

# BEYOND PREEMPTION OF GENERIC DRUG CLAIMS

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*Recent research indicates that the current cost of generic medications in the United States is the highest in history. Many patients are no longer able to afford life saving medications that were once affordable only five years ago. Concurrent to the rising prices of generic drugs, pharmaceutical companies have lauded preemption as a necessary and viable solution to combat the increasing prices. Two recent Supreme Court decisions, *PLIVA, Inc. v. Mensing* and *Mutual Pharmaceutical Co. v. Bartlett*, have agreed with this logic, and have attempted to pervert the Hatch-Waxman Act, and its corresponding ANDA approval process to shield generic drug manufacturers from liability. Not only has this immunity done nothing to combat the price of drugs, but it has also decreased incentives for generic manufacturers from engaging in thorough pre-market testing and studies, putting consumers of generic drugs at an increased risk of injury.*

*Mensing and Bartlett have impressed upon the courts a strong directive to preempt any product liability claims made against a generic manufacturer. However, by shielding generic drug manufacturers from liability, *Mensing* and *Bartlett* have placed consumers, especially low income consumers, at an increased risk of injury. Additionally, *Mensing* and *Bartlett* may ultimately hurt, rather than help the generic drug industry. While there has been an effort to introduce regulatory action that minimizes the impact of the decisions, the FDA seems largely powerless for the time being to implement any*

*regulatory changes. Plaintiff attorneys have also met limited success in attempting to circumvent, reframe or distinguish the holdings in Mensing and Bartlett. However, as long as regulatory change is stagnant, expect plaintiff attorneys to continue to try and poke holes in holdings in Mensing and Bartlett with limited success in narrow circumstances.*

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Recent research indicates that the current cost of generic medications in the United States is the highest in history.<sup>1</sup> Many patients are no longer able to afford life saving medications that were once affordable only five years ago.<sup>2</sup> Concurrent to the rising prices of generic drugs, pharmaceutical companies have lauded preemption as a necessary and viable solution to combat the increasing prices.<sup>3</sup> Two recent Supreme Court decisions, *PLIVA, Inc. v. Mensing*<sup>4</sup> and *Mutual Pharmaceutical Co. v. Bartlett*,<sup>5</sup> have agreed with this logic, and have attempted to pervert the Hatch-Waxman Act, and its corresponding ANDA approval process to shield generic drug manufacturers from liability. Not only has this immunity done nothing to combat the price of drugs, but it has also decreased incentives for generic manufacturers from engaging in thorough pre-market testing and studies, putting consumers of generic drugs at an increased risk of injury.<sup>6</sup>

This paper proceeds in six parts. Part I provides background of preemption as well as the FDA's "NDA" and "ANDA" approval processes for generic drugs. Part II explores the preemption analysis of generic drug claims made in three recent Supreme Court decisions. Part III explores in-depth the damaging effects that these decisions have on the safety of consumers, and the long-term vitality of the generic drug industry. Having established that preemption of generic drug claims is undesirable, Part IV identifies recent attempts by the FDA to introduce regulatory changes that eliminate preemption of generic drugs. Part V explores cutting edge strategies that have been used by plaintiff lawyers to circumvent, reframe and distinguish the Supreme Court decisions. Part VI concludes.

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1. See Diana J. Masters, *Mutual Pharmaceutical Co. v. Bartlett and the Demise of Recovery for Consumers of Generic Drugs*, 60 LOY. L. REV. 399, 422 (2014).

2. *Id.*

3. *Id.*

4. 131 S. Ct. 2567 (2011).

5. 133 S. Ct. 2466 (2013).

6. Masters, *supra* note 1, at 422.

## I. PREEMPTION AND ITS APPLICATION TO FDCA

a. *Preemption*

The Supremacy Clause of the United States Constitution states that federal law “shall be the supreme law of the land.”<sup>7</sup> Federal law invalidates state laws that “interfere with, or are contrary to federal law.”<sup>8</sup> The Supreme Court has established two categories of preemption of state law, express preemption and implied preemption.<sup>9</sup> The section of the Food, Drug and Cosmetic Act (FDCA),<sup>10</sup> which governs prescription drugs, does not have an explicit preemption provision.<sup>11</sup> Therefore, state tort claims will be preempted under the FDCA only if it can be shown that Congress implicitly intended to preempt these types of state law claims.<sup>12</sup> While the Supreme Court has historically abided by a strong presumption against implied preemption,<sup>13</sup> the Court has displayed a growing willingness to reverse their traditional preemption doctrine.<sup>14</sup> This is especially true in their decisions relating to the FDCA and the preemption of claims made against manufacturers of generic drugs.<sup>15</sup>

b. *“NDA” Approval Process*

The Food, Drug and Cosmetic Act requires that the FDA approve brand name and generic drugs before they are sold to the public.<sup>16</sup> Under the FDCA, a company that is seeking to gain FDA approval for a new drug must first file an investigational new drug application, or an “NDA” with the FDA.<sup>17</sup> Estimates suggest that “for every five thousand NDA’s screened, only five

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

8. *Hillsborough Cty. v. Automated Med. Labs. Inc.*, 471 U.S. 707, 712–13 (1985).

9. See Lesley A. Stout, *Making Changes: Generic Drug Labeling and the Case Against Federal Preemption*, 98 KY. L.J. 623, 630 (2010).

10. Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C. § 301-399d (2012)).

11. Stout, *supra* note 9, at 630.

12. *Id.*

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

14. See Stout, *supra* note 9, at 633-34.

15. See Richard L. Cupp, Jr., *Preemption’s Rise (and Bit of a Fall) as Products Liability Reform: Wyeth, Riegel, Altria, and the Restatement (Third)’s Prescription Product Design Defect Standard*, 74 BROOK. L. REV. 727, 746 (2009).

16. See 21 U.S.C.A. § 355 (West 2012).

17. See 21 U.S.C.A. § 355(a)-(i) (West 2012). See generally Jasper L. Tran, *Timing Matters: Prior Art’s Age Infers Patent Nonobviousness*, 50 GONZ. L. REV. 189, 207–08 (2015) for a discussion on pharmaceutical litigation.

will proceed to clinical testing, and only one will eventually be approved by the FDA.”<sup>18</sup> The NDA process is an extremely expensive and time-consuming process, costing upwards of a billion dollars and up to ten years to complete.<sup>19</sup>

c. “ANDA” Approval Process

In 1984, Congress introduced the Hatch-Waxman Act, which introduced new drug application, “ANDA” for generic drugs seeking to be approved by the FDA.<sup>20</sup> Recognizing a need for cheaper, more available drugs, Congress intended the ANDA process to be a less demanding standard for drugs that are similar to previously approved brand-name drugs.<sup>21</sup> Under the ANDA approval process, a generic manufacturer need only show bioequivalence between a NDA approved drug and the ANDA drug it seeks to have approved.<sup>22</sup> Additionally, the generic drug’s label must be identical to the brand name drug’s label.<sup>23</sup> Any dissimilarity between the two labels will result in the FDA denying a submitted ANDA.<sup>24</sup> A generic manufacturer is also required to timely update its label to reflect any new changes made by the brand-name counterpart.<sup>25</sup> Courts have dubbed these stringent requirements as “the duty sameness.”<sup>26</sup>

## II. “DUTY OF SAMENESS” AS IMPLIED CONFLICT PREEMPTION

Over the past five years, the Supreme Court has addressed whether the ANDA approval process and its corresponding federal “sameness” requirement, conflicts with duties imposed by state tort law.<sup>27</sup> Manufacturers

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18. Veronica S. Jae, *Simplifying FDASIA: The “Fast Track” to Expedited Approval Efficiency*, 66 ADMIN. L. REV. 173 (2014).

19. *Id.* at 177.

20. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as 21 U.S.C. § 301 (2012)). See generally Jasper L. Tran, *Software Patents: A One-Year Review of Alice v. CLS Bank*, 97 J. PAT. & TRADEMARK OFF. SOC’Y 532 (2015) for a discussion on the current patent landscape.

21. Sarah E. Eurek, Comment, *Hatch-Waxman Reform and Accelerated Market Entry of Generic Drugs: Is Faster Necessarily Better?*, 2003 DUKE L. & TECH. REV. 1, 4 (2003).

22. 21 U.S.C.A. § 355(j)(2)(A)(iv) (West 2013).

23. 21 U.S.C.A. § 355(j)(2)(A)(v) (West 2013).

24. Eurek, *supra* note 21, at 6.

25. See Louis E. Fogel & Peter H. Hanna, *Drug Safe Labeling*, PHARMACEUTICAL COMPLIANCE MONITOR (Apr. 10, 2015), <https://www.pharmacompliancemonitor.com/drug-safety-labeling-generic-versus-branded/8857/> (“federal law does not permit generic drug makers to update their warnings independently”).

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

27. *Masters*, *supra* note 1, at 417.

of generic drugs contend that it is impossible to comply with both this federal “sameness” requirement and the state law duty to keep a drug reasonably safe since a generic drug is required to remain the same as its brand-name counterpart.<sup>28</sup> Although a conflict of duties seems to suggest that preemption is appropriate, the Courts have disagreed over the extent to which the FDCA preempts state law claims.<sup>29</sup> In their decisions, courts have wrestled over the importance of affordability and accessibility of medication balanced against the potential harms to consumers of those generic products.<sup>30</sup> There have been three Supreme Court decisions within the past five years that have attempted to demarcate the precise preemptive scope of the Hatch-Watchman Act.

a. *Wyeth v. Levine*

*Wyeth v. Levine* was the first Supreme Court case that addressed the “duty of sameness” within the realm preemption of prescription drug claims.<sup>31</sup> The plaintiff in *Wyeth* was injured when a she was injected with Phenergan, a brand-name antihistamine used for the treatment of headaches.<sup>32</sup> The drug was administered directly into her vein using the “IV push” method, causing irreversible gangrene, and eventually led to the loss of her arm.<sup>33</sup> The plaintiff in *Wyeth* brought a failure-to-warn action against the manufacturer of Phenergan, alleging that it had failed to instruct physicians to use the less-risky “IV-drip” method.<sup>34</sup> The Supreme Court ultimately held that because the FDCA did not preclude a brand-name drug manufacturer from unilaterally changing their label, it was possible to comply with both federal and state law.<sup>35</sup> The Court ultimately held that claims against brand-name manufacturers are not preempted.<sup>36</sup>

b. *PLIVA, Inc. v. Mensing*

While the holding in *Wyeth* was limited to preemption of claims made against brand name manufacturers, the Supreme Court in *PLIVA, Inc. v.*

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28. *Id.* at 415.

29. Brittany Croom, *Buyer Beware: Mutual Pharmaceutical Co. v. Bartlett Continues to Alter the True Costs and Risks of Generic Drugs*, 15 N.C.J.L. & TECH. ON. 1, 16 (2014).

30. *Id.* at 4-5.

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

32. *Id.* at 558-59.

33. *Id.*

34. *Id.* at 558.

35. *Id.* at 571.

36. *Id.*

*Mensing* was the first to address preemption in the generic drug context.<sup>37</sup> *Mensing* involved failure-to-warn claim against a generic manufacturer of metoclopramide, a drug designed to assist the digestive system.<sup>38</sup> After taking metoclopramide, the plaintiff developed severe and irreversible neurological disorders.<sup>39</sup> Although studies surfaced early on that the brand-name compound caused neurological damage in almost one-third of its users, it was years before the manufacturer of the brand name product was forced to make significant changes to its warning label.<sup>40</sup> By then, the plaintiff had ingested the generic equivalent and been severely injured.<sup>41</sup> The generic manufacturer of metoclopramide argued for preemption, arguing that they were barred by federal law from making any unilateral changes to the label of metoclopramide.<sup>42</sup> The Supreme Court agreed, reasoning it was not possible for the generic drug manufacturer to fulfill state tort law requirements and a federal law that forbade generic drug manufacturers from having a label different than the brand-name manufacturer.<sup>43</sup>

*c. Mutual Pharmaceutical Co. v. Bartlett*

Most recently, in *Mutual Pharmaceutical Co. v. Bartlett*, the Supreme Court finally addressed preemption within the context of design defect claims of generic drug products.<sup>44</sup> In *Bartlett*, a woman was severely injured after taking Cliniril, a generic form of an anti-inflammatory drug Sulindac.<sup>45</sup> The woman subsequently sued the manufacturer of Cliniril under defective design for failing to provide adequate warnings on the label.<sup>46</sup> In New Hampshire's risk/utility analysis for design defect, the court balances the drugs usefulness, feasibility of alternative design, and presence and efficacy of a warning.<sup>47</sup> In response, Mutual claimed federal law had prohibited them from independently changing their labels, and as such, it was unable to take

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37. 131 S. Ct. 2567 (2012).

38. *Id.* at 2572.

39. *Id.*

40. *Id.* See generally Jasper L. Tran & Derek Tri Tran, *(De)Regulating Neuroenhancement*, 37 U. LA VERNE L. REV. 179, 186-91 (2015) (discussing neurological effects of brand name drugs).

41. 131 S. Ct. at 2573.

42. *Id.*

43. *Id.* at 2581.

44. 133 S. Ct. 2466 (2013).

45. *Id.* at 2472.

46. *Id.*

47. Michael J. Wagner & Laura L. Peterson, *The New Restatement (Third) of Torts—Shelter from the Product Liability Storm for Pharmaceutical Companies and Medical Device Manufacturers?*, 53 FOOD & DRUG L.J. 225 (1998).

remedial action required to avoid liability under New Hampshire state law.<sup>48</sup> Relying heavily upon the decision in *Mensing*, The Supreme Court held that that New Hampshire's common law duty of making sure one's product is on the positive side of the balancing inquiry is preempted by the federal provision disallowing changes to a generic drug's design and label.<sup>49</sup>

### III. IMPLICATIONS OF *MENSING* AND *BARTLETT*

Following the decisions of *Wyeth*, *Mensing* and *Bartlett*, plaintiffs injured by generic drugs are essentially barred from all areas of redress. However, a plaintiff injured using an identical, brand-name product is still afforded the legal remedies of failure-to-warn and design defect. By shielding generic drug manufacturers from liability, *Mensing* and *Bartlett* place consumers at an increased risk. Additionally, low-income consumers, who cannot afford brand name drugs, are now in a disproportionate and unnecessary danger. Furthermore, the decisions in *Mensing* and *Bartlett* may ultimately hurt, rather than help the generic drug industry.

#### *a. Preemption of Generic Drug Claims Decreases Incentive for Product Safety*

The risk of injury and the threat of subsequent liability motivate drug manufacturers to engage in thorough testing, safety studies, and to provide adequate warnings.<sup>50</sup> Threat of liability also provides incentive for drug manufacturers to collect post-market data and to promptly report adverse reactions to the FDA.<sup>51</sup> Shielding generic drug manufacturers from state tort liability therefore, decreases incentives for generic manufactures from engaging in thorough pre-market testing and studies.<sup>52</sup> It also makes it less likely that the generic manufacturer will vigorously pursue reports of risks uncovered after the product has been marketed.<sup>53</sup> *Mensing*, *Bartlett*, and a litany of lower federal courts following their example, point to the Hatch-Waxman Act's policy considerations of keeping the prices of generic drugs low.<sup>54</sup> However, this line of reasoning assumes that Congress values the

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48. *Bartlett*, 133 S. Ct. at 2470.

49. *Id.* at 2470, 2473.

50. James M. Beck, *Federal Preemption in FDA-Regulated Product-Liability Litigation: Where We Are and Where We Might Be Headed*, 32 *HAMLIN L. REV.* 657, 691 (2009).

51. *Id.* at 691.

52. Cupp, Jr., *supra* note 15, at 745 n. 126.

53. *Id.* at 746.

54. *Bartlett*, 133 S. Ct. at 2471; *PLVIA Inc. v. Mensing*, 131 S. Ct. 2567, 2592 (2011); *In re Fosamax Prods. Liab. Litig.*, 965 F. Supp. 2d 414 (S.D.N.Y. 2013).

health and safety of consumers less than it values cheap alternatives to brand name drugs. It is unlikely that Congress, through the Hatch-Waxman Act, knowingly put the lives of a class of American consumers at risk in order to benefit the very same class.

*b. Preemption of Generic Drug Claims Disproportionately Affects Low-Income Consumers*

This void in pre-market and post-market safety for generic drugs is particularly troubling considering that the market for generic drugs increases exponentially every year, and that the primary consumers of generic drugs are low income.<sup>55</sup> In this respect, the class of consumer who would benefit the most from compensation if injured, is effectively precluded from doing so following the decisions of *Bartlett* and *Mensing*. These consumers are left with debilitating injuries, heavy medical expenses, and no compensation for their pain and suffering.<sup>56</sup> The problem is further compounded by the fact that many of these consumers do not have a say in whether they receive a brand name or generic drug.<sup>57</sup> Indeed, branded drug sales usually cease once the brand name drug goes generic.<sup>58</sup> According to a Public Citizen amicus brief, there are 434 generic drugs for which no brand-name drugs are being marketed.<sup>59</sup> A 2012 study by the Generic Pharmaceutical Association determined that for forty-five percent of generic drugs sold, no brand-name counterpart exists on the market.<sup>60</sup> Therefore, if generic manufacturers are not actively monitoring their products, there is no manufacturer doing it at all.

*c. Preemption of Generic Drug Claims Hurts the Generic Drug Industry*

Supporters of the *Mensing* and *Bartlett* decisions mistakenly assume that preemption helps, rather than hurts the generic drug industry. They point to the decreased costs of business that comes with lower exposure to liability

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55. Daniel Perrone, *Crafting an Exception to the Mensing Ruling*, JURIST (Apr. 11, 2013, 9:55 AM), <http://jurist.org/datetime/2013/04/daniel-perrone-generic-drugs.php>.

56. *Id.*

57. See, e.g., Marissa Evans, *Price Matters: Consumers Want Cheap, Generic Drugs*, MORNING CONSULT (Oct. 7, 2014), <http://morningconsult.com/2014/10/consumers-want-cheap-generic-drugs-retail-stores/>.

58. José P. Sierra, *Supreme Court Rejects Design Defect End-Around of Pliva v Mensing Ruling*, PHARMARISC (June 26, 2013), <http://www.pharmarisc.com/2013/06/supreme-court-rejects-design-defect-end-around-of-pliva-v-mensing-ruling/>.

59. *Id.*

60. GENERIC PHARM. ASS'N, SAVINGS \$1 TRILLION OVER 10 YEARS: GENERIC DRUG SAVINGS IN THE U.S. 9 (4th ed. 2012).

and argue that decreased costs will be subsequently passed on to the consumer in the form of lower drug prices.<sup>61</sup> However, shielding generic drugs from state tort law liability runs the risk of ultimately hurting, rather than helping the generic drug industry in the long run. Doctors, concerned over the “ethical dilemma” of prescribing generic drugs, may prescribe generic drugs less and may avoid generic substitutions.<sup>62</sup> Doctors may also have less altruistic concerns, especially as it relates to increased liability for themselves. For example, a patient injured by a generic drug who has not been “made whole” by a generic manufacturer, may pursue a claim against a doctor for partial compensation in the form of a medical malpractice lawsuit.<sup>63</sup> Doctors, who have virtually unchecked powers to prevent generic substitutions, may increasingly refuse to prescribe generic drugs in order to avoid future liability.<sup>64</sup>

Pharmacies, concerned for many of the same reasons, will refrain from filling prescriptions with a generic substitute.<sup>65</sup> Consumers become more educated about the potential risks and lack of legal remedies for generic drugs will request brand-name drugs.<sup>66</sup> States, concerned over the lack of generic manufacturer accountability, and preemption of its own state defect standards, may begin to implement laws that discourage generic substitution.<sup>67</sup> While the long-term impacts of the *Mensing* and *Bartlett* decisions have yet to be felt in full force, we should expect many of these changes if generic manufacturers continue to be shielded from liability.

#### IV. LEGISLATIVE EFFORTS

Given the huge ramifications of *Mensing* and *Bartlett*, there has been a tremendous effort to introduce regulatory action that minimizes the impact of the decisions. In November 2013, the FDA introduced a proposed rule that would enable generic drug manufactures to unilaterally update their labels, irrespective of whether the revised labeling differs from its brand-name

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61. See generally Steve Yahn, *Generic Drug Manufacturers May Face Increased Premiums and Higher Risk Management Costs Due to a Proposed FDA Rule*, RISK & INS., (Feb. 19, 2015), <http://www.riskandinsurance.com/rule-change/> (finding erosion of the rule will lead to claim expenses and potential judgments).

62. 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, 1577 (2014).

63. Daniel Kazhdan, *Wyeth and PLIVA: The Law of Inadequate Drug Labeling*, 27 BERKELEY TECH. L.J. 893, 914-15 (2012).

64. *Id.* at 914.

65. *Id.* at 915.

66. Boyd, *supra* note 62, at 1577.

67. *Id.*

counterpart.<sup>68</sup> The updated labeling will be submitted as a “Changes Being Effected Supplement”, or a “CBE-O”, and permits the generic drug manufacturer to implement a revised label while it submits the changes to the FDA.<sup>69</sup> The generic manufacturer is also required to notify its brand-name counterpart of its intention to change its label and the reasons behind the change.<sup>70</sup> In a supplemental report, the FDA lists the social costs associated with the new rule as minimal, only \$4,237 to \$25,852 annually.<sup>71</sup>

*a. Criticism of the “CBE-O” Proposal*

Not surprisingly, The FDA’s “ANDA CBE-O proposal” has been met with sharp criticism by Republican members of Congress. These congressmen have decried the proposal as “conflict[ing] directly with the statute, thwart[ing] the law’s purposes and objectives and imposing significant costs on the drug industry and healthcare consumers.”<sup>72</sup> In response to the FDA’s proposed rule, conservative consulting groups have generated numbers that refute the FDA’s net social cost estimates. In February 2013, a consulting group estimated that increased liability as a result of the new rule would lead to increased costs to generic drug manufacturers at \$4 billion, or 1.16 per prescription.<sup>73</sup> These studies’ criticism of the FDA’s report centers largely on their failure to factor into their analysis the increased costs associated with higher exposure to liability.<sup>74</sup>

*b. Criticism of the “CBE-O” Proposal Is Unwarranted*

The criticism directed at the FDA’s proposed rule is unwarranted. First, it is well known that the FDA has historically refrained from considering as a dispositive factor in its decisions costs associated with increased civil

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68. Jennifer M. Thomas, *FDA Proposes a Rule that Would Undercut Generic Drug Preemption*, FDA L. BLOG (Nov. 12, 2013), <http://www.fdalawblog.net>.

69. *Id.*

70. *Id.*

71. ALEX BRILL, FDA’S PROPOSED GENERIC DRUG LABELING RULE: AN ECONOMIC ASSESSMENT, MATRIX GLOBAL ADVISORS 3 (Feb. 5, 2014), [http://www.gphaonline.org/media/cms/Economic\\_Impact\\_Study\\_FDA\\_Labeling\\_Rule\\_-\\_MGA.pdf](http://www.gphaonline.org/media/cms/Economic_Impact_Study_FDA_Labeling_Rule_-_MGA.pdf).

72. Press Release, Liz Wogemuth, Alexander Leads Inquiry into FDA’s Proposed Change to Generic Drug Labeling Policy (Jan. 22, 2014), <http://www.help.senate.gov/chair/newsroom/press/alexander-leads-inquiry-into-fdas-proposed-change-to-generic-drug-labeling-policy>.

73. BRILL, *supra* note 71, at 10.

74. *Id.* at 8.

liability to a manufacturer.<sup>75</sup> Rather, the FDA's primary function has historically been to protect consumers from risks and the harmful effects of drugs.<sup>76</sup> The newly proposed CBE-O is consistent with this function by putting the most up-to-date information and risks in the hands of consumers and their doctors. Second, critics overlook the potential social savings of the proposed rule. For example, critics blast the FDA formula as shortsighted for failing to include the increased costs of liability into their formula.<sup>77</sup> In the same breath however, these critics overlook the social *costs of injuries* that result from the preemption of generic drug claims. The CBE-O proposal will allow consumers and their doctors to avoid costly injuries by making informed choices, with the most up-to-date information and up to date risks of the drug. Most importantly, heightened threat of liability to generic manufacturers ensures that they engage in thorough pre-market and post market testing and studies, making the safest product possible and avoiding costly injuries.

*c. CBE-O Unlikely to Be Implemented*

Despite the promise that CBE-O proposal holds for consumers of generic drugs and the drug industry, the recent taking of the Senate majority by the GOP largely ensures that these proposals will not be implemented.<sup>78</sup> The GOP is likely to mount challenges to the proposal, including lawsuits that challenge the FDA's authority to unilaterally implement these types of changes.<sup>79</sup> Alternatively, the GOP may introduce legislation that explicitly prohibits generic manufacturers from changing their labels, essentially undermining any FDA attempt to alter the status quo.<sup>80</sup>

## V. PLAINTIFF STRATEGIES FOLLOWING *MENSING* AND *BARTLETT*

While the FDA seems largely powerless for the time being to implement any regulatory changes, two things remain certain. First, *Mensing* and

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75. See, e.g., Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37434, 37437 (June 26, 1979) (to be codified at 21 C.F.R. pt. 201 and 202) ("It is not the intent of FDA to influence the civil tort liability of the manufacturer or the physician.").

76. *Id.* at 37437.

77. BRILL, *supra* note 71, at 8.

78. Sindhu Sundar, *GOP Poised to Slow down Obama Product Safety Measures*, LAW360 (Nov. 5, 2014, 12:54 AM), <http://www.law360.com/articles/593051/>.

79. *Id.*

80. *Id.*

*Bartlett* have impressed upon the courts a strong directive to preempt any product liability claims made against a generic manufacturer.<sup>81</sup> Second, as long as generic manufacturers continue to market drugs and regulatory change is stagnant, plaintiff attorneys will continue to try and poke holes in the *Mensing* and *Bartlett* decisions.<sup>82</sup> Although no strategy has proven exceptionally successful, three have proven to be marginally useful for litigants.

a. *Failure-to-Update*

The most well known plaintiff strategy in the wake of *Bartlett* and *Mensing* relates to failure to timely update labeling to match the labeling of the brand manufacturer.<sup>83</sup> While a generic manufacturer is not allowed to unilaterally change their label or drug composition per *Mensing*, it is still required to update their label to match a brand name manufacturer if the brand name manufacturer has made any changes to its label.<sup>84</sup> Plaintiffs have seized onto this requirement, and many state courts have proven to be sympathetic towards plaintiffs asserting failure-to-update claims. Most recently, the Appellate Division in New Jersey in *In Re Reglan Litigation* held that a “failure-to-update” claim survives impossibility preemption.<sup>85</sup> There are also multiple petitions for writ of certiorari that are pending before the U.S. Supreme Court on this issue.<sup>86</sup>

While failure-to-update claims have seen some success in state courts, litigators and scholars alike are dubious regarding the future success and viability of this strategy. Jim Beck, a leading defense attorney, expert and blogger on drug and device litigation recently called the strategy a “really lousy cause of action” and stated that he would “not be losing any sleep over it.”<sup>87</sup> In his blog, Beck points to a litany of thorny causation issues which

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81. Jesse Morris, *Third Circuit Confirms Preemption Scope of Mensing and Bartlett*, PROD-LIAB. MONITOR (May 6, 2014, 3:14 PM), <http://product-liability.weil.com/preemption/third-circuit-confirms-preemption-scope-of-mensing-and-bartlett/>.

82. *Id.*

83. CHARLES S. ZIMMERMAN, PHARMACEUTICAL AND MEDICAL DEVICE LITIGATION § 15A:28 (2014).

84. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2476 (2013); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2575 (2011).

85. *In re Reglan Litigation*, 2014 WL 5840281, at 4 (N.J. Sup. Ct. Nov. 12, 2014); *see also* *Teva Pharm. USA, Inc. v. Superior Court*, 217 Cal. Rptr. 3d 150, 157 (Ct. App. 2013).

86. *See* Arnold & Porter LLP, *U.S. Supreme Court to Consider Review of Federal Preemption for Generic Drug Manufacturers*, LEXOLOGY (Oct. 15, 2014), <http://www.lexology.com/library/detail.aspx?g=d7b2b18d-adc8-4ee0-bc8b-d0d4adb94eb7>.

87. James M. Beck, *On Generic Plaintiffs' Preemption "Win" in New Jersey*, DRUG & DEVICE LAW (Nov. 18, 2014), <http://www.druganddevicelaw.blogspot.com>.

plaintiffs will face in asserting this cause of action.<sup>88</sup> Recently, the Eighth Circuit touched on some of these causation issues when it denied a failure-to-update claim in part because the plaintiff and prescriber neither read nor relied on the outdated, generic warning.<sup>89</sup>

*b. Innovator Liability*

Another strategy that plaintiffs have been testing as a work-around to the *Mensing* and *Bartlett* is “innovator liability.” The theory of innovator liability holds brand name manufacturers responsible for injuries resulting from the generic version of the drug.<sup>90</sup> While the majority of courts have repeatedly slammed the door shut on “innovator liability” lawsuits, a small minority of jurisdictions has extended liability to brand name manufacturers on the grounds that these manufacturers owe a duty of care to generic drug consumers.<sup>91</sup> In 2008, The California Court of Appeals in *Conte v. Wyeth* was the first to find innovator liability, holding that a brand-name manufacturer’s common-law duty to use due care in preparing its product warnings extends to patients whose doctors foreseeably rely on its product information.<sup>92</sup> This holds true even when the prescription is not written for the brand name drug, but its generic equivalent.

Following the decision in *Conte*, a District Court in Vermont similarly held that innovators can be held liable for negligence or fraud where prescribers relied on brand name warnings, even when the plaintiff did not ingest the brand name drug.<sup>93</sup> Recently, in *Wyeth v. Weeks*, Alabama joined the small, but growing minority of jurisdictions that recognize innovator liability as a viable alternative for recovery.<sup>94</sup> In *Weeks*, the court held that a brand name manufacturer could be held liable for injuries for failure to warn of side effects of long-term use.<sup>95</sup> Although the plaintiff had not taken the brand name drug, but the generic equivalent, the court found that it was foreseeable that customers of the generic drug would rely on the brand name warnings.<sup>96</sup> Illinois and Virginia are also jurisdictions that have begun to

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88. *See id.*

89. *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1138-39 (8th Cir. 2014).

90. Wesley E. Weeks, Comment, *Picking up the Tab for Your Competitors: Innovator Liability After PLIVA, Inc. v. Mensing*, 19 GEO. MASON L. REV. 1257, 1279-80 (2012).

91. *Id.* at 1269.

92. 85 Cal. Rptr. 3d 299, 304-05 (Ct. App. 2008).

93. *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 706 (D. Vt. 2010).

94. 159 So. 3d 649, 670 (Ala. 2014).

95. *Id.*

96. *Id.*

allow certain limited causes of action to proceed against innovators.<sup>97</sup> While jurisdictions that have adopted “innovator liability” are generally viewed as outliers, plaintiffs will continue to test the waters in jurisdictions that have not taken a stance on the issue.<sup>98</sup>

*c. The Misbranding Footnote*

The decision in *Bartlett* established that state law design defect claims are preempted under federal law.<sup>99</sup> However, hidden away in footnote four, the Supreme Court indicated that its ruling, “does not address state design defect claims that parallel the federal misbranding statute.”<sup>100</sup> The parallel misbranding statute requires a manufacturer to pull an FDA approved drug from the market if it is “dangerous to health” even if “used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.”<sup>101</sup> A drug is only misbranded when liability “is based on new and scientifically significant information that was not before the FDA.”<sup>102</sup> Following the decision in *Bartlett*, plaintiffs seized upon this footnote, arguing that because federal law required the drug in question to be removed from the market, a state law duty to not market the drug is not preempted.<sup>103</sup> For a time, commentators had lauded the misbranding exception as a promising avenue following the decisions in *Mensing* and *Bartlett*.<sup>104</sup>

Recently however, the Sixth Circuit *In re: Darvocet, Darvon, and Propoxyphene Products Liability Litigation* delivered a huge blow to the parallel misbranding strategy before it was able to gain any real traction.<sup>105</sup> While the court in *Darvocet* did not rule directly upon the existence of the parallel misbranding preemption exception, the court laid out exceedingly difficult pleading requirements for those wishing to assert parallel misbranding.<sup>106</sup> Being the first circuit court to analyze and apply the

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97. *See* *Colas v. Abbvie, Inc.*, No. 14 C 1452, 2014 WL 2699756, at 1-3 (N.D. Ill. June 13, 2014).

98. *See* *Weeks*, *supra* note 90, at 1266 n.67.

99. *See* *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2473 (2013).

100. *Id.* at 2477 n.4.

101. 21 U.S.C.A § 352(j) (West 2012).

102. *Bartlett*, 133 S. Ct. at 2477 n.4.

103. Brian Wolfman & Anne King, *Mutual Pharmaceutical Co. v. Bartlett and Its Implications*, 82 U.S.L. WK. 1, 7-8 (2013).

104. *Id.* at 7-9.

105. 756 F.3d 917, 929-30 (6th Cir. 2014).

106. Shagha Tousi, *Product Liability in 2014: What Did and Didn't Happen*, LAW360 (Dec. 22, 2014, 1:04 PM), <http://www.law360.com/articles/593051/>.

misbranding exception, *Darvocet* will undoubtedly dissuade future plaintiffs from asserting the exception.<sup>107</sup>

## VI. CONCLUSION

The decisions in *Mensing* and *Bartlett* have impressed upon the courts a strong directive to preempt any product liability claims made against a generic manufacturer. However, by shielding generic drug manufacturers from liability, *Mensing* and *Bartlett* have placed consumers, especially low income consumers, at an increased risk of injury. Additionally, the decisions in *Mensing* and *Bartlett* may ultimately hurt, rather than help the generic drug industry. While there has been an effort to introduce regulatory action that minimizes the impact of the decisions, the FDA seems largely powerless for the time being to implement any regulatory changes. Plaintiff attorneys have also met limited success in attempting to circumvent, reframe or distinguish the holdings in *Mensing* and *Bartlett*. However, as long as regulatory change is stagnant, expect plaintiff attorneys to continue to try and poke holes in holdings in *Mensing* and *Bartlett* with limited success in narrow circumstances.

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107. Beth S. Rose, *Is There a "Parallel Misbranding" Exception to Generic Drug Preemption?*, SILLS CUMMIS & GROSS (Aug. 2014), [http://www.sillscummis.com/Repository/Files/Alert\\_-\\_In\\_re\\_Darvocet\\_Is\\_There\\_a\\_Parallel\\_Misbranding\\_Exception\\_to\\_Generic\\_Drug\\_Preemption.pdf](http://www.sillscummis.com/Repository/Files/Alert_-_In_re_Darvocet_Is_There_a_Parallel_Misbranding_Exception_to_Generic_Drug_Preemption.pdf). The possibility of consumers 3D printing drugs in the comfort of their own home will likely make the battle between brand name and generic drug manufacturers even more interesting. Cf. Jasper L. Tran, *To Bioprint or Not to Bioprint*, 17 N.C. J.L. & TECH. 123 (2015) (regulation of 3D-printed organs). See generally Jasper L. Tran, *3D Printing & the Law*, 31 J. MARSHALL J. INFO. TECH. & PRIVACY L. 505 (2015) for a discussion on the current laws on 3D printing; and Jasper L. Tran, *Press Clause and 3D Printing*, 14 NW. J. TECH. & INTELL. PROP. 75 (2016) for more discussion on 3D printing.