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## Duty of “Sameness”?: *Bartlett* Preserves Generic Drug Consumers’ Design Defect Claims

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# DUTY OF “SAMENESS”?: *BARTLETT* PRESERVES GENERIC DRUG CONSUMERS’ DESIGN DEFECT CLAIMS

**Abstract:** On May 2, 2012, the U.S. Court of Appeals for the First Circuit held in *Bartlett v. Mutual Pharmaceutical Co.* that the Federal Food, Drug, and Cosmetic Act (FDCA) does not preempt design defect claims against generic manufacturers. The court reasoned that, by not manufacturing the drug, a generic manufacturer could avoid state design defect liability without violating the federal requirement that a generic drug remain “the same” as a listed brand-name drug. This Comment argues that, in so holding, the First Circuit misconstrued Supreme Court precedent and contravened the objectives of the Hatch-Waxman Amendments. It further argues that, on review, the Supreme Court should hold that the FDCA preempts design defect claims against generic manufacturers. Finally this Comment proposes that Congress enact a federal damages remedy to give injured consumers some relief.

## INTRODUCTION

The Federal Food, Drug, and Cosmetic Act (FDCA) requires that the U.S. Food and Drug Administration (FDA) deem all drugs “safe” and “effective” before they are marketed for sale.<sup>1</sup> Whereas the FDA drug approval process is lengthy and rigorous, the Hatch-Waxman Amendments established an abbreviated process for generic versions of FDA-approved drugs.<sup>2</sup> The abbreviated process aims to ensure that prescription drugs remain accessible to consumers without compromising drug safety and effectiveness.<sup>3</sup> Congress struck a balance between these competing goals by implementing a “sameness” requirement.<sup>4</sup>

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<sup>1</sup> See Federal Food, Drug, and Cosmetic Act § 505, 21 U.S.C. § 355(b)(1) (2006 & Supp. IV 2010).

<sup>2</sup> See Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments), Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1585–92 (codified at 21 U.S.C. § 355(j) (2006 & Supp. IV 2010)).

<sup>3</sup> See 21 U.S.C. § 355(j) (2) (C) (i).

<sup>4</sup> See *id.* § 355(j) (2) (A). Under the abbreviated approval process, a generic manufacturer must show that the new drug is the same as a listed drug in terms of its active ingredients, dosage, strength, route of administration, and label to satisfy the “sameness” requirement. See *id.*

It is an open question whether the Hatch-Waxman Amendments' "sameness" requirement preempts state law design defect claims asserted against generic manufacturers.<sup>5</sup> In 2011, the U.S. Supreme Court held that this "duty of sameness" preempts state law failure-to-warn claims against generic manufacturers.<sup>6</sup> The Court, however, did not address whether the FDCA would also preempt other state law tort claims.<sup>7</sup>

In 2012, in *Bartlett v. Mutual Pharmaceutical Co.*, the U.S. Court of Appeals for the First Circuit became the first federal appeals court to address whether the FDCA preempts design defect claims asserted against generic manufacturers.<sup>8</sup> The court held that, despite the federal requirement that generic drugs remain the same as their FDA-approved brand-name counterparts, design defect claims against generic manufacturers are not preempted.<sup>9</sup> According to the court, a generic manufacturer could comply with both state and federal law regarding drug design if it refrains from making the drug.<sup>10</sup>

The First Circuit's reasoning, however, sharply diverged from the rationale of many district courts that have addressed this issue.<sup>11</sup> These district courts have concluded that design defect claims are preempted by the FDCA because compliance with both state and federal law is impossible.<sup>12</sup> The desire to preserve an injured consumer's only means of

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<sup>5</sup> See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577 (2011) (internal quotation marks omitted). A design defect claim is a state tort cause of action asserted against a manufacturer when a drug is allegedly sold in a defective condition (i.e., its foreseeable risks outweigh its benefits). See *RESTATEMENT (THIRD) OF TORTS: PROD. LIAB.* § 6(c) (1998).

<sup>6</sup> *Mensing*, 131 S. Ct. at 2575, 2581. A failure-to-warn claim is a state tort cause of action asserted against a manufacturer that allegedly failed to provide a warning label that "renders [a drug] reasonably safe." See *id.* at 2572-73; *RESTATEMENT (THIRD) OF TORTS: PROD. LIAB.* § 6(d) (1998).

<sup>7</sup> See *Mensing*, 131 S. Ct. at 2581.

<sup>8</sup> See *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 36 (1st Cir. 2012), *cert. granted*, 133 S. Ct. 694 (U.S. Nov. 30, 2012) (No. 12-142).

<sup>9</sup> See *id.* at 37-38.

<sup>10</sup> See *id.* at 37.

<sup>11</sup> See, e.g., *Aucoin v. Amneal Pharm., L.L.C.*, No. 11-1275, 2012 WL 2990697, at \*9 (E.D. La. July 20, 2012); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, No. 2:11-md-2226-DCR, 2012 WL 718618, at \*3 (E.D. Ky. Mar. 5, 2012); *In re Pamidronate Prods. Liab. Litig.*, 842 F. Supp. 2d 479, 484 (E.D.N.Y. 2012); see also *infra* notes 61-70 and accompanying text (discussing the reasoning of these cases).

<sup>12</sup> See *Aucoin*, 2012 WL 2990697, at \*9; *In re Darvocet*, 2012 WL 718618, at \*3; *In re Pamidronate*, 842 F. Supp. 2d at 484. Rejecting the argument that withdrawing a product from the market is a sufficiently meaningful choice to avoid impossibility, these courts reasoned that a generic manufacturer cannot alter a drug's design without violating the federal requirement that its design remain the same as that of its brand-name counterpart. See *Aucoin*, 2012 WL 2990697, at \*9; *In re Darvocet*, 2012 WL 718618, at \*3; *In re Pamidronate*, 842 F. Supp. 2d at 484.

redress motivated the First Circuit's conclusion in *Bartlett*.<sup>13</sup> Indeed, preemption would leave many injured consumers unable to obtain compensation.<sup>14</sup> But preempting these claims ensures that generic drugs remain inexpensive for all consumers.<sup>15</sup> Thus, preempting these claims is preferable.<sup>16</sup>

Part I of this Comment discusses the FDCA's preemptive scope and the *Bartlett* court's holding that preemption does not extend to design defect claims against generic drug manufacturers.<sup>17</sup> Part II addresses alternative interpretations of the federal requirement of "sameness" in the context of design defect claims against generic manufacturers.<sup>18</sup> Finally, Part III argues that the First Circuit's decision misconstrues Supreme Court precedent and contravenes the objectives of the Hatch-Waxman Amendments.<sup>19</sup> Thus, Part III urges the Supreme Court to hold that the FDCA preempts design defect claims against generic drug manufacturers and proposes that Congress enact a federal compensation scheme to provide limited compensatory relief for injured consumers.<sup>20</sup>

## I. THE PREEMPTIVE SCOPE OF THE FDCA

The preemptive scope of the FDCA turns on the interplay between state and federal duties imposed on prescription drug manufacturers.<sup>21</sup> By introducing an abbreviated approval procedure for generic drugs and requiring that a generic drug remain the same as its brand-name counterpart, the Hatch-Waxman Amendments created the potential for conflict between state and federal law.<sup>22</sup> Indeed, the Supreme Court has interpreted the extent to which the FDCA preempts state law tort claims

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<sup>13</sup> See *Bartlett*, 678 F.3d at 38 ("[H]aving lost her warning claim by the mere chance of her drug store's selection of a generic, the Supreme Court might be less ready to deprive *Bartlett* of her remaining avenue of relief.").

<sup>14</sup> See *Mensing*, 131 S. Ct. at 2592 (Sotomayor, J., dissenting); *Bartlett*, 678 F.3d at 38.

<sup>15</sup> See *Mensing*, 131 S. Ct. at 2574, 2582.

<sup>16</sup> See *id.*; *infra* notes 71–92 and accompanying text.

<sup>17</sup> See *infra* notes 21–60 and accompanying text.

<sup>18</sup> See *infra* notes 61–70 and accompanying text.

<sup>19</sup> See *infra* notes 71–92 and accompanying text.

<sup>20</sup> See *infra* notes 86–92 and accompanying text.

<sup>21</sup> See *Mensing*, 131 S. Ct. at 2577. For example, in 2011, in *PLIVA, Inc. v. Mensing*, the U.S. Supreme Court held that the FDCA preempted failure-to-warn claims against generic drug manufacturers because state tort law required a generic manufacturer to strengthen its warning label to sufficiently warn consumers of the risks, but federal law prohibited these manufacturers from making unilateral changes. See *id.*

<sup>22</sup> See *id.* at 2582.

against drug manufacturers.<sup>23</sup> The Court, however, has not yet articulated the FDCA's precise preemptive scope.<sup>24</sup> Section A discusses the "duty of sameness" imposed on generic manufacturers and how this duty may interact with state law duties to alter a drug.<sup>25</sup> Section B explores the First Circuit's *Bartlett* decision in light of the Supreme Court's recent preemption jurisprudence.<sup>26</sup>

#### A. Duty of "Sameness": The Hatch-Waxman Amendments to the FDCA

In 1984, the Hatch-Waxman Amendments introduced an abbreviated new drug application ("ANDA") procedure for FDA approval of generic drugs shown to be "safe" and "effective."<sup>27</sup> Generic manufacturers that utilize this process have an "ongoing federal duty of sameness" that requires that a generic drug remain the same as its brand-name counterpart.<sup>28</sup> To submit a valid ANDA, a manufacturer must show that the generic drug is the same as its brand-name counterpart in terms of its active ingredients, dosage, strength, route of administration, and label.<sup>29</sup> This abbreviated procedure enables generic manufacturers to develop new "copycat drugs" inexpensively.<sup>30</sup> The ANDA process, therefore, is intended to reduce medical costs by increasing the production and consumption of generic drugs.<sup>31</sup> As a result, the consumption of generic drugs has become much more widespread.<sup>32</sup>

The ANDA procedure, and its corresponding federal "sameness" requirement, may conflict with duties imposed by state tort law.<sup>33</sup> A fed-

<sup>23</sup> *Mensing*, 131 S. Ct. at 2581; *Wyeth v. Levine*, 555 U.S. 555, 581 (2009).

<sup>24</sup> *See Mensing*, 131 S. Ct. at 2581; *Levine*, 555 U.S. at 581; *Bartlett*, 678 F.3d at 37.

<sup>25</sup> *See infra* notes 27–37 and accompanying text.

<sup>26</sup> *See infra* notes 38–60 and accompanying text.

<sup>27</sup> *See* 21 U.S.C. § 355(j)(2)(A), (j)(2)(C)(i) (2006 & Supp. IV 2010). The process for approving new brand-name drugs is much more extensive. *See id.* § 355(b)(1).

<sup>28</sup> *See Mensing*, 131 S. Ct. at 2575 (internal quotation marks omitted).

<sup>29</sup> 21 U.S.C. § 355(j)(2)(A). These requirements ensure that the ANDA procedure does not compromise the FDA's requirement that any marketed drug be "safe" and "effective." *See id.* § 355(b)(1)(A), (j)(2)(C)(i).

<sup>30</sup> *See Bartlett*, 678 F.3d at 37. The sale of generic drugs is permitted only after the patent on the brand-name drug has expired. *See Mensing*, 131 S. Ct. at 2581 n.9.

<sup>31</sup> *See Bartlett*, 678 F.3d at 37; *see also Mensing*, 131 S. Ct. at 2583 (Sotomayor, J., dissenting) (explaining that the ANDA procedure eliminates "the need for generic manufacturers to prove . . . safety and efficacy independently"); H.R. REP. NO. 98-857, at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647 ("The purpose . . . is to make available more low cost generic drugs by establishing a generic drug approval procedure . . .").

<sup>32</sup> *See Mensing*, 131 S. Ct. at 2584 (Sotomayor, J., dissenting) (noting that the consumption of generic drugs has grown from approximately 19% of the drugs sold in 1984 to 75% in 2009).

<sup>33</sup> *See id.* at 2582 (majority opinion).

eral preemption analysis traditionally begins with a presumption against preemption and assesses whether Congress manifested its intent to preempt state law.<sup>34</sup> If this intention is not expressly indicated in the text of a statute, intent can be implied when a federal statute directly conflicts with state law, rendering compliance with both requirements impossible.<sup>35</sup> Given that a generic drug must remain the same as its brand-name counterpart, it would be impossible (without choosing to not make a drug) for a generic manufacturer to comply with both this ongoing federal “sameness” requirement and the state law duty to alter a drug to avoid strict liability to injured consumers.<sup>36</sup> Although this conflict of duties for generic manufacturers suggests that federal preemption may be implied, courts have disagreed on the extent to which the FDCA preempts state law tort claims.<sup>37</sup>

### B. *The First Circuit Limits the FDCA's Preemptive Scope in Bartlett*

In *Bartlett*, the First Circuit considered whether the FDCA preempts design defect claims against generic manufacturers.<sup>38</sup> Karen Bartlett asserted a design defect claim against the manufacturer, Mutual Pharmaceutical Company (“Mutual”), after she ingested generic sulindac for her shoulder pain, experienced severe skin deterioration, and spent seventy days in the hospital.<sup>39</sup> Ms. Bartlett was diagnosed with Stevens-Johnson syndrome (“SJS”), a hypersensitivity reaction, which

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<sup>34</sup> See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). These two components (i.e., presumption and intent) are the cornerstones of the preemption analysis. See *Levine*, 555 U.S. at 565 (citing *Retail Clerks Int'l Ass'n v. Schermerhorn*, 375 U.S. 96, 103 (1963)). This analysis is grounded in the notion of dual sovereignty embodied by the federal system. See *Lohr*, 518 U.S. at 485.

<sup>35</sup> *Mensing*, 131 S. Ct. at 2577 & n.5. Intent to preempt can also be implied when a statute completely occupies the regulated field or when state law interferes with the purposes and objectives embodied by the federal statute. See *Lohr*, 518 U.S. at 507–08.

<sup>36</sup> See *Mensing*, 131 S. Ct. at 2577; *Aucoin*, 2012 WL 2990697, at \*9.

<sup>37</sup> Compare *Mensing*, 131 S. Ct. at 2581 (holding that the FDCA preempts failure-to-warn claims because it is impossible for a manufacturer to comply with both a state law duty to strengthen its warning label and a federal requirement that the label remain the same), and *Aucoin*, 2012 WL 2990697, at \*9 (finding that the FDCA preempts design defect claims against generic manufacturers), with *Bartlett*, 678 F.3d at 38 (concluding that the FDCA does not preempt design defect claims because a manufacturer can comply with both state and federal requirements by not manufacturing the drug).

<sup>38</sup> *Bartlett*, 678 F.3d at 35–36.

<sup>39</sup> *Id.* at 34. Although her doctor prescribed brand-name Clinoril for her pain, a New Hampshire pharmacy filled her prescription with the generic version of sulindac pursuant to the state's generic drug substitution law. See *id.*; see also N.H. REV. STAT. ANN. § 318:47-d (2008).

progressed to potentially fatal toxic epidermal necrolysis (“TEN”).<sup>40</sup> These conditions were known risks of ingesting sulindac.<sup>41</sup> Due to the drug’s propensity to cause these conditions, Ms. Bartlett sued Mutual in 2008 for, among other things, defective design.<sup>42</sup> After Ms. Bartlett prevailed at trial, Mutual appealed to the First Circuit to determine whether Ms. Bartlett’s claim was preempted by federal law.<sup>43</sup>

Because the First Circuit is the only federal appeals court that has directly addressed whether the FDCA preempts design defect claims against generic manufacturers, and the Supreme Court has not yet ruled on preemption of design defect claims, the *Bartlett* court looked to two Supreme Court cases in the failure-to-warn context for guidance.<sup>44</sup> In 2009, in *Wyeth v. Levine*, and in 2011, in *PLIVA, Inc. v. Mensing*, the Court addressed federal preemption of failure-to-warn claims.<sup>45</sup> Together, these decisions establish that the FDCA preempts failure-to-warn claims against generic, but not brand-name, manufacturers.<sup>46</sup>

In *Levine*, the Supreme Court held that the FDCA does not preempt state law failure-to-warn claims against brand-name manufacturers.<sup>47</sup> Beginning with the traditional presumption against preemption, the Court observed that a brand-name manufacturer is not bound by a federal “sameness” requirement.<sup>48</sup> The Court thus concluded that a brand-name manufacturer can simultaneously comply with state and federal labeling duties by strengthening its label.<sup>49</sup> Because the FDA had traditionally viewed state tort law as “a complementary form of drug regulation,” the Court reasoned that complying with the state duty to include a stronger label to avoid tort liability would not obstruct the purpose of the FDCA.<sup>50</sup> Finally, the Court reasoned that the lack of

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<sup>40</sup> See *Bartlett*, 678 F.3d at 34.

<sup>41</sup> *Bartlett v. Mut. Pharm. Co. (Bartlett I)*, 731 F. Supp. 2d 135, 142 (D.N.H. 2010).

<sup>42</sup> *Bartlett v. Mut. Pharm. Co. (Bartlett II)*, 760 F. Supp. 2d 220, 228–29, 246 (D.N.H. 2011). Mutual removed all of Ms. Bartlett’s common law tort claims from a New Hampshire trial court to the U.S. District Court for the District of New Hampshire. *Bartlett I*, 731 F. Supp. 2d at 141. The district court found that the FDCA did not preempt Ms. Bartlett’s design defect claim and denied Mutual’s motion for judgment on the pleadings. *Id.*

<sup>43</sup> *Bartlett*, 678 F.3d at 35. The First Circuit also considered the merits of Ms. Bartlett’s design defect claim, specifically whether a propensity to cause SJS/TEN is a sufficient defect to assert a claim, even though sulindac is a one molecule drug that lacks an alternative design. *Id.* at 36.

<sup>44</sup> *Id.* at 37–38.

<sup>45</sup> See *Mensing*, 131 S. Ct. at 2577; *Levine*, 555 U.S. at 565.

<sup>46</sup> See *Mensing*, 131 S. Ct. at 2581; *Levine*, 555 U.S. at 581.

<sup>47</sup> *Levine*, 555 U.S. at 581.

<sup>48</sup> See *id.* at 565, 568.

<sup>49</sup> See *id.* at 573.

<sup>50</sup> See *id.* at 575, 578.

an express preemption provision in the statute suggested that Congress did not intend to preempt state law tort claims against brand-name drug manufacturers.<sup>51</sup>

In *Mensing*, however, the Court did not extend its rationale in *Levine* to the generic drug context.<sup>52</sup> Instead, it held that failure-to-warn claims against generic manufacturers are preempted.<sup>53</sup> Justice Clarence Thomas, writing for the majority, reasoned that, unlike the duties of brand-name manufacturers, the distinct state and federal obligations imposed on generic manufacturers directly conflict.<sup>54</sup> The Court observed that generic manufacturers cannot independently strengthen a warning label as required to avoid tort liability without violating the “ongoing federal duty of sameness.”<sup>55</sup> Consequently, the Court concluded that the FDCA preempts failure-to-warn claims asserted against generic manufacturers.<sup>56</sup>

Relying on the Supreme Court’s reasoning in *Levine* and distinguishing *Mensing*, the First Circuit held in *Bartlett* that the FDCA does not preempt design defect claims against generic manufacturers on three grounds.<sup>57</sup> First, the court concluded that *Levine* articulated a general rule that the FDCA does not preempt state law tort claims against drug manufacturers.<sup>58</sup> Second, the court distinguished *Mensing* because it is possible for a generic manufacturer to avoid design defect liability if it refrains from manufacturing the drug.<sup>59</sup> Third, preserving

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<sup>51</sup> See *id.*; cf. Federal Food, Drug, and Cosmetic Act § 521, 21 U.S.C. § 360k(a) (2006) (expressly preempting any state requirement “different from, or in addition to, any [FDCA] requirement” for medical devices).

<sup>52</sup> See *Mensing*, 131 S. Ct. at 2577.

<sup>53</sup> See *id.* at 2581.

<sup>54</sup> See *id.* at 2574–75.

<sup>55</sup> See *id.* at 2575, 2581 (internal quotation marks omitted). Approval through the ANDA procedure requires that the generic manufacturer include a label that is “the same” as the brand-name drug’s label unless the manufacturer seeks the assistance of the FDA to change the label. See *id.* at 2575–76.

<sup>56</sup> See *id.* at 2579, 2581.

<sup>57</sup> See *Bartlett*, 678 F.3d at 38. Recently, a few district courts have cited approvingly the First Circuit’s rationale in *Bartlett*. See *Caouette v. Bristol-Myers Squibb Co.*, No. C-12-1814 EMC, 2012 WL 3283858, at \*4 (N.D. Cal. Aug. 10, 2012) (“[I]t is not obvious that *Mensing* impossibility preemption would apply to a design defect claim.”); *Halperin v. Merck, Sharpe & Dohme Corp.*, No. 11 C 9076, 2012 WL 1204728, at \*3 (N.D. Ill. Apr. 10, 2012) (“Neither the *Mensing* opinion, nor the underlying proceedings in the Fifth and Eighth Circuits, directly address strict liability design defect claims.”).

<sup>58</sup> See *Bartlett*, 678 F.3d at 37–38.

<sup>59</sup> See *id.* at 38. According to the court, the availability of this choice distinguished design defect claims from failure-to-warn claims because once a drug is manufactured, “the generic maker has no choice as to label.” See *id.* Although a manufacturer could theoretically avoid a failure-to-warn claim by not manufacturing a drug, state law does not require



injured consumers' ability to sue generic manufacturers drove the ultimate conclusion that the FDCA does not preempt design defect claims.<sup>60</sup>

## II. DUTY OF "SAMENESS" AND IMPOSSIBILITY: ALTERNATIVE APPROACHES TO DESIGN DEFECT PREEMPTION

Although the First Circuit is the only federal appeals court to directly consider the issue, many federal district courts have found, contrary to *Bartlett's* holding, that the FDCA does preempt design defect claims against generic manufacturers.<sup>61</sup> In part, this disagreement arises from differing interpretations of "impossibility" when assessing a generic manufacturer's ability to avoid state tort liability while complying with the federal "sameness" requirement.<sup>62</sup> The fact that generic drug manufacturers could comply with both state and federal requirements by not making a drug drove the First Circuit's conclusion that design defect claims are not preempted.<sup>63</sup>

In contrast, some district courts have rejected this option as a false choice and consequently have concluded that design defect claims

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a manufacturer to do so. *See* Brief for Respondent in Opposition at 26, *Mut. Pharm. Co. v. Bartlett*, No. 12-142 (U.S. Oct. 31, 2012). Thus, as Ms. Bartlett contends, complying with both state and federal law is possible in the design defect context because state law does not obligate a manufacturer to refrain from making a drug. *See id.*

<sup>60</sup> *See Bartlett*, 678 F.3d at 38.

<sup>61</sup> *See, e.g., Aucoin v. Amneal Pharm., L.L.C.*, No. 11-1275, 2012 WL 2990697, at \*9 (E.D. La. July 20, 2012) (finding that the FDCA preempts design defect claims against generic manufacturers); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, No. 2:11-md-2226-DCR, 2012 WL 718618, at \*3 (E.D. Ky. Mar. 5, 2012) (same); *In re Pamidronate Prods. Liab. Litig.*, 842 F. Supp. 2d 479, 484 (E.D.N.Y. 2012) (same). Although other federal appeals courts have addressed federal preemption after the Supreme Court's decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), the rulings are limited to the failure-to-warn context. *See Gaeta v. Perrigo Pharm. Co.*, 469 F. App'x 556, 556 (9th Cir. 2012) (concluding that the FDCA preempts failure-to-warn claims against generic manufacturers), *vacating* 630 F.3d 1225 (9th Cir. 2011); *Mensing v. Wyeth, Inc. (Mensing Order)*, 658 F.3d 867, 867 (8th Cir. 2011) (same), *vacating in relevant part* 588 F.3d 603, 611 (8th Cir. 2009); *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011) (same); *Demahy v. Actavis, Inc.*, 650 F.3d 1045, 1045 (5th Cir. 2011) (same), *reversing* 593 F.3d 428 (5th Cir. 2010).

<sup>62</sup> *Compare Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 38 (1st Cir. 2012), *cert. granted*, 133 S. Ct. 694 (U.S. Nov. 30, 2012) (No. 12-142) (holding no preemption because it was possible to comply with both state and federal law by choosing not to make the drug), *with In re Darvocet*, 2012 WL 718618, at \*3 (finding preemption because "the idea that [the generic manufacturers] should have simply stopped selling [the drug] is an oversimplified solution").

<sup>63</sup> *See Bartlett*, 678 F.3d at 38.

against generic manufacturers are preempted.<sup>64</sup> These district courts have held such claims are preempted because the Supreme Court in *PLIVA, Inc. v. Mensing* impliedly rejected the “failure-to-withdraw” reasoning that the *Bartlett* court relied on to distinguish failure-to-warn claims.<sup>65</sup> Although the Court in *Mensing* did not explicitly ground its decision in the “failure-to-withdraw” rationale,<sup>66</sup> the Eighth Circuit, on remand, vacated the portion of its opinion that relied on this reasoning.<sup>67</sup> Thus, many lower courts continue to hold that refraining from manufacturing a drug is not a sufficient ground to show that a generic manufacturer could independently comply with state law.<sup>68</sup> Instead, the *Mensing* rationale supports preemption of design defect claims because it is otherwise impossible for a generic manufacturer to comply with a state law duty to alter a drug’s design without violating the FDCA.<sup>69</sup> Other district courts omit discussion about “failure-to-withdraw” and have simply found that the Supreme Court’s rationale in *Mensing* applies directly to the defective design context due to the federal “sameness” requirement.<sup>70</sup>

### III. THE BETTER APPROACH: PREEMPTING DESIGN DEFECT CLAIMS AGAINST GENERIC MANUFACTURERS

The First Circuit’s conclusion that the FDCA does not preempt design defect claims against generic manufacturers misconstrues U.S. Supreme Court precedent and contravenes the objectives of the Hatch-Waxman Amendments by failing to ensure that generic drugs remain accessible for consumers.<sup>71</sup> The Supreme Court has granted review of

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<sup>64</sup> See *Aucoin*, 2012 WL 2990697, at \*9; *In re Darvocet*, 2012 WL 718618, at \*3; *In re Pamidronate*, 842 F. Supp. 2d at 484.

<sup>65</sup> See *Mensing*, 131 S. Ct. at 2577–78; *Aucoin*, 2012 WL 2990697, at \*8–9; *In re Darvocet*, 2012 WL 718618, at \*3.

<sup>66</sup> See *Mensing*, 131 S. Ct. at 2577, 2581 n.8.

<sup>67</sup> See *Aucoin*, 2012 WL 2990697, at \*8; see also *Mensing Order*, 658 F.3d at 867.

<sup>68</sup> See *Aucoin*, 2012 WL 2990697, at \*9; *In re Darvocet*, 2012 WL 718618, at \*3.

<sup>69</sup> See *Aucoin*, 2012 WL 2990697, at \*9; *In re Darvocet*, 2012 WL 718618, at \*3. *But see supra* note 59 and accompanying text.

<sup>70</sup> See *Lyman v. Pfizer, Inc.*, No. 2:09-cv-262, 2012 WL 368675, at \*4 (D. Vt. Feb. 3, 2012); *In re Pamidronate*, 842 F. Supp. 2d at 484.

<sup>71</sup> Compare 21 U.S.C. § 355(j)(2)(A) (2006 & Supp. IV 2010) (implementing a requirement that an ANDA drug be “the same as” a listed drug to ensure that generic drugs remain affordable without compromising safety), and *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574–75 (2011) (referring to a generic drug manufacturer’s “ongoing federal duty of ‘sameness’”), with *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 38 (1st Cir. 2012) (emphasizing the importance of preserving a cause of action for generic consumers because it is possible for a manufacturer to comply with both state and federal requirements by choosing not to manufacture a drug), *cert. granted*, 133 S. Ct. 694 (U.S. Nov. 30, 2012) (No. 12-142).

the First Circuit's *Bartlett* decision.<sup>72</sup> Although affirming *Bartlett* would preserve a cause of action for generic drug consumers, a conclusion that the FDCA does not preempt these claims would require manufacturers to absorb the costs of inevitable lawsuits, potentially forcing affordable drugs off of the market.<sup>73</sup> Instead, the Supreme Court should hold that the FDCA preempts design defect claims.<sup>74</sup> Congress could then enact a limited compensatory damages remedy to protect consumers injured by generic drugs.<sup>75</sup>

The First Circuit's *Bartlett* decision misconstrues the Supreme Court's decisions in *PLIVA, Inc. v. Mensing* and *Wyeth v. Levine*.<sup>76</sup> The fact that generic drug manufacturers could not comply with both state and federal law by changing their warning labels was central to the Court's holding in *Mensing* that failure-to-warn claims against generic manufacturers are preempted.<sup>77</sup> In *Levine*, however, the Court held that failure-to-warn claims against brand-name manufacturers are not preempted because a brand-name manufacturer can independently strengthen its label, and thereby comply with both state and federal law while continuing to sell its drug.<sup>78</sup> Given that a generic manufacturer is unable to comply with both state and federal requirements while continuing to sell its drug, it is inconsistent with *Levine* and *Mensing* to draw a distinction, as the *Bartlett* court did, between failure-to-warn and design defect claims on the basis of a "choice" to not manufacture a generic drug.<sup>79</sup>

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<sup>72</sup> *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 694 (2012).

<sup>73</sup> See *Wyeth v. Levine*, 555 U.S. 555, 626 (2009) (Alito, J., dissenting) (arguing that a cost-benefit analysis should consider "the interests of all potential users" rather than only those of injured consumers); cf. *Mensing*, 131 S. Ct. at 2592–93 (Sotomayor, J., dissenting) (observing that preemption eliminates a cause of action for many injured consumers).

<sup>74</sup> See *Bartlett*, 678 F.3d at 38 ("Given the widespread use of generic drugs . . . this issue needs a decisive answer from the only court that can supply it."); *infra* notes 76–88 and accompanying text.

<sup>75</sup> See *Mensing*, 131 S. Ct. at 2582 ("Congress and the FDA retain the authority to change the law and regulations if they so desire."); *infra* notes 89–92 and accompanying text.

<sup>76</sup> See *Bartlett*, 678 F.3d at 38 (acknowledging that distinguishing design defect claims from failure-to-warn claims on the basis of a choice not to manufacture a drug is in tension with part of the rationale in *Mensing*); *infra* notes 77–87 and accompanying text.

<sup>77</sup> See *Mensing*, 131 S. Ct. at 2574–75, 2581.

<sup>78</sup> See *Levine*, 555 U.S. at 568, 578; cf. *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009) (reasoning that generic manufacturers "could have simply stopped selling the product" to comply with both state and federal law), *vacated in relevant part by* 658 F.3d 867 (8th Cir. 2011).

<sup>79</sup> See *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, No. 2:11-md-2226-DCR, 2012 WL 718618, at \*3 (E.D. Ky. Mar. 5, 2012) (explaining that a generic manufacturer's ability to stop selling a drug is an insufficient choice to distinguish *Mensing* or to justify a finding that design defect claims are not preempted); cf. *Bartlett*, 678 F.3d at 38

Moreover, allowing design defect claims against generic manufacturers, as the First Circuit did in *Bartlett*, contravenes the Hatch-Waxman Amendments' twin goals of providing inexpensive and accessible drugs for consumers without compromising drug safety and effectiveness.<sup>80</sup> That is, allowing injured consumers to assert design defect claims against manufacturers of a generic drug that the FDA deemed "safe" and "effective" undercuts these congressional goals.<sup>81</sup> The risk of strict liability, and perhaps excessive compensatory damages, requires a generic manufacturer to decide whether to produce a drug and absorb the costs of inevitable tort liability or to remove its drug from the market altogether.<sup>82</sup>

Preempting these claims, on the other hand, leaves existing safety and effectiveness protections intact while furthering Congress's goal of providing inexpensive drugs for consumers.<sup>83</sup> First, because an approved generic drug must remain "the same" as a listed brand-name drug, consumers are protected by the extensive initial FDA approval process that requires documentation of the drug's safety and effectiveness.<sup>84</sup> Second, eliminating excessive tort liability costs will ensure that

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(noting that not making a drug would avoid design defect claims as well as failure-to-warn claims).

<sup>80</sup> See *Mensing*, 131 S. Ct. at 2574, 2577 (explaining that the Hatch-Waxman Amendments enable inexpensive drug production); see also H.R. REP. NO. 98-857, at 14–15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647 ("The purpose . . . is to make available more low cost generic drugs by establishing a generic drug approval procedure"); cf. *Bartlett*, 678 F.3d at 37 ("There is no doubt that Congress wanted to reduce medical costs by spurring generic copycat drugs . . .").

<sup>81</sup> See *Bartlett*, 678 F.3d at 37–38. Allowing design defect claims undercuts these goals by empowering a jury to analyze the risks and benefits of a generic drug, and thereby to second-guess the FDA's findings. See *id.* Moreover, the fact that a state jury can contravene a federal agency's risk-benefit analysis likely violates the Supremacy Clause. See U.S. CONST. art. VI, cl. 2 ("[T]he Laws of the United States . . . shall be the supreme Law of the Land . . ."); see also *Reigel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008) ("Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard is less deserving of preservation. . . . A jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.").

<sup>82</sup> See *Bartlett*, 678 F.3d at 38.

<sup>83</sup> See *infra* notes 84–85 and accompanying text.

<sup>84</sup> See 21 U.S.C. § 355 (b)(1)(A) (2006 & Supp. IV 2010) (instructing new drug applicants to submit investigation reports "to show whether or not such drug is safe for use and . . . effective in use"); *id.* § 355(j)(2)(A) (requiring a manufacturer to show that a generic drug is the same as an already approved listed drug); *supra* notes 27–29 and accompanying text.

the ANDA approval process remains inexpensive in practice, rather than only in theory.<sup>85</sup>

Therefore, upon review, the Supreme Court should hold that the FDCA preempts design defect claims.<sup>86</sup> Doing so will ensure that generic drugs remain accessible to consumers.<sup>87</sup> To address the First Circuit's concern that this result fails adequately to protect the interests of consumers injured by generic drugs, however, Congress must act.<sup>88</sup>

Congress should enact a limited compensatory damages remedy to provide injured generic drug consumers with a means to obtain compensation.<sup>89</sup> A federal statutory remedy that limits available compensatory relief for injured consumers and excludes punitive damages will compensate consumers while increasing the availability of beneficial and inexpensive generic drugs.<sup>90</sup> Given the market dominance of generic drugs, a federal remedy is necessary to protect the consumers

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<sup>85</sup> See *Mensing*, 131 S. Ct. at 2574 (citing 21 U.S.C. § 355(j)(2)(A)) (explaining that the ANDA procedure does not require a manufacturer to conduct “the clinical trials already performed,” which enables inexpensive generic drug production); H.R. REP. NO. 98-857, at 14–15, reprinted in 1984 U.S.C.C.A.N. 2647, 2647.

<sup>86</sup> See *supra* notes 76–85 and accompanying text.

<sup>87</sup> See *Levine*, 555 U.S. at 626 (Alito, J., dissenting) (arguing that, unlike juries, the FDA's drug-approval determinations consider “the interests of all potential users”). Preemption is particularly important to protect consumers who benefit from generic drugs that lack an alternative design because the risk of design defect liability could result in the drug's removal from the market. See *id.*; *Bartlett*, 678 F.3d at 37 (observing that Mutual “cannot legally make sulindac in another composition”).

<sup>88</sup> See *Bartlett*, 678 F.3d at 38 (“[H]aving lost her warning claim by the mere chance of her drug store's selection of a generic, the Supreme Court might be less ready to deprive Bartlett of her remaining avenue of relief.”); cf. *Mensing*, 131 S. Ct. at 2582 (“Congress and the FDA retain the authority to change the law and regulations if they so desire.”).

<sup>89</sup> See *Mensing*, 131 S. Ct. at 2582; see also Peter H. Schuck, *FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot*, 13 ROGER WILLIAMS U. L. REV. 73, 113–14 (2008) (arguing that the FDA and Congress are better positioned to determine liability risks than “a multitude of lay state court juries [that] wield different and notoriously opaque standards”). Notably, the FDCA as originally introduced “would have provided a federal cause of action for damages for injured consumers.” See *Levine*, 555 U.S. at 574 n.7 (citing H.R. 6110, 73d Cong. § 25 (1st Sess. 1933)). Moreover, the feasibility of a compensatory damages remedy is reinforced by the success of the federal no-fault compensation program for victims of vaccine injuries. See *Bruesewitz v. Wyeth*, 131 S. Ct. 1068, 1099–1100 (2011) (explaining that, by implementing this program, Congress intended to establish a scheme that would compensate victims while relieving the financial burden on vaccine manufacturers).

<sup>90</sup> See *Levine*, 555 U.S. at 626 (Alito, J., dissenting) (emphasizing “the interests of all potential users” rather than only those of injured consumers); H.R. REP. NO. 98-857 (1984), at 14–15, reprinted in 1984 U.S.C.C.A.N. 2647, 2647. But see Allison Stoddart, Note, *Missing After Mensing: A Remedy for Generic Drug Consumers*, 53 B.C. L. REV. 1967, 1997–98, 2000 (2012) (arguing that the FDA should amend its regulations to allow a generic manufacturer unilaterally to strengthen its label, even if doing so increases liability costs).

who will inevitably be injured by them.<sup>91</sup> Unlike state tort liability, a federal statutory remedy that provides limited compensatory relief will adequately compensate consumers without forcing affordable, beneficial drugs off of the market.<sup>92</sup>

#### CONCLUSION

Generic drug manufacturers must be shielded from the risk of excessive state tort liability. In *Bartlett*, the First Circuit concluded that the FDCA does not preempt design defect claims against generic manufacturers, reasoning that it is possible to comply with both state and federal requirements by choosing not to make a drug. Although this holding preserves a cause of action for injured consumers, it contravenes the goals of the Hatch-Waxman Amendments by increasing the costs of generic drug production to the detriment of consumers who benefit from the availability of inexpensive alternatives to brand-name drugs.

The U.S. Supreme Court, which has granted review of the First Circuit's decision in *Bartlett*, should extend *PLIVA, Inc. v. Mensing* to preempt design defect claims asserted against generic manufacturers. At the same time, to protect the interests of all generic drug consumers, Congress should expressly displace state tort liability with a federal remedy enabling limited compensatory relief under the FDCA. A federal damages remedy will protect consumers who benefit from generic drugs while compensating the injured.

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<sup>91</sup> See *Mensing*, 131 S. Ct. at 2582 (observing that "it is the special, and different, regulation of generic drugs that . . . [brought more generic drugs] more quickly and cheaply to the market"); cf. *id.* at 2583, 2592–93 (Sotomayor, J., dissenting) (arguing that, due to generic substitution laws, a consumer's ability to sue now turns on the "happenstance of whether her pharmacist filled her prescription with a brand-name or generic drug").

<sup>92</sup> See *Levine*, 555 U.S. at 626 (Alito, J., dissenting); H.R. REP. NO. 98-857, at 14–15, reprinted in 1984 U.S.C.C.A.N. 2647, 2647.