim and to the notion that state-law-based claims may assert obligations paralleling those established in federal law.<sup>339</sup>

The plaintiff in *Huck* had taken metoclopramide, a generic version of the brand-name drug Reglan, and had developed tardive dyskinesia.<sup>340</sup> These core facts were also present in most of the previously discussed decisions by federal courts of appeal and most of the state court decisions to be discussed later.<sup>341</sup> Although the lower courts in *Huck* had relied on *Mensing* in granting the generic manufacturer summary

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336. See *infra* text accompanying notes 457–504.

337. *Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014).

338. See *infra* text accompanying notes 354–456.

339. See *Huck*, 850 N.W.2d at 363–69.

340. *Id.* at 359.

341. See cases cited *supra* notes 302–20. See also *infra* text accompanying notes 370–504 (discussing other state court decisions).



judgment on the ground that the plaintiff's claims were preempted, the Supreme Court of Iowa focused on Reglan-related facts that distinguished the plaintiff's causes of action from failure-to-warn claims falling squarely within *Mensing's* preemption rationale.<sup>342</sup>

When Huck's physician prescribed Reglan for her in 2004, the physician relied on information in the Physician's Desk Reference.<sup>343</sup> This information included the Reglan labeling that the FDA had approved 24 years earlier.<sup>344</sup> As permitted by state law, a pharmacist filled the prescription with the defendant's generic version of the drug.<sup>345</sup> Approximately five months after the plaintiff began using the medication, the FDA approved a revised Reglan label that contained a stronger warning about the tardive dyskinesia danger than the original label had provided.<sup>346</sup> Neither the brand-name manufacturer nor the defendant generic manufacturer, PLIVA, Inc., communicated the revised label's information to Huck or her physician.<sup>347</sup> In addition, PLIVA did not employ the strengthened label for its generic version of Reglan.<sup>348</sup> Huck continued to use PLIVA's generic for approximately two years and was then diagnosed with tardive dyskinesia.<sup>349</sup>

Emphasizing PLIVA's failure to use the strengthened label approved by the FDA, the Supreme Court of Iowa observed that the case's facts "present a narrow path around *Mensing* preemption."<sup>350</sup> The court concluded that Huck's negligence, misrepresentation, fraud, and breach of implied warranty claims could credibly be characterized as failure-to-update claims that would not be subject to impossibility preemption under *Mensing*.<sup>351</sup> In *Mensing*, of course, the Court emphasized that under the duty of sameness established by federal law, generic makers were obligated to use the same label approved

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342. *Huck*, 850 N.W.2d at 359, 362–69.

343. *Id.* at 359.

344. *Id.* at 358.

345. *Id.* at 359.

346. *Id.*

347. *Id.*

348. *Id.*

349. *Id.*

350. *Id.* at 364.

351. *Id.* at 362–67. The court pointed out that there were no failure-to-update allegations in *Mensing*. Hence, the Supreme Court did not rule on any such claim. *Id.* at 362.

by the FDA for the brand-name drug.<sup>352</sup> The Court reasoned there that impossibility preemption applied because the defendant could not simultaneously satisfy its federal duty to use the approved label and fulfill what the plaintiff's state-law-based claims contemplated: the use of a label with stronger warnings.<sup>353</sup>

But *Huck* was different, Iowa's highest court maintained. Whereas the generic manufacturer's federal duty of sameness pointed in favor of preemption on impossibility grounds in *Mensing*, that duty cut the other way in *Huck*. Once the FDA approved a strengthened label for Reglan, PLIVA became obligated to use that strengthened label.<sup>354</sup> This federal obligation to use the strengthened label was consistent with what *Huck*'s state-law-based claims contemplated: the use of a stronger warning. Hence, the federal and state obligations in *Huck* were not impossible to fulfill simultaneously and were not otherwise in conflict.<sup>355</sup>

Importantly, too, PLIVA could have sought to satisfy its federal duty to use the revised label through the previously discussed CBE regulation.<sup>356</sup> The FDA's position has been that the CBE route to using a revised label without prior approval from the FDA is normally available only to brand-name manufacturers and not to generic manufacturers.<sup>357</sup> However, the FDA has concluded that generic manufacturers may rely on the CBE regulation in an exceptional situation of direct relevance to the case: when they begin using a revised label because that revised label is the one approved by the FDA for the brand-name drug.<sup>358</sup> The court thus determined that even

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352. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574–75 (2011).

353. *Id.* at 2575, 2580–81.

354. *See Huck*, 850 N.W.2d at 364.

355. *Id.* at 364–66. Neither was preemption warranted on purposes-and-objectives grounds. The court noted that Congress did not include an express preemption provision in the federal drug regulations laws and that the Supreme Court has commented favorably on the complementary role that state-law-based tort claims may play alongside FDA regulation. *Id.* at 366–67. *See also Wyeth v. Levine*, 555 U.S. 555, 574, 579 (2009). Hence, the *Huck* court concluded that allowing claims such as those brought by the plaintiff would not undermine federal objectives. *Huck*, 850 N.W.2d at 366–67.

356. *Huck*, 850 N.W.2d at 364. For discussion of the CBE regulation, see *supra* text accompanying notes 45–47.

357. *See supra* note 47.

358. *See PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2575 (2011); *see also Huck*, 850 N.W.2d at 364.

though the impossibility rationale led the Supreme Court to a preemption finding in *Mensing*, that same rationale logically led to a rejection of preemption in *Huck*.<sup>359</sup>

The *Huck* court also stressed that the plaintiff's failure-to-update claims were not an effort to enforce a purely federal obligation. Had they been such an effort, the court reasoned, the claims would be problematic because the federal drug regulation laws do not authorize a federal right of action in favor of private plaintiffs.<sup>360</sup> The plaintiff in *Huck*, however, acted permissibly by seeking to enforce duties and obligations set under state tort and warranty law. Those duties, the court emphasized, are independent of—and parallel to—duties under federal law.<sup>361</sup> In this sense, the court appeared to pick up on Justice Alito's *Bartlett* footnote, in which he hinted that state-law-based claims might survive *Mensing-Bartlett* preemption if the duties contemplated are parallel to federal duties.<sup>362</sup>

In holding that the plaintiff should be able to go forward with her failure-to-update claims, the *Huck* court relied on *Fulgenzi v. PLIVA, Inc.*, a United States Court of Appeals for the Sixth Circuit decision.<sup>363</sup> Like *Huck*, *Fulgenzi* was a case in which the plaintiff used a generic version of Reglan, developed tardive dyskinesia, and based her lawsuit on the generic manufacturer's failure to use the strengthened label after the FDA approved it for the drug.<sup>364</sup> *Fulgenzi*'s explanation of why *Mensing*'s impossibility preemption rationale did not apply to a failure-to-update claim proved influential not only to the court

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359. *Huck*, 850 N.W.2d at 364–66.

360. *Id.* at 367–69.

361. *Id.* at 368–69. Accordingly, the case was not like *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). In that case, the Supreme Court held that a plaintiff could not proceed with a claim that the defendant committed fraud upon the FDA during the regulatory process, because the matter of defrauding the FDA when seeking regulatory approval was specifically and exclusively addressed in federal law. The plaintiff's claim, therefore, invoked only federal law, as opposed to a preexisting state-law-based obligation. *See id.* at 347–53; *see also* Sharkey, *supra* note 296, at 369–71 (noting that *Buckman* should be interpreted narrowly, in light of its fraud-on-the-agency facts and claim).

362. *See* Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2577 n.4. (2013); *Huck*, 850 N.W.2d at 368–69.

363. *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013). *See Huck*, 850 N.W.2d at 357, 363 n.7, 364, 367–69.

364. *Fulgenzi*, 711 F.3d at 580.

in *Huck*, but also to other state courts.<sup>365</sup> The same was true of *Fulgenzi*'s rejection of the argument that preemption was warranted on purposes-and-objectives grounds.<sup>366</sup>

The *Huck* court followed *Fulgenzi*'s lead in another sense, by spurning the generic manufacturer's argument that the failure-to-update claim, even if not preempted, should fail because the plaintiff had separately contended that the strengthened label approved by the FDA still would not have provided a fully adequate warning.<sup>367</sup> In rejecting that argument, the courts in *Huck* and *Fulgenzi* declined to deprive the plaintiffs of the opportunity to prove a sufficient causation link between the allegedly inadequate warning used by the defendants and the harm the plaintiffs experienced.<sup>368</sup> Both courts indicated that the plaintiffs should get a chance to establish that a moderately stronger warning, even if less than optimal, could have prevented the harm that the defendants' inadequate warning failed to prevent.<sup>369</sup>

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365. See *Huck*, 850 N.W.2d at 367–69. For examples of how the decision has influenced state courts, see *infra* text accompanying notes 400–23. For discussion of *Fulgenzi* and failure-to-update claims, see Sharkey, *supra* note 296, at 366–67.

366. See *infra* text accompanying note 423.

367. See *Huck*, 850 N.W.2d at 363–64 n.7 (citing *Fulgenzi*, 711 F.3d at 587–88).

368. See *id.*

369. See *id.* Although it was not the only federal court of appeals decision recognizing that failure-to-update claims are not preempted by federal drug regulation law, *Fulgenzi* stands out for taking a softer line on whether such claims should survive a dismissal motion premised on other grounds. *Fulgenzi*, 711 F.3d at 587–88. In other decisions in which courts of appeal concluded that failure-to-update claims escaped preemption, the courts nevertheless agreed with the defendants that dismissal of the claims was warranted for reasons similar to the argument rejected in *Fulgenzi* or for other reasons. See *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1137–39 (8th Cir. 2014) (failure-to-update claim not preempted, but claim rejected on basis of learned intermediary doctrine because prescribing physician had received strengthened label's information from brand-name manufacturer, causing causal link to be broken); *Germain v. Teva Pharms. USA, Inc.* 756 F.3d 917, 931–32 (6th Cir. 2014) (failure-to-update claim not preempted, but claim rejected as improperly pleaded); *Eckhardt v. Qualitest Pharm., Inc.*, 751 F.3d 674, 679–80 (5th Cir. 2014) (failure-to-update claim not preempted, but claim rejected as inadequately pleaded); *Moretti v. Wyeth, Inc.*, No. 12-16334, 2014 U.S. App. LEXIS 11333, at \*6 (9th Cir. June 17, 2014) (failure-to-update claim presumably not preempted, but claim rejected because plaintiff was no longer using medication when FDA required stronger warning); *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 399–400 (6th Cir. 2013) (failure-to-update claim presumably not preempted, but claim rejected as inadequately pleaded because of lack of facts showing plaintiff was using medication at relevant

B. NARROWLY INTERPRETING *MENSING* AND *BARTLETT*: THE *HASSETT* APPROACH

The same drug at issue in *Huck* and many of the other previously discussed cases—metoclopramide, the generic form of the brand-name drug Reglan—has been the subject of mass tort litigation in Pennsylvania courts. In *Hassett v. Defoe*,<sup>370</sup> one of two closely related appeals decided by the Superior Court of Pennsylvania,<sup>371</sup> two generic manufacturers appealed from the lower court's overruling of their demurrer to the master complaint filed by the named plaintiff, who was among the more than two thousand consumers claiming to have been harmed after they used the defendants' metoclopramide.<sup>372</sup> The plaintiff pleaded various claims, including negligence, strict liability, misrepresentation, fraud, and breach of express and implied warranties.<sup>373</sup> The defendants argued that the lower court should have dismissed the complaint because, in their view, *Mensing* and *Bartlett* preempted all of the plaintiff's claims.<sup>374</sup>

Early in its opinion, the *Hassett* court signaled that it would not be issuing a sweeping ruling of the sort the defendant wanted.<sup>375</sup> The court emphasized that the only preempted claims would be failure-to-warn claims based on the content of generic labels that were consistent with the FDA-

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time); Fullington v. Pfizer, Inc., 720 F.3d 739, 747 (8th Cir. 2013) (same); Bell v. Pfizer, Inc., 716 F.3d 1087, 1097–98 (8th Cir. 2013) (same). *But see* Johnson v. TEVA Pharms., USA, Inc., 758 F.3d 605, 611–12 (5th Cir. 2014) (suggesting that failure-to-update claim would be preempted and, alternatively, rejecting claim as improperly pleaded attempt to enforce an exclusively federal obligation); Lashley v. Pfizer, Inc., 750 F.3d 470, 474–76 (5th Cir. 2014) (failure-to-update claim preempted; alternatively, claim rejected as logically incoherent, given plaintiff's allegations to effect that no approved labels during relevant time period provided adequate warning) (citing Morris v. PLIVA, Inc., 713 F.3d 774, 777–78 (5th Cir. 2013)); Guarino v. Wyeth, LLC, 719 F.3d 1245, 1248–50 (11th Cir. 2013) (suggesting that failure-to-update claim would be preempted and, alternatively, rejecting claim as improperly pleaded and as barred by learned intermediary doctrine).

370. *Hassett v. Defoe*, 74 A.3d 202 (Pa. Super. Ct. 2013).

371. The Superior Court decided a companion case, *In re Reglan/Metoclopramide Litig.*, 81 A.3d 80 (Pa. Super. Ct. 2013), the same day as *Hassett* and used the same opinion text used in *Hassett*. Therefore, further discussion and citations will refer only to *Hassett* rather than to both of the decisions.

372. *Hassett*, 74 A.3d at 205–06.

373. *Id.* at 202.

374. *Id.* at 205–06.

375. *See id.* at 206.

approved brand-name label—and even then, only if those claims arose prior to the 2007 amendments to the federal drug regulation laws.<sup>376</sup> Such claims would be barred under the impossibility rationale outlined in *Mensing*.<sup>377</sup>

Reading *Mensing* narrowly, the *Hassett* court picked up on the footnote in which Justice Thomas, writing for the *Mensing* majority, stated that the Court was deciding the case in light of pre-2007 law and without regard for the 2007 amendments because the key facts in the case took place prior to 2007.<sup>378</sup> Although the *Mensing* footnote did not take a position on whether the 2007 amendments might have made a difference, the *Hassett* court took the footnote as an invitation to think about whether the amendments could affect the analysis of claims whose underlying facts occurred after the 2007 enactment.<sup>379</sup> The amendments arguably confirmed an obligation on the part of generic manufacturers to ask the FDA to strengthen an approved label if later-acquired safety information suggested a need for the label revision, and gave the FDA the authority to require use of a particular revised label (as opposed to the pre-2007 rule that only empowered the FDA to seek the brand-name manufacturer's agreement on the content of a revised label).<sup>380</sup>

The court concluded in *Hassett* that the 2007 amendments could indeed make a difference in the analysis of failure-to-warn cases arising after 2007 because, in its view, the impossibility rationale outlined in *Mensing* could be weakened to the point of not being controlling in that context.<sup>381</sup> In *Mensing*, the Court stated that even if it were assumed that generic manufacturers are obligated to ask the FDA for approval of a revised label in the event that it acquired important safety-related information, the legal reality that the FDA could then only negotiate with the brand-name manufacturer about a potential revised label meant that, at most, there was only a possibility that a strengthened label would result.<sup>382</sup> That possible, but hardly definite, outcome, Justice Thomas explained, was not enough to alter the

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376. *Id.*

377. *See* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2580–82 (2011).

378. *See id.* at 2574 n.1.

379. *See Hassett*, 74 F.3d at 206–07, 217.

380. *Id.* at 217 n.13. *See also supra* text accompanying notes 55–57.

381. *See Hassett*, 74 F.3d at 217 n.13.

382. *See Mensing*, 131 S. Ct. at 2578–80.

conclusion that under existing law, it was impossible for the generic manufacturer to comply with its federal duty of sameness regarding the label and with what state-law-based failure-to-warn claims contemplated.<sup>383</sup> According to the *Hassett* court, however, the 2007 amendments' elimination of the need for the FDA to negotiate with the brand-name manufacturer caused the road to a strengthened label to be less attenuated and therefore promising enough to make the impossibility argument ill-fitting.<sup>384</sup> The court concluded, therefore, that in the absence of court decisions clearly addressing the effect of the 2007 amendments on preemption analysis, it would be "premature" to dismiss post-2007 failure-to-warn claims.<sup>385</sup>

As noted earlier, *Hassett's* narrow interpretation of *Mensing* acknowledged that failure-to-warn claims would be preempted if they arose prior to 2007 and were based on generic labels' consistency with the FDA-approved labels for the relevant brand-name medications.<sup>386</sup> A failure-to-update claim of the sort present in previously discussed cases, however, would escape preemption because it would be based on generic labels' *lack of consistency* with the relevant FDA-approved labels.<sup>387</sup> The plaintiff in *Hassett* brought such a claim, alleging that the defendants had failed to adopt the strengthened Reglan label approved by the FDA in 2004.<sup>388</sup> As the Supreme Court of Iowa had concluded in *Huck v. Wyeth, Inc.*,<sup>389</sup> the *Hassett* court held that the failure-to-update claim was not preempted and could therefore go forward.<sup>390</sup>

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383. *See id.*, at 2577–81.

384. *See Hassett*, 74 F.3d at 216–17 & n.13.

385. *Id.* at 217.

386. *See supra* text accompanying notes 375–77.

387. *See Hassett*, 74 F.3d at 206, 216. For earlier discussion of failure-to-update claims, *see supra* text accompanying notes 354–69.

388. *See Hassett*, 74 F.3d at 216.

389. *Huck v. Wyeth, Inc.*, 850 N.W. 2d 353 (Iowa 2014). For discussion of the failure-to-update claim in *Huck*, *see supra* text accompanying notes 354–69.

390. *See Hassett*, 74 F.3d at 216. Alternatively, the court concluded that the failure-to-update allegations could be considered as a negligence per se claim, on the theory that the violation of the federal statutory duty of sameness regarding the approved drug label could serve to satisfy the duty and breach elements of negligence per se. *Id.*

Keeping in mind the presumption against preemption,<sup>391</sup> the *Hassett* court turned to consideration of the plaintiff's other claims and to whether they would be preempted under *Mensing* and *Bartlett*.<sup>392</sup> The court declined to ascribe much significance to the federal court decisions giving *Mensing* and *Bartlett* sweeping effect.<sup>393</sup> The federal court decisions were not binding and, in the *Hassett* majority's view, did not always reflect careful analysis of what the different states' common law claims contemplated.<sup>394</sup> The court concluded that the plaintiff's negligence and strict liability claims of the design-defect variety did not, under Pennsylvania common law, contemplate a need to change the drug's design or labeling.<sup>395</sup> Rather, the court maintained, they sought the imposition of liability because the defendants allegedly sold a defective and perhaps unreasonably dangerous product.<sup>396</sup> Therefore, the court suggested, the plaintiff's Pennsylvania-law-based claims did not call for what the Supreme Court, in *Bartlett*, construed another state's common-law defective-design claims as contemplating.<sup>397</sup> According to the *Hassett* majority, this also meant that *Bartlett*'s rationale did not dictate preemption of the plaintiff's claims under Pennsylvania common law.<sup>398</sup>

The *Hassett* majority's narrow interpretations of *Mensing* and *Bartlett* contrasted sharply with the tendencies displayed by the federal courts of appeal in applying those decisions.<sup>399</sup> As earlier discussion revealed, the circuit courts have read

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391. See *id.* at 210.

392. *Id.* at 211.

393. *Id.*

394. *Id.* at 211–12; see *id.* at 214.

395. *Id.* at 212.

396. *Id.*

397. *Id.*

398. See *id.* at 212–15. Through similar reasoning, the court concluded in *Hassett* that the plaintiff's breach of express and implied warranty claims, as well as his misrepresentation and fraud claims, escaped preemption under *Mensing* because those claims were not premised on a supposed deficiency in the product's label. *Id.* at 214–15. Instead, they were based on the product's failure to live up to how it was represented on the label or in advertisements. *Id.*

399. The majority opinion prompted a sharp dissent premised on the notion that the court had unduly restricted the effect of *Mensing* and *Bartlett*. See *id.* at 217–21 (Platt, Senior J., concurring and dissenting).



*Mensing* and *Bartlett* as contemplating broad-ranging preemptive effect.<sup>400</sup>

#### C. OTHER STATE COURT DECISIONS IN CASES AGAINST GENERIC MANUFACTURERS

The Court of Appeals of Missouri decided two similar cases in which plaintiffs who took generic metoclopramide and developed tardive dyskinesia sued the relevant generic manufacturers. In *Franzman v. Wyeth, Inc.*<sup>401</sup> and *Nicely v. Wyeth, Inc.*,<sup>402</sup> the respective plaintiffs pleaded various state-law-based claims, including negligent failure to warn, strict liability, misrepresentation, fraud, and breach of warranty. In each case, the lower court had dismissed all of the plaintiff's claims on the ground of preemption.<sup>403</sup> Because the two cases presented the same key issues and were decided the same day, the appellate court provided a full explanation of its reasoning in *Franzman* and then, in *Nicely*, expressly adopted that reasoning.<sup>404</sup>

In *Franzman*, the court reviewed *Mensing* and *Bartlett* and construed the plaintiff's variously denominated claims as effectively failure-to-warn claims.<sup>405</sup> As such, the court concluded, nearly all of those claims were preempted under the impossibility rationale laid out in the Supreme Court's decisions.<sup>406</sup> One claim, however, would escape preemption: the plaintiff's failure-to-update claim, which was based on the generic manufacturers' failure to adopt the strengthened Reglan warning label approved by the FDA in 2004.<sup>407</sup>

The *Franzman* court reasoned that the impossibility rationale of *Mensing* and *Bartlett* did not apply to the failure-

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400. See *supra* text accompanying notes 299–332. Later, the Article will analyze and assess *Hassett*. See *infra* text accompanying notes 565–77.

401. *Franzman v. Wyeth, Inc.*, 451 S.W.3d 676 (Mo. App. 2014).

402. *Nicely v. Wyeth, Inc.*, 451 S.W.3d 694 (Mo. App. 2014).

403. *Franzman*, 451 S.W.3d at 678–79, 682–83, 686; *Nicely*, 451 S.W.3d at 695–96. Although the cases were filed in a Missouri court, Kentucky law applied to each case. *Franzman*, 451 S.W.3d at 678; *Nicely*, 451 S.W.3d at 696 n.6.

404. *Franzman*, 451 S.W.3d at 679–94; *Nicely*, 451 S.W.3d at 696–97.

405. *Franzman*, 451 S.W.3d at 685–87.

406. *Id.*

407. *Id.* at 687–89. In support of its holding on the failure-to-update claim, the court cited two decisions discussed earlier in the article: *Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014); and *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013). See *supra* text accompanying notes 337–69.

to-update claim and that the generic manufacturers' federal duty of sameness regarding labeling required them to use the revised label.<sup>408</sup> Moreover, the court observed, the duty to provide the stronger warning in the revised label was not purely a matter of federal law.<sup>409</sup> The notion of providing a stronger warning was an independent duty that stemmed from state law and was contemplated by the plaintiffs' state-law-based claims.<sup>410</sup> Hence, for purposes of the failure-to-update claim, the generic manufacturers' federal and state-law obligations were consistent rather than being in conflict.<sup>411</sup> The reasoning articulated in *Franzman* led to the same result in *Nicely*, as the court there held that the plaintiff's failure-to-update claim escaped preemption but that her other failure-to-warn claims did not.<sup>412</sup>

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408. *Franzman*, 451 S.W.3d at 687–88.

409. *Id.* at 688–89.

410. *Id.*

411. *Id.* at 689. In a case presenting facts similar to those in *Franzman*, the Georgia Court of Appeals relied on *Franzman*'s reasoning in holding that a failure-to-update claim and other failure-to-warn claims under state law survived preemption. See *PLIVA, Inc. v. Dement*, 335 Ga. App. 398, 780 S.E.2d 735, 2015 Ga. App. LEXIS 772, at \*2–3, \*5–9, \*9–10 n.17 (Ga. Ct. App., Nov. 20, 2015). Once the brand-name maker of Reglan began using a strengthened label and the defendant manufacturer of the generic version did not employ the strengthened label, the defendant allegedly violated not only a federal duty but also a parallel state duty to provide a meaningful warning. *Id.* at \*5–9. The federal and state duties thus were consistent rather than impossible to fulfill simultaneously. *Id.* at \*7–9.

412. *Nicely v. Wyeth, Inc.*, 451 S.W.3d 694, 697 (Mo. App. 2014). In another case dealing with metoclopramide, a Florida trial court used reasoning similar to that employed in *Franzman* and *Nicely* in holding that the plaintiff's failure-to-update claim escaped *Mensing* preemption and that the defendant, accordingly, was not entitled to judgment on the pleadings. *Swaw v. Wyeth LLC*, No.16-2011-CA-002492, 2013 Fla. Cir. LEXIS 150, at \*1–5 (July 22, 2013). However, a later decision of a Florida appellate court in a different case leaves uncertainty about the status of failure-to-update claims under Florida law. See *Dietrich v. Actavis*, 138 So. 3d 1163 (Fla. Dist. Ct. App. 2014). In a cryptic per curiam opinion that was one paragraph in length, the Court of Appeal of Florida gave sweeping preemptive effect to *Mensing* and may have suggested that even a failure-to-update claim would not survive. *Id.* The *Swaw* court also held that a strict liability design-defect claim was not preempted under *Mensing* and so could go forward. *Swaw*, 2013 Fla. Cir. LEXIS 150, at \*5–6. However, the court did not appear to have considered *Bartlett*, which the Supreme Court had decided a month earlier. See *id.* The ruling on the design-defect claim may therefore be open to question. The court suggested, however, that the defendant's failure to employ the strengthened label approved by the FDA was a factor bearing upon whether strict liability should apply. *Id.* at \*4–5. That factor might arguably make *Bartlett*'s

Similar reasoning led the Court of Appeal of California to hold, in *Teva Pharmaceuticals USA, Inc. v. Superior Court*,<sup>413</sup> that the plaintiff's failure-to-update claim was not preempted and that the lower court had not erred in overruling the defendants' demurrer.<sup>414</sup> As in other cases already discussed, the plaintiff contended that even though the FDA had approved a revised label for the relevant brand-name drug, the generic manufacturers whose version she used had failed to employ the revised label.<sup>415</sup> Accordingly, the plaintiff did not receive the stronger warning that the revised label furnished regarding the type of harm she later experienced as a result of using the medication.<sup>416</sup>

The California court concluded that *Mensing's* impossibility rationale, which would mandate preemption of failure-to-warn claims to the extent that they called for use of a stronger warning than provided for in the relevant FDA-approved label, would not apply to the failure-to-update claim.<sup>417</sup> It was not impossible for the generic manufacturers to employ the revised label; indeed, they were required to use it after it received FDA approval.<sup>418</sup> Moreover, the *Teva* court reasoned, state law contemplated a duty to use adequate warnings—a duty parallel to the federal obligation to use the revised label.<sup>419</sup> The plaintiff, therefore, was not seeking to enforce a purely federal duty, and the generic manufacturers could simultaneously have satisfied both their federal obligation and their state law-based duties.<sup>420</sup>

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impossibility reasoning less applicable. See *supra* text accompanying notes 185–97.

413. *Teva Pharms. USA, Inc. v. Super. Ct.*, 158 Cal. Rptr. 3d 150 (Ct. App. 2013).

414. *Id.* at 152–53, 156–59.

415. *Id.* at 152–53.

416. *Id.* at 153, 156–57. For discussion of other cases in which the plaintiff made a similar claim, see *supra* text accompanying notes 337–412. This time, however, the drug was something other than metoclopramide. The plaintiff in *Teva* had used generic versions of the brand-name drug Fosamax. *Teva Pharms. USA, Inc.*, 158 Cal. Rptr. 3d at 153.

417. *Teva Pharms. USA, Inc.*, 158 Cal. Rptr. 3d at 152–53, 156–58.

418. See *id.* at 157–58.

419. See *id.* at 158.

420. See *id.* In so concluding, the court relied heavily on *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013). See *Teva Pharms. USA, Inc.*, 158 Cal. Rptr. 3d at 157–58. For discussion of *Fulgenzi*, see *supra* text accompanying notes 363–69. See also *PLIVA, Inc. v. Dement*, 335 Ga. App. 398, 780 S.E.2d 735, 2015 Ga. App. LEXIS 772, at \*5–11 (Ga. Ct. App., Nov.

In *Teva*, the court noted other cases in which courts had concluded that failure-to-update claims escaped preemption.<sup>421</sup> The California court, however, declined to do what various federal courts had done when they held that such a claim was not preempted but rejected it for reasons such as inadequate pleading or supposed inconsistency with other contentions raised by the plaintiff.<sup>422</sup> The court observed that differences between federal and state pleading standards could account for some of those decisions and suggested that given the preliminary posture of the case, the plaintiff should get a chance to prove in later proceedings that the use of the revised warning would have caused her to stop using the medication.<sup>423</sup> That chance should be afforded, the court noted, even if the plaintiff contended elsewhere in her complaint that the warning in the revised label, though strengthened, did not go as far as an optimal warning would have gone.<sup>424</sup>

*Guvnoz v. Target Corp.*,<sup>425</sup> one of the most recent state court cases against generic manufacturers, merits attention because of its factual configuration and the court's careful analysis. The plaintiff's decedent (her husband) had been prescribed Darvocet but received a generic version when the prescription was filled.<sup>426</sup> In various claims against the manufacturer of the generic her husband had used, the plaintiff contended that the medication caused him to experience a cardiac arrest and brain injuries that led to his death.<sup>427</sup> *Guvnoz* also presented an important factual wrinkle not present in the previously discussed cases: an eventual FDA order banning the sale of the medication at issue.<sup>428</sup> Approximately six months after the cardiac arrest the plaintiff's decedent experienced, the FDA ordered that Darvocet and generic versions of it be withdrawn from the

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20, 2015) (employing similar reasoning regarding failure-to-update claim and other state-law-based claims that paralleled federal duties).

421. *See Teva Pharms. USA, Inc.*, 158 Cal. Rptr. 3d at 157–61.

422. *See id.* at 160. For discussion of those federal court decisions, see *supra* note 369.

423. *Teva Pharms. USA, Inc.*, 158 Cal. Rptr. 3d at 160.

424. *Id.* The court observed that the plaintiff was entitled to plead inconsistent facts. *Id.*

425. *Guvnoz v. Target Corp.*, 30 N.E.3d 404 (Ill. App. 2015).

426. *Id.* at 409.

427. *Id.* at 408–09, 411–12.

428. *Id.* at 410.

market.<sup>429</sup> The plaintiff's claims included negligence and strict liability claims dealing with the design, production, and distribution of the medication, as well as misrepresentation and fraud claims dealing with statements about the drug's safety.<sup>430</sup> The generic manufacturer moved for dismissal, arguing that *Mensing* and *Bartlett* called for preemption of all of the claims.<sup>431</sup>

Utilizing a procedure allowed under Illinois law, the trial court sent the Appellate Court of Illinois certified questions that asked whether the plaintiff's claims were preempted.<sup>432</sup> The appellate court appeared to set the tone early in its *Guvenoz* opinion with this statement:

Defendants ask us to adopt a position, whereby consumers of generic drugs cannot sue the brand-name manufacturer because they did not ingest the brand-name drug, but they are also barred from suing the generic manufacturer because, since federal law requires the generic manufacturer to be in lock-step with the brand-name manufacturer, federal law then preempts their claims, thereby leaving generic consumers without any recovery. In essence, what defendants are arguing on this appeal and at this early pleading stage of the litigation is that they should be able to market a drug, even assuming that they know that it is dangerous and useless, until the Federal Drug Administration (FDA) officially stops them, and then bear no financial responsibility for the consequences.<sup>433</sup>

The court then launched an analysis leading to the conclusion that all of the plaintiff's claims escaped preemption.<sup>434</sup>

In *Guvenoz*, the court examined the impossibility rationale set forth in *Mensing* and *Bartlett* and noted that the facts in the two Supreme Court cases had occurred prior to a 2007 change in federal law.<sup>435</sup> The facts in *Guvenoz*, however, occurred after 2007.<sup>436</sup> Although it stated that it was not taking a firm position on the effect of the 2007 amendments,<sup>437</sup> the *Guvenoz* court suggested that

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429. *Id.* at 410–11.

430. *Id.* at 409–10.

431. *See id.* at 411.

432. *Id.* at 409, 412.

433. *Id.* at 409 (internal citation omitted).

434. *See id.* at 413–26.

435. *Id.* at 413.

436. *Id.* at 413, 416.

437. *Id.* at 413, 417. The court also characterized *Mensing* as having “expressed no view as to whether its holding applied to post-2007 cases like

[b]y removing at least some of the discretion afforded the [brand-name] manufacturer that made it impossible for generic manufacturers to comply with both federal and state law, the amendment[s] arguably change[] the landscape for generic manufacturers and may make their situation closer to the brand-name manufacturer held liable in *Wyeth v. Levine*.<sup>438</sup>

*Bartlett's* impossibility rationale, the *Guvenoz* court explained, rested on the notion that the plaintiff's tort claims called for the generic manufacturer to do things that federal law prohibited it from doing: changing the FDA-approved design of the drug and using a product label other than the FDA-approved one.<sup>439</sup> But that rationale should not apply, according to the Illinois court, when no remedial measure could have made enough of a safety difference anyway, as evidenced by the fact that the FDA ultimately ordered the unreasonably dangerous drug withdrawn from the market instead of directing that a stronger warning be used.<sup>440</sup> The *Guvenoz* court noted *Bartlett's* statement that "an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability."<sup>441</sup> However, the Illinois court observed that the statement in which the Supreme Court rejected the so-called stop-selling argument "was made in the context of the *Bartlett* case, where the drug was safe and effective for the vast majority of the people taking it, and ceasing to act would have benefitted only '[the] very small number' of people who suffered an adverse reaction."<sup>442</sup> The *Guvenoz* context was different, the court observed, because "the FDA concluded that the public at

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the one here." *Id.* at 416. See also *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 n.1 (2011).

438. *Guvenoz*, 30 N.E.3d at 417. Recall that in *Wyeth v. Levine*, 555 U.S. 555 (2009), the Supreme Court rejected the brand-name manufacturer's impossibility argument. *Id.* at 568, 570–73. For discussion of *Levine*, see *supra* text accompanying notes 68–127. The *Guvenoz* court also noted *Levine's* invocation of the presumption against preemption, its emphasis on the demanding nature of the preemption defense, and its indications that Congress, in not creating a private right of action in the federal drug regulation laws, contemplated a role for state-law-based causes of action in providing remedies to harmed consumers. *Guvenoz*, 30 N.E.3d at 414–15. Moreover, the *Guvenoz* court observed, Congress did not include an express preemption provision in the drug regulation statutes. *Id.* at 417.

439. *Guvenoz*, 30 N.E.3d at 418. See *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2473 (2013).

440. *Guvenoz*, 30 N.E.3d at 418–19.

441. *Id.* at 418 (quoting *Bartlett*, 133 S. Ct. at 2477).

442. *Id.* (alteration in original).

large would not benefit from [the] drug [at issue] and ordered it withdrawn from the market.”<sup>443</sup>

The court elaborated on the differences between *Guvenoz* and the Supreme Court’s decisions:

In the case at bar, plaintiff alleged that the drug was simply unsafe and should not have been sold at all, and there was no warning that could have cured the problem. By contrast, in both *Bartlett* and *Mensing*, the problem was addressed by the FDA with an improved warning.<sup>444</sup>

The court concluded, accordingly, that “the logic of *Bartlett* and *Mensing* does not apply to plaintiff’s claims, and their holdings do not preempt the state-law claims in this case.”<sup>445</sup>

Rejecting the defendant’s argument that preemption under *Mensing* and *Bartlett* was necessary because the plaintiff’s claims contemplated actions the defendant was barred from taking by federal law,<sup>446</sup> the *Guvenoz* court commented more specifically on why the particular claims brought by the plaintiff should not be preempted. The court noted that the plaintiff’s negligence claims did not call for the defendant to change the design of the drug or the warnings accompanying it.<sup>447</sup> Rather, the court observed, the negligence claims focused on a supposed failure to use reasonable care in the sense that the generic manufacturer “knew or should have known of the risk posed by the drug at the time of its manufacture.”<sup>448</sup> With its focus on whether the product was unreasonably dangerous, the plaintiff’s strict liability claim created “no direct and positive conflict with [the generic manufacturer’s] duty of sameness, when the drug should not have been sold.”<sup>449</sup>

The *Guvenoz* court also explained that the misrepresentation and fraud claims did not amount to calls for the defendant to alter the product label.<sup>450</sup> Instead, those claims rested on the premise that “there was no way to market this drug, which was effectively useless and full of unreasonable risk, without fraudulently misrepresenting its

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443. *Id.*

444. *Id.* at 419.

445. *Id.*

446. *Id.* at 422.

447. *Id.*

448. *Id.*

449. *Id.* at 423.

450. *Id.* at 424.

qualities”<sup>451</sup> and on the related premise that “there were no warnings which would have magically transformed [the drug into one] that was safe and effective.”<sup>452</sup> With none of the plaintiff’s claims being preempted, the appellate court remanded the case for further proceedings.<sup>453</sup>

Of course, plaintiffs in cases against generic manufacturers typically have not fared as well on the preemption question as the plaintiff did in *Guvenoz*.<sup>454</sup> In response to the “unfortunate hand” they have been dealt with regard to claims against generic manufacturers,<sup>455</sup> harmed consumers have sometimes sued the relevant brand-name manufacturer even though they ingested only a generic version. Earlier discussion in the Article revealed that various federal courts have dismissed claims against brand-name manufacturers under such circumstances.<sup>456</sup> The following subsection examines state courts’ treatment of such claims.

#### D. STATE COURT DECISIONS IN CASES AGAINST BRAND-NAME MANUFACTURERS

In four post-*Mensing* and post-*Bartlett* cases decided by state appellate courts, plaintiffs who experienced harm after taking a generic drug have attempted to sue the brand-name manufacturer. Only once has the plaintiff’s claim survived the defendant’s dismissal or summary judgment motion, though dissenting judges in one of the other three cases took the position that a claim along those lines should be recognized.<sup>457</sup>

Earlier discussion focused on the Supreme Court of Iowa’s treatment, in *Huck v. Wyeth, Inc.*,<sup>458</sup> of claims against a generic manufacturer.<sup>459</sup> The plaintiff in *Huck* also sued the relevant brand-name manufacturer on various grounds, including negligence and misrepresentation grounds.<sup>460</sup> The claims against the brand-name manufacturer revolved around the

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451. *Id.*

452. *Id.* at 425.

453. *Id.* at 426.

454. See *supra* text accompanying notes 299–324.

455. See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2581 (2011).

456. See *supra* text accompanying notes 308–10, 333–35.

457. See *infra* text accompanying notes 460–504.

458. *Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014).

459. The earlier discussion of *Huck* appears at *supra* text accompanying notes 337–69.

460. See *Huck*, 850 N.W.2d at 360.



notions that the approved label for the drug did not emphasize safety concerns to the extent it should have, that the brand-name manufacturer should have proposed a strengthened label or should have begun to use one under the previously discussed CBE regulation, and that because generic makers must use the same label used for the brand-name version, consumers of generics foreseeably would be harmed in the absence of a strengthened label.<sup>461</sup>

The Supreme Court of Iowa held in *Huck* that the brand-name maker was entitled to summary judgment.<sup>462</sup> Although all seven members of the court had subscribed to the portion of Justice Waterman's opinion dealing with the plaintiff's claims against the generic manufacturer,<sup>463</sup> the portion of the opinion dealing with the claims against the brand-name manufacturer proved to be a plurality analysis because only three justices agreed to it.<sup>464</sup> The court's chief justice merely concurred in the result on the brand-name manufacturer aspect of the case, and three other members of the court dissented.<sup>465</sup>

The fact that the plaintiff did not use the brand-name drug proved fatal to her claims, according to the plurality, given a "well-settled requirement of Iowa law—[that] the plaintiff must prove injury caused by a product sold or supplied by the defendant."<sup>466</sup> This requirement applied, Justice Waterman explained, regardless of how the plaintiff denominated her claims.<sup>467</sup> The plurality also declined the invitation to "change Iowa law to impose a new duty on manufacturers to those who never used their products and were instead harmed by use of a competitor's product."<sup>468</sup> In ruling that the brand-name manufacturer did not owe the plaintiff a duty and that the requisite causation link was also lacking, the plurality said the court would be joining the "overwhelming majority" of courts

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461. *See id.* at 369–74.

462. *See id.* at 356, 381.

463. *See id.* at 381.

464. *See id.* at 382 (Hecht, J., joined by Wiggins and Appel, JJ., concurring in part and dissenting in part) ("I respectfully dissent from the majority's analysis and disposition of the claims against the brand defendants.").

465. *See id.* at 381 (Cady, C.J., concurring specially); *id.* at 382 (Hecht, J., joined by Wiggins and Appel, JJ., concurring in part and dissenting in part).

466. *Id.* at 369.

467. *See id.* at 371 ("[T]he product-identification causation requirement applied regardless of the theory which liability is predicated upon.").

468. *Id.* at 369.

that had ruled similarly regarding claims against brand-name makers when the plaintiff had used only a generic.<sup>469</sup>

Speaking from a policy perspective, the *Huck* plurality observed that it was “unwilling to make brand name manufacturers the de facto insurers for competing generic manufacturers”<sup>470</sup> and added that “[t]he unfairness resulting from *Mensing* is best addressed by Congress or the FDA.”<sup>471</sup> Although Chief Justice Cady provided the necessary vote for the outcome on the brand-name manufacturer aspect of the case, he concurred in the result rather than subscribing to the plurality’s reasoning.<sup>472</sup> “I agree with much of the dissent on the claims against the brand defendant,” he noted, “but decline at this time to conclude the public policy considerations that ultimately drive the decision in this case, on balance, support the imposition of a duty of care as suggested by [the dissent].”<sup>473</sup> Three justices joined in a dissent stressing that the brand-name manufacturer should have been regarded as owing a duty to persons such as the plaintiff, that a reasonable jury could find causation, and that the claims should not have been snuffed out at the summary judgment stage.<sup>474</sup>

In two previously discussed cases, the Court of Appeals of Missouri was faced with deciding whether the lower court had been correct in granting a brand-name manufacturer summary judgment on the plaintiff’s negligence and misrepresentation claims against it. The respective plaintiffs in the two cases, *Franzman v. Wyeth, Inc.*<sup>475</sup> and *Nicely v. Wyeth, Inc.*,<sup>476</sup> had

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469. *Id.* (“An overwhelming majority of courts adjudicating this issue have affirmed judgments or granted dispositive motions dismissing claims against the brand defendants when the plaintiff used only the generic formulation.”). See also *id.* at 380.

470. *Id.* at 380.

471. *Id.* The plurality spoke approvingly of the proposed FDA rule that, if promulgated, would allow generic makers to use the CBE regulation as a basis for beginning to use a strengthened label without prior approval from the FDA. See *id.* at 369, 380–81. The proposed rule would be “the appropriate way to address the unfairness resulting from *Mensing*, rather than turning Iowa tort law upside down.” *Id.* at 369. For discussion of the CBE regulation and the proposed but long-stalled rule, see *supra* text accompanying notes 45–47 and *supra* notes 234, 268.

472. *Huck*, 850 N.W.2d at 381 (Cady, C.J., concurring specially).

473. *Id.* (Cady, C.J., concurring specially). See also *id.* at 382 (Hecht, J., joined by Wiggins and Appel, JJ., concurring in part and dissenting in part).

474. See *id.* at 382 (Hecht, J., joined by Wiggins and Appel, JJ., concurring in part and dissenting in part).

475. *Franzman v. Wyeth, Inc.*, 451 S.W.3d 676 (Mo. App. 2014).

used only a generic version of the drug at issue, not the brand-name version.<sup>477</sup> This critical fact doomed each plaintiff's chances. Employing reasoning similar to what the *Huck* plurality articulated in the Iowa case,<sup>478</sup> the Missouri court held in *Franzman* and *Nicely* that regardless of the particular legal theories the plaintiff sought to employ, applicable state law would not permit the imposition of liability on the brand-name manufacturer when its product was not the one the plaintiff used.<sup>479</sup> The lower court, therefore, had ruled correctly on the claims against the brand-name manufacturer.<sup>480</sup>

One state's highest court, however, has swum against the tide of decisions rejecting claims against brand-name manufacturers when the plaintiffs ingested only generic versions of the drug rather than the brand-name medication. In *Wyeth, Inc., v. Weeks*,<sup>481</sup> a 2014 decision, the Supreme Court of Alabama answered certified questions from a federal district court and held that certain claims against brand-name manufacturers could go forward despite the fact that the plaintiff had not used the brand-name drug.<sup>482</sup> A six-justice majority so ruled, with three justices in dissent.<sup>483</sup> The relevant brand-name drug, Reglan, was one whose name figures prominently in most of the cases discussed previously. As was true of the plaintiffs in those other cases, plaintiff Danny Weeks developed the disorder known as tardive dyskinesia

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476. *Nicely v. Wyeth, Inc.*, 451 S.W.3d 694 (Mo. App. 2014).

477. *Franzman*, 451 S.W.3d at 678; *Nicely*, 451 S.W.3d at 694. For discussion of the court's treatment of the plaintiffs' claims against the generic manufacturer in *Franzman* and *Nicely*, see *supra* text accompanying notes 401–12.

478. See *supra* text accompanying notes 354–66.

479. *Franzman*, 451 S.W.3d at 689–92; *Nicely*, 451 S.W.3d at 696–97. In each case, Kentucky law provided the relevant rules. *Franzman*, 451 S.W.3d at 689–90; *Nicely*, 451 S.W.3d at 696.

480. See *Franzman*, 451 S.W.3d at 692; *Nicely*, 451 S.W.3d at 697. The Georgia Court of Appeals recently ruled the same way, upholding grants of summary judgment in favor of brand-name manufacturers in cases in which the plaintiffs consumed only generic versions of the relevant medication. *PLIVA, Inc. v. Dement*, 335 Ga. App. 398, 780 S.E.2d 735, 2015 Ga. App. LEXIS 772, at \*19–21 (Ga. Ct. App., Nov. 20, 2015).

481. *Wyeth, Inc., v. Weeks*, 159 So. 3d 649 (Ala. 2014).

482. See *id.* at 676 (“Under Alabama law, a brand name-drug company may be held liable for fraud or misrepresentation . . . by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company.”).

483. See *id.* at 677.

after using metoclopramide, the generic equivalent of Reglan.<sup>484</sup>

The Alabama court noted at the outset that the plaintiffs had brought a fraud claim.<sup>485</sup> They alleged that the brand-name manufacturers “falsely and deceptively misrepresented or knowingly suppressed facts about Reglan or metoclopramide, such that Danny Weeks’s physician, when he prescribed the drug to Danny, was materially misinformed and misled about the likelihood that the drug would cause . . . tardive dyskinesia and related movement disorders.”<sup>486</sup> The court pointed out that under the plaintiffs’ theory of the case, the brand-name manufacturers (hereinafter referred to collectively as “Wyeth”)<sup>487</sup> were obligated “to warn Danny’s physician about the risks” of long-term use of the drug and that the plaintiffs, “as third parties, have a right to hold Wyeth liable for the alleged breach of the duty.”<sup>488</sup>

This formulation of the issues proved important to the *Weeks* court’s analysis. The court emphasized that because the case was a fraud case rather than a product liability case, it was different from other cases in which courts had rejected claims against brand-name manufacturers.<sup>489</sup> Explaining that “[t]his is not a claim that the drug ingested by Danny was defective,” the court noted that “instead, it is a claim that Wyeth fraudulently misrepresented or suppressed information about the manner in which (i.e., the duration) the drug was to be taken.”<sup>490</sup>

In a further effort to distinguish the case from others in which courts had held that the brand-name manufacturers did not owe a duty to a plaintiff who did not ingest the brand-name drug, the *Weeks* court stressed that the relevant duty in the case before it was a duty on the part of Wyeth to warn the *physician*.<sup>491</sup> That duty could have been satisfied if Wyeth, as allowed by federal drug regulation law, had sought FDA

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484. *Id.* at 653. Weeks’ spouse was also a plaintiff. *Id.*

485. *See id.* at 655.

486. *Id.*

487. The defendants were the original brand-name manufacturer and other companies that manufactured Reglan after evidently having acquired the Reglan rights from the original manufacturer. *See id.* at 653–54.

488. *Id.* at 655.

489. *See id.* at 656–58.

490. *Id.* at 657.

491. *Id.* at 664, 670–73.

approval of a strengthened warning label or had adopted a revised label without prior FDA approval by relying on the CBE regulation.<sup>492</sup> The Alabama court also emphasized that even though the relevant duty was owed to the physician (the learned intermediary), the plaintiffs were third parties entitled to rely on that duty because of the physician-patient connection and because of the nature of the prescription medication system.<sup>493</sup> Patients cannot obtain prescription medications directly from a manufacturer; rather, the court noted, they can only acquire such medications after obtaining a prescription from a physician.<sup>494</sup>

The *Weeks* court therefore answered the certified question by stating that under Alabama law, “a brand-name drug company may be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture of a brand-name prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company.”<sup>495</sup> According to the court, it was “not fundamentally unfair” to hold the brand-name manufacturer liable for inadequate warnings even though it did not produce the product, because “the manufacturing process is irrelevant” when the case is based on warning deficiencies rather than manufacturing defects.<sup>496</sup> As a further reason for concluding that such a result was not unfair, the court noted that the alleged misrepresentations on which the case would be based “were drafted by the brand-name manufacturer and merely repeated, as allowed by the FDA, by the generic manufacturer.”<sup>497</sup>

Denying that it was “turning [tort law] on its head,”<sup>498</sup> the *Weeks* court stated that the question it was answering arose in

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492. See *id.* at 659–61, 672–73. The court noted that in allowing claims against the brand-name manufacturers to go forward, it was not deciding the merits of the case. *Id.* at 677 n.11.

493. *Id.* at 664, 670–74.

494. *Id.* at 674.

495. *Id.* at 676.

496. *Id.* at 677.

497. *Id.*

498. *Id.* The court also denied that it was creating some species of “innovator liability.” *Id.* One of the dissenting justices had expressed concern that the court’s reasoning could lead to instances in which firms that devote the time, money, and effort to develop truly new products (the innovators) might be held liable for problems with similar products later produced by

“the sui generis context in which we find prescription medication.”<sup>499</sup> That context stemmed from “[t]he unique relationship between brand-name and generic drugs as a result of federal law and FDA regulations, combined with the learned intermediary doctrine and the fact that representations regarding prescription drugs are made not to the plaintiff but to a third party.”<sup>500</sup> Following up on the “sui generis” point, the court offered this bit of dictum: “Nothing in this opinion suggests that a plaintiff can sue Black & Decker for injuries caused by a power tool manufactured by Skil based on labeling or otherwise.”<sup>501</sup>

Three justices offered separate dissents.<sup>502</sup> In the most fully developed of the dissents, Justice Murdock expressed the view that the majority, in trying to correct what it perceived as a wrong, had committed a second wrong.<sup>503</sup> He worked through many cases that pointed in a contrary direction and asserted that with the decision in *Weeks*, the court “stand[s] alone as the only appellate court in the country to hold that a brand-name manufacturer may be responsible for injuries caused to a party who ingests a generic drug that the brand-name manufacturer did not manufacture or sell.”<sup>504</sup>

#### IV. DETERMINING NEXT STEPS AND ASSESSING THE STATE COURTS’ EFFORTS

As revealed in Section III’s analysis, the reasoning employed in *Mensing* and *Bartlett* (the second and third decisions in the Supreme Court’s pharmaceuticals trilogy) suffers from various deficiencies. Now, a “happenstance” plays

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companies that did not have to devote the level of resources the innovators devoted. *See id.* at 706–08 (Murdock, J., dissenting).

499. *Id.* at 677.

500. *Id.* The relevant context also included indications that Congress regards state-law-based tort cases as complementary to the federal regulatory efforts. *Id.* at 661–62, 676–77.

501. *Id.* at 677.

502. *Id.* at 681 (Moore, C.J., dissenting), 683 (Parker, J., dissenting), 684 (Murdock, J., dissenting).

503. *Id.* at 686 (Murdock, J., dissenting).

504. *Id.* at 704. *See also id.* at 696–703. For extensive discussion of the major arguments against allowing consumers harmed by generic drugs to sue brand-name manufacturers, see Victor E. Schwartz, Phil Goldberg, & Cary Silverman, *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 *FORDHAM L.J.* 1835, 1855–72 (2013).

a critical and outsized role in determining the patient's possible rights if she is harmed by a prescription drug. Did the pharmacist fill the patient's prescription with the brand-name drug or, instead, a generic equivalent?<sup>505</sup> If a consumer experienced harm after using a generic that arguably bore inadequate warnings or was otherwise insufficiently safe, the "unfortunate hand" operates and the *Mensing-Bartlett* duo extinguishes, or at least severely limits, her ability to pursue seek legal relief against the generic manufacturer.<sup>506</sup> Of course, she would be free to pursue such relief against the relevant drug maker if the happenstance had gone the other way and the pharmacist had dispensed the brand-name drug to which the generic was equivalent.<sup>507</sup>

Given the pervasive presence of generics in the marketplace and the laws that encourage their use, far more harmed consumers will be dealt the unfortunate hand than will receive the more favorable one.<sup>508</sup> The question then becomes what, if anything, to do about it. For the majority in *Mensing* and *Bartlett*, the answer was easy: Congress, having enacted the rules that created the unfortunate hand, can always change the rules to eliminate it.<sup>509</sup> But that convenient answer is disingenuous. Even if one assumes that the Court was right in laying the blame on Congress (as opposed to the Court itself for its strained, faulty determination of the Hatch-Waxman Act's effects), political realities make it exceedingly unlikely that Congress would amend the drug regulation statutes and accomplish a legislative overruling of *Mensing-Bartlett*.<sup>510</sup> As noted earlier, legislative moves along those lines have gone nowhere,<sup>511</sup> no doubt in large part because of opposition from

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505. See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2583 (2011) (Sotomayor, J., dissenting) ("[W]hether a consumer harmed by inadequate warnings can obtain relief turns solely on the happenstance of whether her pharmacist filled her prescription with a brand-name or generic drug.").

506. See *id.* at 2581 ("We acknowledge the unfortunate hand that federal drug regulation has dealt.").

507. *Id.*

508. See *supra* text accompanying notes 8–9; *supra* note 10.

509. *Mensing*, 131 S. Ct. at 2582 ("As always, Congress and the FDA retain the authority to change the law and regulations if they so desire.").

510. See S. 2295 (112th): *Patient Safety and Generic Labeling Improvement Act*, GOVTRACK.US (Apr. 18, 2012), <https://www.govtrack.us/congress/bills/112/s2295> ("The bill was introduced April 18, 2012, in a previous session of Congress, but was not enacted.").

511. See *supra* note 267.

the generic pharmaceuticals industry.<sup>512</sup> An industry heavily insulated against tort liability by Supreme Court decisions interpreting the relevant statutes is unlikely to sit idly by during a legislative move to undo those decisions. Throw in those in Congress who wish to rein in tort litigation, and turning to Congress for relief from the unfortunate hand becomes an unrealistic option.

What about the FDA? Justice Thomas suggested in *Mensing* that perhaps the FDA could take action in a way that would eliminate the unfortunate hand.<sup>513</sup> Shortly after the decision in *Bartlett*, the FDA signaled interest in moving in that direction with the previously noted November 2013 announcement of a proposed regulation.<sup>514</sup> If promulgated, the proposed regulation would permit generic manufacturers to take the CBE route and begin using a strengthened label without prior FDA approval.<sup>515</sup> Recall that in *Wyeth v. Levine*, the brand-name manufacturer's ability to invoke the CBE regulation was a key reason why the Court rejected the argument for preemption on the ground of impossibility, whereas the generic maker's inability to invoke the CBE regulation helped support the *Mensing* conclusion that impossibility preemption was appropriate.<sup>516</sup> One assumes, therefore, as the FDA did, that if the proposed regulation were to become a final rule, *Mensing* would be administratively undone and tort claims against generic manufacturers could proceed just as such claims can proceed against brand-name manufacturers under *Levine*.<sup>517</sup> But there are potential problems with that assumption.

First, there are serious questions about whether the proposed regulation will survive to final rule stage in its present form. As explained in earlier discussion, the move the FDA wished to make has remained in the proposed regulation stage for a long period of time, with the usual comment period

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512. *Id.*

513. *See Mensing*, 131 S. Ct. at 2582 (“As always, Congress and the FDA retain the authority to change the law and regulations if they so desire.”).

514. *See Paradise*, *supra* note 267.

515. *See supra* note 268. For discussion of the CBE regulation, see *supra* text accompanying note 47.

516. *Levine*, 555 U.S. 555, 568–70 (2009); *Mensing*, 131 S. Ct. at 2575–76.

517. *See Paradise*, *supra* note 267 (“The proposed rule discusses *Wyeth*, *PLIVA*, and *Bartlett*, noticeably understating that the rule ‘may’ eliminate preemption for generic drugs.”).



closing, another comment period later opening up and closing, and a public meeting for further comments having taken place.<sup>518</sup> Generic manufacturers and groups affiliated with them have registered their opposition to the proposed rule for reasons similar to why they would oppose unfortunate-hand-altering legislation from Congress: they are largely exempted from tort liability under *Mensing* and *Bartlett*, and they would like to preserve that enviable position (as compared with the position in which brand-name manufacturers find themselves under *Levine*).<sup>519</sup> Challenges in court to the validity of the regulation, if it were promulgated, would be likely.<sup>520</sup> Depending upon the outcome, those challenges would either delay the effective date of the regulation or derail it entirely.<sup>521</sup>

Another sign that the proposed regulation may not achieve final rule status is the previously noted fact that alternative versions of the rule have been offered by interested parties.<sup>522</sup> Comments on alternative versions have been invited by the FDA and are being considered by the agency.<sup>523</sup> It seems a safe bet that if an alternative version were adopted, it would reflect enough watering-down that there would be little, if any, dent in the impossibility rationale set forth in *Mensing* and *Bartlett*.

A further problem is that even if the proposed regulation were promulgated, there is no guarantee that it would have the FDA-desired effect of undoing *Mensing-Bartlett* and treating generic manufacturers and brand-name manufacturers alike in terms of potential tort liability. Although Justice Thomas hinted in *Mensing* that either Congress or the FDA might act to alter the governing rules, Justice Alito's opinion for the Court in *Bartlett* mentioned only Congress, and not the FDA, as having the authority to change the relevant legal landscape.<sup>524</sup>

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518. See *supra* note 268.

519. *Id.*

520. *Id.*

521. See *id.*

522. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products; Public Meeting; Request for Comments; Reopening of the Comment Period, 80 Fed. Reg. 8577 (proposed Feb. 18, 2015) (to be codified at 21 C.F.R. pt. 314, 601) ("The purpose of the meeting is to provide a public forum for FDA to listen to comments on the proposed rule on 'changes being effected' supplements that was published in the Federal Register of November 13, 2013 and alternatives offered to this proposed rule.").

523. See *supra* note 268.

524. See *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2480 (2013).

Perhaps the failure to mention the FDA was a deliberate omission; perhaps not.

In any event, courts—and potentially the Supreme Court—would have occasion to determine whether the regulation, if it were promulgated, would really have the effect of undercutting the *Mensing-Bartlett* rationale and making *Levine*-like reasoning apply in cases against generic manufacturers. The impossibility rationale set forth in *Mensing* included Justice Thomas's addition of an independent-action element that seemingly had not been part of the impossibility doctrine before.<sup>525</sup> In *Mensing*, the FDA had taken the position that when generic manufacturers become aware of important safety information after their product has been on the market, they have a duty to propose that the FDA approve a strengthened label.<sup>526</sup> The Court declined to defer to that agency interpretation but stated that even if generic manufacturers were assumed to have such a duty under those circumstances, impossibility preemption would remain applicable because the generic makers still would be unable to act “independently” to satisfy their state-law-based obligations without violating federal law.<sup>527</sup> Because FDA approval of such a proposal would still be necessary, the Court reasoned, the proposal would not be enough of an independent action by the generic makers to avoid impossibility preemption.<sup>528</sup>

An FDA regulation opening up the CBE avenue to generic manufacturers would permit such manufacturers to begin using a strengthened label without prior approval, just as brand-name manufacturers can, and would seem to be more of an independent action than the mere proposal for FDA action commented on in *Mensing*.<sup>529</sup> Yet even when the CBE route is

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525. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577–81 (2011). *See also id.* at 2582, 2586 (Sotomayor, J., dissenting).

526. *Id.* at 2577 (“The FDA argues that . . . [i]f a generic drug manufacturer believes new safety information should be added to a product’s labeling, it should contact the FDA . . .”).

527. *Id.* at 2579.

528. *Id.* at 2580–81.

529. *Examining Concerns Regarding FDA's Proposed Changes to Generic Drug Labeling: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 113th Cong. 5 (2014) (statement of Janet Woodcock, Director, Center for Drug Evaluation & Research, Food & Drug Administration) (“Under the proposed rule, generic drug application holders would have the same ability as brand drug application holders to update product labelings . . .”).

pursued, the FDA must ultimately approve the strengthened label if use of it is to continue over the long term.<sup>530</sup> The CBE regulation permits use of the revised label without prior approval, but the drug maker pursuing the CBE route must simultaneously initiate an FDA approval process with regard to the revised label.<sup>531</sup> It is conceivable that because of the independent-action element added to the impossibility doctrine in *Mensing*, the Court could determine in a later case that even the CBE option, if made available to generic manufacturers, would not be sufficient independent action because FDA approval would still be necessary.<sup>532</sup> Such a conclusion by the Court would require a further gloss on the impossibility doctrine and perhaps a bit of recasting of *Levine*, but it is a possibility that should not be discounted, given the content and tone of *Mensing* and *Bartlett*.

As explained previously, the federal courts of appeal have done little to lessen the impact of *Mensing* and *Bartlett* on consumers harmed by the generic drugs they used.<sup>533</sup> That is not surprising, of course, given the obligation to follow *Mensing* and *Bartlett*. With the two Supreme Court decisions reasonably lending themselves to a broad interpretation, the duty to be faithful to those decisions and the desire to avoid being reversed seemingly have given the federal courts of appeal little inclination to be adventurous when they determine the preemptive reach of *Mensing* and *Bartlett*. Those courts have paid little or no attention, as noted earlier, to *Mensing* and *Bartlett* footnotes containing language that a court might interpret as suggestions of possible ways to make the preemptive sweep of the decisions at least marginally smaller.<sup>534</sup>

Moreover, even when they have held that a potentially important claim—the previously discussed failure-to-update claim—is not preempted, most of the federal courts of appeal have gone on to reject the claim on the basis of inadequate pleading or supposed logical inconsistency.<sup>535</sup> Thus, despite

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530. *See id.* ("Under the proposed rule, . . . FDA would reach a decision regarding the approvability of the labeling proposed by the generic and brand drug application holders regarding the safety issue at the same time.").

531. *See id.*

532. *See Mensing*, 131 S. Ct. at 2577–81.

533. *See supra* text accompanying notes 299–330.

534. *See supra* text accompanying notes 322–23.

535. *See supra* notes 306, 313, 369.

appearing to throw consumers harmed by generics the failure-to-update bone, most of the federal courts of appeal then moved quickly to retrieve the bone before the plaintiffs could pick it up.

Some of the federal courts have commented on the “Catch-22” circumstances facing harmed consumers of generics and have otherwise acknowledged their plight, but have felt, as a Sixth Circuit panel noted, “compelled [by] the controlling caselaw” to rule as they did.<sup>536</sup> Some courts have noted that Congress or the FDA might remedy the problem with appropriate action.<sup>537</sup> The Tenth Circuit even suggested that state courts could play a key role in ameliorating the situation by weighing the relevant policy considerations and shaping state tort law in ways that might escape *Mensing-Bartlett* preemption.<sup>538</sup>

With federal courts understandably not feeling free to do much, if anything, about the *Mensing-Bartlett* problem for consumers harmed by generics, some state courts have partially filled the void.<sup>539</sup> The cases discussed in Section IV of the Article suggest that state courts have been more inclined than the federal courts to consider ways of respecting *Mensing* and *Bartlett* yet keeping their preemptive effect within reasonable bounds. In doing so, these state courts have seized upon the previously mentioned *Mensing* and *Bartlett* footnotes, have engaged in careful comparisons of the facts in the cases before them with the facts in *Mensing* and *Bartlett* (sometimes finding important differences), and seemingly have picked up on the Tenth Circuit’s suggestion regarding the crafting of state tort law.<sup>540</sup> The state courts thus appear to have stood up for their citizens against the potential steamrolling effect of *Mensing-Bartlett* and the Catch-22 that tandem contemplates.

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536. *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 407 (6th Cir. 2013) (noting “Catch-22” of having claims against generic manufacturers preempted and not being able to sue brand-name manufacturers because only generics were used); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1290 (10th Cir. 2013) (noting the same “Catch-22”).

537. *See Strayhorn*, 737 F.3d at 407; *Schrock*, 727 F.3d at 1290; *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1253 (11th Cir. 2013).

538. *Schrock*, 727 F.3d at 1290 (“[F]ederal law does not prevent a state from providing a damages remedy for claims premised on a violation of FDA regulations.”).

539. *See e.g.*, *Guvenoz v. Target Corp.*, 30 N.E.3d 404, 426 (Ill. App. 2015); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014).

540. *See supra* text accompanying notes 337–56.

As the following assessment reveals, the state courts' efforts sometimes have been both admirable and sound but other times, despite being commendable, have fallen short in terms of soundness.

#### A. FAILURE-TO-UPDATE CLAIMS AND THE STATE COURTS' SOLID GROUND

Considering the content and thrust of *Mensing* and *Bartlett*, state courts are on the most solid ground in their decisions holding that failure-to-update claims are not preempted. Such claims are a particular type of failure-to-warn claim—and both *Mensing* and *Bartlett* held that the failure-to-warn claims before the Court were preempted.<sup>541</sup> As some of the state courts have sensibly recognized, however, failure-to-update claims are meaningfully different from the failure-to-warn claims held preempted in *Mensing-Bartlett*.<sup>542</sup>

The Supreme Court of Iowa's decision in *Huck v. Wyeth, Inc.*,<sup>543</sup> provided the most complete roadmap to a conclusion that failure-to-update claims are not preempted. Four of the other state court decisions discussed above offered similar reasoning.<sup>544</sup> *Huck* and the other decisions recognizing failure-to-update claims take the position that the preemption rationale articulated in *Mensing* and applied in *Bartlett* should point in the opposite direction with regard to failure-to-update claims.<sup>545</sup> *Huck* and company establish this well-reasoned proposition: If the duty of sameness contemplated by the Hatch-Waxman Act and relied on in *Mensing* bars a generic manufacturer from using a label containing a stronger warning than is set forth in the FDA-approved label for the brand-name drug, the duty of sameness should help to furnish the basis for liability if the generic manufacturer did not use the

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541. *See* *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2569 (2011) (“[F]ederal law preempted state laws imposing the duty to change the drug’s label upon generic drug manufacturers.”).

542. *See supra* text accompanying notes 354–66, 387–90, 401–24.

543. *See Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014).

544. For discussion of those decisions, *see supra* text accompanying notes 387–90, 401–24.

545. For discussion of those decisions, *see supra* text accompanying notes 387–90, 401–24.

strengthened, later-approved label that the brand-name manufacturer has employed.<sup>546</sup>

Through this reasoning, *Huck*'s conclusion (and that of other state courts) can be seen as consistent with *Mensing*'s rationale despite the different outcome on the preemption question.<sup>547</sup> Thus, the duty of sameness does not change in its substantive content. What changes, depending on the circumstances, is its effect. Sometimes the generic manufacturer cannot use a revised label (as in *Mensing*, so preemption applies there).<sup>548</sup> Other times the generic manufacturer must use a revised label (as in *Huck*, so preemption does not apply there).<sup>549</sup>

The state courts' failure-to-update cases, especially *Huck* and *Franzman v. Wyeth, Inc.*,<sup>550</sup> illustrate another important point for plaintiffs to keep in mind if they wish to have their claims—whether failure-to-update claims or other causes of action—escape preemption. Courts must keep the same point in mind when they consider such claims. As made clear in *Huck* and *Franzman*, the plaintiff cannot simply assert a violation of federal law and use that violation as the legal reason why the plaintiff should receive legal relief.<sup>551</sup> Why not? Recall that the federal drug regulation laws do not include any provision authorizing a private right of action to enforce the obligations set forth there.<sup>552</sup> Plaintiffs must be able to point to state law, whether statutory or common law, that contemplates the same obligation set forth in federal law or a duty arguably

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546. See *Huck*, 850 N.W.2d at 364–66. For the article's earlier discussion of *Huck* and *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013), the federal court decision that proved influential in *Huck*, see *supra* text accompanying notes 337–69.

547. See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574–78; *Huck*, 850 N.W.2d at 364–66. If a case presenting a failure-to-update claim such as the one in *Huck* and the other state court cases were to make its way to the Supreme Court, the Court would be hard-pressed to find it preempted unless the Court ignored what *Mensing* said and put an unwarranted spin on that decision. See *id.*

548. See *Mensing*, 131 S. Ct. at 2578.

549. See *Huck*, 850 N.W.2d at 364 (“PLIVA needed only go through the ‘changes being effected’ process to revise its label to match the updated brand-name label.”).

550. *Franzman v. Wyeth, Inc.*, 451 S.W.3d 676 (Mo. App. 2014). For the article's earlier discussion of *Franzman*, see *supra* text accompanying notes 401–12.

551. *Huck*, 850 N.W.2d at 367–68, 369; *Franzman*, 451 S.W.3d at 688–89.

552. *E.g.*, *Wyeth v. Levine*, 555 U.S. 555, 574 (2009).

comparable to the federal duty.<sup>553</sup> In other words, the plaintiff's state-law-based claim must depend upon the existence of a duty that is parallel to a federal duty.<sup>554</sup> The federal duty, of course, is relevant to the case and will no doubt be addressed as the case progresses, but the plaintiff's claim ultimately is based on the parallel state duty.<sup>555</sup>

In the failure-to-update context, the state law duty comparable to the federal duty to use the strengthened, FDA-approved label is the defendant's common-law obligation to provide suitable warnings regarding its product if the product poses meaningful risks to the user.<sup>556</sup> An inquiry can be made with regard to state-law-based tort or warranty claims that contemplate duties arguably parallel to the duty contemplated by the federal misbranding statute, which classifies a drug as misbranded if its labeling does not adequately warn against safety hazards.<sup>557</sup> Thus, state courts fashioning and applying common law rules and legislatures enacting statutory duties may be able, as two federal courts of appeal have suggested, to recognize state-law bases of liability that afford harmed consumers some relief from the *Mensing-Bartlett* unfortunate hand.<sup>558</sup> Importantly, to the extent that legislatures and state courts (particularly their highest courts) provide meaningful content to such causes of action under state law, the federal courts will have to respect those state determinations rather than guessing what a state might or might not recognize under its law.

In addition, states that recognize duties parallel to those in federal law may take advantage of a possible signal that Justice Alito sent in *Bartlett*. In a footnote, he observed that the Court was not considering a tort claim meant to parallel

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553. See *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 586–87 (6th Cir. 2013).

554. *Fulgenzi*, 711 F.3d at 586–87; *Huck*, 850 N.W.2d at 368.

555. See *Fulgenzi*, 711 F.3d 578, 586–89; *PLIVA, Inc. v. Dement*, 335 Ga. App. 398, 780 S.E.2d 735, 2015 Ga. App. LEXIS 772, at \*5–11 (Ga. Ct. App., Nov. 20, 2015); *Huck*, 850 N.W.2d at 368–69.

556. See *Huck*, 850 N.W.2d at 368–69; *Dement*, 2015 Ga. App. LEXIS 772, at \*8–10.

557. See *Dement*, 2015 Ga. App. LEXIS 772, at \*11.

558. See *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 407 (6th Cir. 2013); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1290 (10th Cir. 2013). For discussion of the misbranding statute, see *supra* text accompanying notes 48–53. See also *Dement*, 2015 Ga. App. LEXIS 772, at \*10–12 (concluding that state-law duties not to sell misbranded drugs parallel the federal duty in that regard).

the duty provided for in the federal misbranding statute.<sup>559</sup> With this statement, Justice Alito suggested at least the possibility that cases dealing with parallel duties might not get the *Mensing-Bartlett* preemption treatment.<sup>560</sup> State courts and legislatures may wish to treat that possibility as a reality—and thereby give harmed consumers some ability to seek legal relief from generic manufacturers—unless and until the Supreme Court specifically rules to the contrary.

The state court decisions on failure-to-update claims are also noteworthy in their display of an apparent let's-give-the-plaintiff-her-day-in-court mindset. As previously noted, federal courts of appeal have held that failure-to-update claims are not preempted under *Mensing-Bartlett*.<sup>561</sup> Most of these courts, however, have dismissed the claims because they were not properly pleaded or because of supposed logical inconsistency stemming from the plaintiff's separate allegations that a fully adequate warning would have gone beyond the warning in the label later approved by the FDA.<sup>562</sup> This treatment of failure-to-update claims may result in part from enhanced federal pleading requirements called for in a 2009 Supreme Court decision.<sup>563</sup> However, the logical inconsistency rationale comes across as a hyper-technical objection that unduly restricts plaintiffs' ability to argue in the alternative and unnecessarily restricts their opportunity to prove what they need to prove in order to prevail. Unlike most of the federal courts of appeal, the state courts appear to take the position that plaintiffs should receive a reasonable chance to prove that even a less-than-ideal warning along the lines of the later-approved label would still have been sufficient to alert them, as well as their physicians, regarding the dangers and to influence them to pursue a different medical treatment.<sup>564</sup>

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559. *Mut. Pharm. Co. v. Bartlett*, 133 S.Ct. 2466, 2477 n.4 (2013).

560. *Id.*

561. See *supra* text accompanying note 330.

562. For discussion of those decisions, see *supra* notes 306, 313, 369.

563. See *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

564. See *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 587–88 (6th Cir. 2013); see, e.g., *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 363 n.7 (Iowa 2014).



D. STATE COURTS' ATTEMPTS TO NARROW THE SWEEP OF  
*MENSING-BARTLETT*

In *Hassett v. Defoe*,<sup>565</sup> the Superior Court of Pennsylvania concluded not only that a failure-to-update claim should go forward, but also that some other failure-to-warn and design defect claims should escape preemption under *Mensing* and *Bartlett*.<sup>566</sup> The court interpreted the two Supreme Court decisions as narrowly as possible. Certain failure-to-warn claims based on generic labels' content that corresponded to the FDA-approved label clearly had to be considered preempted under *Mensing* and *Bartlett*, but the *Hassett* court limited the preempted category so that it would cover only failure-to-warn claims arising prior to the 2007 amendments to the federal drug regulation laws.<sup>567</sup> In neither of the two Supreme Court decisions did the Court expressly limit its preemption holding in that way.<sup>568</sup> However, in the *Mensing* footnote noted various times in the Article, Justice Thomas did observe that the court was applying the federal law as it existed prior to the 2007 amendments and that it was not considering whether the 2007 amendments might affect the analysis.<sup>569</sup> Unlike the federal courts of appeal, which have not ascribed any significance either way to the *Mensing* footnote, the *Hassett* court seized on it.<sup>570</sup>

The Pennsylvania court regarded the 2007 amendments as important in two respects: for supposedly confirming an obligation on the part of all drug manufacturers to seek FDA approval for a revised label if they later acquire important safety-related information; and for empowering the FDA to order the use of a strengthened label rather than merely being able to negotiate with the brand-name manufacturer about the prospect of adopting a revised label.<sup>571</sup> The latter aspect of the

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565. *Hassett v. Defoe*, 74 A.3d 202 (Pa. Super. Ct. 2013).

566. *Id.* at 217.

567. *Id.* at 206, 217. Earlier discussion of *Hassett* appears at *supra* text accompanying notes 370–400.

568. See *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013); *PLIVA, Inc., v. Mensing*, 131 S. Ct. 2567 (2011).

569. *Mensing*, 131 S. Ct. at 2574 n.1.

570. See *Hassett*, 74 A.3d at 206–07, 217. For discussion of the federal courts' silence on the *Mensing* footnote, see *supra* text accompanying notes 321–24.

571. See *Hassett*, 74 F.3d at 217 & n.13. Discussion of the 2007 amendments appears at *supra* text accompanying notes 55–57.

amendments seemed especially significant to the *Hassett* court. It regarded that grant of power to the FDA as removing some of the uncertainty about whether a strengthened label would ultimately result—uncertainty the *Mensing* majority noted in concluding that the supposed obligation to approach the FDA about a strengthened label was not enough to defeat impossibility preemption.<sup>572</sup> The *Hassett* court concluded, therefore, that *Mensing* should not be treated as calling for preemption of claims based on facts that arose after the 2007 amendments.<sup>573</sup> At least it would be “premature,” the court noted, to hold such claims preempted.<sup>574</sup>

*Hassett*’s above-described approach to whether failure-to-warn claims are preempted is at least plausible. It is not unreasonable to conclude that through the *Mensing* footnote, Justice Thomas may have sent a signal about such an approach. Yet it is far from clear that the Supreme Court, if it were to review a case presenting a failure-to-claim based on post-2007 facts, would decide that the 2007 amendments indeed make a difference in the controlling analysis. Until we receive more definite word from the Supreme Court, *Hassett*’s approach to whether failure-to-warn claims are preempted rests on moderately stable, but not rock-solid, ground.

In *Hassett*, the Pennsylvania court went on to hold that despite *Bartlett*, various design-defect claims were not preempted.<sup>575</sup> The court argued that the state-law-based claims did not contemplate a need for the generic manufacturer to change the drug’s composition or warning label—actions that the Supreme Court said the tort claims in *Bartlett* contemplated but that federal law prohibited.<sup>576</sup> The *Hassett* court’s valiant effort to distinguish the design-defect claims at issue from those in *Bartlett* comes off, however, as too much of a stretch and as effectively an attempt by the court to follow the *Bartlett* dissenters rather than what *Bartlett*, rightly or wrongly, held.<sup>577</sup>

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572. *Hassett*, 74 F.3d at 217 & n.13.

573. *See id.*

574. *Id.* at 217.

575. *Id.*

576. *See id.* at 212–14.

577. *See id.*; *see also id.* at 219–21 (Platt, J., concurring in part and dissenting in part) (criticizing majority for not properly interpreting *Bartlett*). For discussion and analysis of the majority and dissenting opinions in *Bartlett*, see *supra* text accompanying notes 176–214, 250–96.

The recent Illinois Court of Appeals decision in *Guvenoz v. Target Corp.*<sup>578</sup> reveals a well-reasoned effort to distinguish *Mensing* and *Bartlett* and thereby narrow their preemptive effect. The *Guvenoz* court seemed motivated by a concern about the generic manufacturer's attempt to avoid responsibility, as evidenced by the previously noted characterization of the defendant's position early in the court's opinion.<sup>579</sup> But in reaching what seemed a foregone conclusion based on that characterization, the court demonstrated careful analysis in holding that the plaintiff's failure-to-warn and design-defect claims escaped *Mensing-Bartlett* preemption.<sup>580</sup>

Although the court noted the possibility that the 2007 amendments to the federal drug regulation laws might be important to a determination of the fate of some claims against generic manufacturers, the *Guvenoz* court ultimately did not rest its decision on that possibility.<sup>581</sup> Instead, the court made the most of an important factual difference between the case before it and the *Mensing-Bartlett* duo. The factual difference was the FDA's eventual decision to order that Darvocet and its generic equivalents (the drug at issue in *Guvenoz*) be withdrawn from the market because of safety concerns.<sup>582</sup> The relevant drugs in *Mensing* and *Bartlett* had not been ordered off the market.<sup>583</sup>

Whereas the Supreme Court said in *Mensing* and *Bartlett* that the state-law-based claims at issue in those cases called for the defendant to do things it could not do under federal law (using a different label or changing the drug's composition), the *Guvenoz* court could use the ultimate fact that the relevant drug was ordered off the market as a credible basis for stating that the plaintiff's claims did not call for a strengthened label or a change in the drug's composition.<sup>584</sup> Rather, as the court noted, the plaintiff's claims rested on the premise that no

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578. *Guvenoz v. Target Corp.*, 30 N.E.3d 404 (Ill. App. Ct. 2015).

579. *Id.* at 409. See also *supra* text accompanying notes 433–34.

580. See *Guvenoz*, 30 N.E.3d at 413–19, 422–26. There was no failure-to-update claim in *Guvenoz*, presumably because there was no factual predicate for such a claim.

581. See *id.* at 416–17.

582. *Id.* at 418–19.

583. See *id.* at 410–11, 418–19.

584. *Id.* at 418–19.

remedial measure could have made the unreasonably dangerous drug sufficiently safe.<sup>585</sup>

Further, the FDA's order that the medication be removed from the market enabled the *Guvenoz* court to assert confidently that *Bartlett's* disapproval of the stop-selling argument should not be an obstacle to the plaintiff's ability to pursue her state-law-based claims.<sup>586</sup> *Bartlett's* rejection of the argument that a defendant could avoid the impossibility problem by simply not selling the drug occurred in a context in which the drug at issue, though harm-causing to some, was clearly beneficial to many.<sup>587</sup> The *Guvenoz* context was very different, the court astutely recognized. Darvocet and its generic equivalents were not to be sold any longer because of FDA concern that its dangers significantly outweighed its benefits.<sup>588</sup> Therefore, claims under state law that the defendant should be held liable for selling an unreasonably dangerous drug—one that probably should not have been on the market anyway—were not inconsistent with federal law.<sup>589</sup>

*Guvenoz* demonstrates that through careful analysis, state courts can sometimes find meaningful differences between the cases before them and the Supreme Court's *Mensing-Bartlett* tandem and can offer some relief from the unfortunate hand dealt to consumers harmed by generic drugs. In doing so, they can offer a reminder that *Mensing* and *Bartlett* are not the only relevant Supreme Court decisions. There is also *Wyeth v. Levine*. Although *Levine* involved tort claims against a brand-name manufacturer, it emphasized the important point that Congress has traditionally envisioned a meaningful role for state-law-based liability as a complement to the federal regulatory regime.<sup>590</sup>

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585. *Id.*

586. *Id.* Importantly, Justice Alito suggested in *Bartlett* that even though the stop-selling argument normally would not be given credence, such an argument might have validity in an instance where the relevant drug had been outlawed. *See* *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2478 n.5 (2013).

587. *Bartlett*, 133 S. Ct. at 2471–72.

588. *Guvenoz*, 30 N.E.3d at 419.

589. *Id.* at 418–19.

590. *Wyeth v. Levine*, 555 U.S. 555, 578–79 (2009).

B. WHETHER STATE COURTS SHOULD ALLOW CONSUMERS  
HARMED BY GENERIC DRUGS TO SUE BRAND-NAME  
MANUFACTURERS

With *Mensing* and *Bartlett* having severely restricted the ability of harmed consumers to proceed with tort claims against the generic manufacturers whose drugs they used, it is understandable that they have tried to pursue claims against manufacturers of the relevant brand-name drugs to which the generics must correspond in composition and label. As noted earlier, however, the federal courts of appeal have unanimously rejected such claims because, in their view, the common law of the relevant states would not allow the imposition of liability—regardless of how the claims were denominated—on defendants whose product the plaintiffs did not use.<sup>591</sup> Some courts of appeal have acknowledged the plaintiffs’ “Catch-22” plight,<sup>592</sup> and two appellate judges, in concurring and dissenting opinions, have voiced some support for the possible recognition of such claims.<sup>593</sup> But the sympathy and tentative support have not translated into federal court approval of such claims.

At the state level, generic-ingesting plaintiffs’ prospects for obtaining relief from brand-name manufacturers seem brighter in the short run, thanks largely to *Wyeth, Inc. v. Weeks*.<sup>594</sup> The Supreme Court of Alabama’s authorization of such claims stands out as the lone appellate decision to go that way, but only four state appellate courts in a total of five decisions (counting *Weeks*) have weighed in on the issue so far. In one of the other decisions, *Huck v. Wyeth, Inc.*,<sup>595</sup> three of the seven Supreme Court of Iowa judges took the position that claims by generic users against brand-name manufacturers should be permitted; a fourth judge leaned strongly that way before reluctantly answering negatively and providing a majority for

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591. See *supra* text accompanying notes 308–10, 333–35.

592. *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 407 (6th Cir. 2013); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1290 (10th Cir. 2013).

593. See *Johnson v. TEVA Pharms. USA, Inc.*, 758 F.3d 605, 617–19 (5th Cir. 2014) (Dennis, J., concurring in part and dissenting in part) (asserting court should have certified question to Louisiana Supreme Court about whether such claims should be permitted); *Fullington v. Pfizer, Inc.*, 720 F.3d 739, 747–48 (8th Cir. 2013) (Murphy, J., concurring) (suggesting such a claim could be viable, but that plaintiff in case before court had failed to raise it at district court level).

594. *Wyeth Inc. v. Weeks*, 159 So. 3d 649 (Ala. 2014).

595. *Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014).

rejecting such claims.<sup>596</sup> In the other three decisions, two by the Missouri Court of Appeals and one by the Georgia Court of Appeals, the courts declined to authorize claims by generic-using plaintiffs against brand-name makers.<sup>597</sup>

Two questions therefore become important. First, will the notion of permitting generic users' claims against brand-name manufacturers catch on with other state courts? Second, *should* that notion catch on? The fact that Alabama's highest court has ruled as it did could make other courts take notice and consider going the same route in interpreting or fashioning their common law. The significant level of support for that notion among the members of the Supreme Court of Iowa could have a similar effect. Importantly, if state courts—particularly states' highest courts—define or interpret their common law as permitting such claims, federal courts would have to respect those decisions and would be limited in their ability to predict that the relevant state would not permit claims of that nature.

The *Weeks* majority laid out a plausible case for permitting generic-ingesting consumers to proceed against brand-name manufacturers claims under Alabama common law. Ultimately, however, the court found it necessary to note the “sui generis” nature of the pharmaceuticals context as both a reason for, and limiting factor regarding, its decision.<sup>598</sup> Troubling questions and potential problems that attend a *Weeks*-like approach, however, may make otherwise-tempted state courts reluctant to sign on to the notion of recognizing such claims as a way of eliminating the Catch-22 plight of consumers harmed by generic medications.

Even though federal court conclusions about whether their state's common law would allow claims are not binding on them, state courts may find it hard to take issue with the large volume and unanimity of the federal-court decisions ruling out

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596. See *id.* at 356, 381 (Cady, C.J., concurring specially), 382 (Hecht, J., joined by Wiggins and Appel, JJ., concurring in part and dissenting in part); see also *supra* text accompanying notes 462–65, 470–74.

597. *PLIVA, Inc. v. Dement*, 335 Ga. App. 398, 780 S.E.2d 735, 2015 Ga. App. LEXIS 772, at \*19–21 (Ga. Ct. App., Nov. 20, 2015); *Franzman v. Wyeth, Inc.*, 451 S.W.3d 676, 689–92, 694 (Mo. App. 2014); *Nicely v. Wyeth, Inc.*, 451 S.W.3d 694, 696–97 (Mo. App. 2014).

598. *Weeks*, 150 So. 3d at 677. For discussion of the court's analysis, see *supra* text accompanying notes 481–501. The dissenting judges in *Huck* also offered a plausible interpretation of Iowa common law in authorizing such claims. See *Huck*, 850 N.W.2d at 382–402 (Hecht, J., concurring in part and dissenting in part).

claims by generic-using consumers against brand-name manufacturers. They may also worry about taking traditional principles regarding duties owed by manufacturers regarding their products and expanding them to include a duty to persons who consumed someone else's product (even though the products are identical). The pharmaceuticals context may be "sui generis," as the *Weeks* court noted,<sup>599</sup> but other courts may not favor adopting what could be construed as a special set of rules regarding pharmaceuticals or may be leery of whether that special set of rules, if adopted, would remain confined to the drug context.

Other state courts may also object to a *Weeks*-like approach on public policy grounds. As Justice Murdock argued in his *Weeks* dissent, it may not be fair to put brand-name manufacturers on the hook for harm experienced by generic users even though generic versions must match the relevant brand-name drugs in composition and label.<sup>600</sup> The extent of liability for the brand-name maker under the *Weeks* approach could be vast, considering the dominant position of generics in the market. Moreover, generic manufacturers have been relieved by Congress of the time-consuming and expensive burden of seeking the safety-and-effectiveness-related approval that brand-name manufacturer must obtain.<sup>601</sup> As a result, generic manufacturers' ability to compete with the brand-name maker on price has been enhanced.<sup>602</sup> With generic makers already having received the competitive benefit just noted, should brand-name makers be expected to carry the liability burden when a generic user is harmed? Even courts bothered by *Mensing-Bartlett's* dealing of the unfortunate hand to consumers harmed by generics may be unlikely to see imposing liability on brand-name manufacturers as a satisfactory solution.

Finally, recognizing claims by harmed generic users against brand-name manufacturers would seem undesirable in a next-steps sense. If the brand-name manufacturer were to face liability in such a situation, should it be able to implead the relevant generic manufacturer on some sort of contribution

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599. *Weeks*, 150 So. 3d at 677.

600. *Id.* at 706–08 (Murdock, J., dissenting). See also Schwartz, Goldberg, & Silverman, *supra* note 504, at 1870–72.

601. See Schwartz, Goldberg, & Silverman, *supra* note 504, at 1844–45.

602. See *supra* text accompanying notes 6–9, 61–64, 283–85.

claim? One would expect the brand-name manufacturer to try doing so because, after all, it was the generic maker's product that the harmed plaintiff consumed. But would such a contribution claim be barred on preemption grounds, given *Mensing-Bartlett*? Whereas the harmed consumer's tort claims against the generic manufacturer were held in *Mensing-Bartlett* to call for changing the drug's composition or approved label (actions barred by federal law),<sup>603</sup> the brand-name manufacturer could argue that its contribution claim, rather than contemplating such actions, merely sought a sharing of responsibility for the harm that was caused. Yet the spirit of *Mensing-Bartlett* might not countenance such a claim. Another question would pertain to whether there would be an independent legal basis for such a contribution claim by the brand-name manufacturer against the generic maker.

These sorts of questions would seem likely to make—and probably should make—most state courts disinclined to use the common law as a vehicle for allowing generic users to pursue claims against brand-name manufacturers. The questions also may be ones that lend themselves better to legislative action.<sup>604</sup> If a state legislature were to consider enacting a statute that authorized harmed generic users to take legal action against brand-name manufacturers, it not only could debate the fundamental question of whether such a claim should be recognized but also could consider related questions regarding whether a contribution claim of the sort noted above should be recognized. Of course, a state statute along those lines would not eliminate possible preemption concerns under *Mensing-Bartlett*, but a legislative determination of policy priorities regarding the imposition of liability in this context would seem preferable to a purely judicial determination.

## V. CONCLUSION

In the *PLIVA, Inc. v. Mensing* and *Mutual Pharmaceutical Co. v. Bartlett* decisions, the Supreme Court ruled that federal law preempts consumers' failure-to-warn-and design-defect claims against the generic manufacturers whose drugs harmed

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603. See *supra* text accompanying notes 162–65, 185–95.

604. See *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 407 (6th Cir. 2013); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1253 (11th Cir. 2013).



them.<sup>605</sup> The Court's earlier decision in *Wyeth v. Levine*, however, permits such claims to go forward if the plaintiff experienced harm as a result of taking the brand-name medication as opposed to its generic equivalent.<sup>606</sup> After *Mensing* and *Bartlett*, then, whether patients harmed by a prescription drug can pursue tort claims against the drug's manufacturer depends largely upon a happenstance: whether the pharmacist who filled the patient's prescription dispensed the brand-name medication or, instead, a generic equivalent. The Court wrongly blamed Congress for this "unfortunate hand" dealt to consumers harmed by generics, when it was the Court's strained application of preemption principles that served as the real culprit. But lower federal and state courts—and, of course, harmed consumers—are stuck with the Court's rulings. Congressional action to remedy the *Mensing-Bartlett* "unfortunate hand"<sup>607</sup> is exceedingly unlikely. A potentially promising regulatory proposal floated by the FDA has become long-stalled, with its prospects of progressing to final-rule stage seeming to dim with age.<sup>608</sup>

The lower federal courts have interpreted *Mensing* and *Bartlett* broadly and have ruled, accordingly, that nearly all state-law-based claims by harmed consumers against generic manufacturers are preempted or otherwise ineligible to go forward. State courts, on the other hand, have shown significantly greater tendencies to resist an overly broad reading of *Mensing* and *Bartlett* and to identify ways of respecting those decisions while carving out room for certain state-law-based claims against generic manufacturers. As this Article has explained, the state court resistance to the *Mensing-Bartlett* steamroller has yielded well-reasoned approaches applicable to certain claims against generic manufacturers, along with others—such as permitting consumers harmed by generics to sue the relevant brand-name manufacturer—that are well-meaning but inadvisable. Going forward, state courts potentially interested in lessening the effect of the *Mensing-Bartlett* unfortunate hand should not be quick to conclude that the answer is to recognize claims by

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605. See *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

606. See *Wyeth v. Levine*, 555 U.S. 555 (2009).

607. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2581 (2011).

608. See *supra* notes 234, 268.

generic users against brand-name manufacturers. Rather, the better approach is to consider, as seen in various state court decisions analyzed above, sensible ways in which certain claims against the relevant generic manufacturers can be held to escape the seemingly broad preemptive sweep of the Supreme Court's decisions.

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