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# SERIOUS SIDE EFFECTS MAY OCCUR: THE PAINFUL SYMPTOMS OF EVOLVING TORT LIABILITY

WILLIAM H.T. RICE\*

## I. INTRODUCTION

The evolution of modern tort law has given rise to a problematic body of precedent for cases involving injured consumers of generic medications, when those consumers are harmed by side-effects not included on a medication's warning label.<sup>1</sup> A restrictive combination of federal preemption and bedrock tort law principles has all but eliminated access to judicial remedy for consumers who have been injured by inadequate warning labels.<sup>2</sup> In short, most state and federal courts have been reluctant to hold either the generic or name-brand manufacturers liable for harm that stems from faulty labeling on generic medications.<sup>3</sup> Generic companies are generally protected from claims related to labeling by the shield of federal preemption, as the generic labels are dictated by Food and Drug Administration regulations.<sup>4</sup> The name-brand manufacturers have largely been absolved of liability under basic negligence theories because, in these cases, the name-brand manufacturers did not produce the medication that was consumed, therefore establishing causation has been problematic.<sup>5</sup> These two precedential bulwarks have facilitated the expansion of a burgeoning

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1. See generally Brian Wolfman & Anne King, *Mutual Pharmaceutical Co. v. Bartlett and Its Implications*, 82 U.S.L.Wk. 1, 1–18 (2013); see also *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013); *PLIVA v. Mensing*, 564 U.S. 604 (2011).

2. *Bartlett*, 570 U.S. 472; *PLIVA*, 564 U.S. 604; RESTATEMENT (SECOND) OF TORTS §§281, 298, 301, 395, 402A, 402B, 430, 431, 435, 440, 441, 442 (AM. LAW INST. 1979);

3. See generally *Bartlett*, 570 U.S. 472; *PLIVA*, 564 U.S. 604; *Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Ala. 2014); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649 (2014).

4. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984); *Cipollone v. Liggett Group*, 505 U.S. 504 (1992).

5. RESTATEMENT (SECOND) OF TORTS, §§281, 430, 431 (AM. LAW INST 1979).

potential plaintiff pool, one that is helplessly underequipped in its fight for justice.

This paper highlights landmark manufacturer liability cases and proceeds by exploring causes of action that could provide much needed judicial redress. Ultimately, this paper examines the Maryland Court of Appeals' legal maneuvering in a recent failure-to-warn case which could alleviate the painful side-effects of evolving tort liability.

## II. BACKGROUND

When a consumer is harmed by the reasonable use or foreseeable misuse of a defective product, the product manufacturer may be held strictly liable.<sup>6</sup> This legal standard, enunciated by Chief Justice Traynor of the California Supreme Court in his concurrence for *Escola v. Coca Cola Bottling Co.*,<sup>7</sup> is the foundation of modern day strict product liability.<sup>8</sup> Due to the wide acceptance of this principle, companies now design, manufacture and distribute products with an understanding that they could be liable for harm suffered as a result of a customer's reasonable use or foreseeable misuse of the manufacturer's product.<sup>9</sup>

Both the common law and governing statutes put manufacturers on notice that they are responsible for harm stemming from their defective products.<sup>10</sup> The development of this area of law has resulted in distinct guidelines that dictate how plaintiffs may attempt to receive fair compensation from manufacturers for harm created by the manufacturers.<sup>11</sup> When bringing a product liability claim, plaintiffs are first required to identify the particular defect that caused their injury. Product defects typically fall into one of three categories: (i) design defects, (ii) manufacturing defects and (iii) warning defects.<sup>12</sup> This paper focuses primarily on warning defects, as failure to warn actions are the central tort claims available to consumers injured by inadequate medication warning labels.<sup>13</sup>

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6. *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 440 (Cal. 1944) (Traynor, J., concurring).

7. *Id.*

8. *Id.*; Gary T. Schwartz, *Understanding Products Liability*, 67 CAL. L. REV. 435 (1979).

9. Keith N. Hylton, *The Law and Economics of Products Liability*, 88 NOTRE DAME L. REV. 2457, 2463 (2013) (explaining how economic incentives paired with the reliance rationale has created a relationship between consumers and manufacturers that provides notice to manufacturers that they can be held liable for their defective products).

10. *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014); *Wyeth, Inc. v. Weeks*, 159 So.3d 649 (Ala. 2014).

11. *Bartlett*, 570 U.S. 472; *PLIVA*, 564 U.S. 604; *Huck*, 850 N.W.2d 353; *Wyeth* 159 So.3d 649.

12. HARRY SHULMAN, FLEMING JAMES, JR., OSCAR GRAY, DONALD GIFFORD, *LAW OF TORTS – CASES AND MATERIALS*, 573–609 (6th ed. 2015).

13. *Id.*; See cases cited *supra* notes 4 & 10.

Personal injury claims resulting from a failure to warn have developed through the evolution of common law as an action that sounded in negligence.<sup>14</sup> These “negligent failure to warn claims” were founded upon harm caused by the negligent conduct of a defendant.<sup>15</sup> For such an action to be viable under a negligence standard, the defendant must have breached a duty owed to the plaintiff by failing to exercise reasonable care in the provision of warnings and that failure must have been a proximate cause of the plaintiff’s harm.<sup>16</sup> “A defendant whose conduct creates a risk of physical or emotional harm can fail to exercise reasonable care by failing to warn of the danger if: (1) the defendant knows or has reason to know: (a) of that risk; and (b) that those encountering the risk will be unaware of it; and (2) a warning might be effective in reducing the risk of harm.<sup>17</sup> In accordance with tort law precedent, “failure to warn” product liability claims arise “when one who supplies chattel for use by another knows, or should realize, that chattel is, or is likely to be, dangerous for use for which it is supplied and fails to exercise reasonable care to warn the user of its dangerous condition.”<sup>18</sup> “Failure to warn is defined as the absence of, or inadequacy of, warnings accompanying a product which causes harm.”<sup>19</sup> “To establish liability for a failure to warn, [a plaintiff] must show that ‘a warning is necessary to make a product . . . reasonably safe, suitable and fit for its intended use,’ that [the defendant(s)] failed to provide such a warning, and that that failure was a proximate cause of [plaintiff’s] injury.”<sup>20</sup> This theory of liability has been codified within the Third Restatement, which further reinforces the view that “a product will be ‘defective’ by reason of a lack or inadequacy of warnings or instructions for safe usage ‘when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable

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14. See *Delmarva Power & Light Co. v. Burrows*, 435 A.2d 716, 718 (1981) (demonstrating that, in Delaware, duties are measured in terms of reasonableness and that a person can breach that duty by not protecting against an event that a reasonably prudent person would protect against, therefore, failing to warn of foreseeable danger can give rise to a negligence claim); see also *Sneed v. Lions Club of Murphy, Inc.*, 273 N.C. 98, 100, 159 S.E.2d 770, 772 (1968) (holding that, under North Carolina law, the owner of a public pool is under a duty to install and maintain proper signs warning patrons of dangerous depths of the water, and that failure to so warn may constitute negligence); *United States v. Washington*, 351 F.2d 913, 916–17 (1965) (reiterating that there is often a legal duty to communicate or to attempt to communicate adequate warnings of existing, foreseeable hazards and that failing to do so may be negligent).

15. *Id.*

16. *E.g.*, *Pa. R.R. Co. v. Goldenbaum*, 269 A.2d 229, 233 (1970) (citing *Jones v. Pa R.R. Co.*, 61 A.2d 691 (1948) (stating, “[t]he issue you must decide then, in the light of the principles of law I have stated to you, is whether or not the defendant was negligent in providing adequate warning devices at the intersection and, if so, whether such negligence was a proximate cause of the accident.”)).

17. RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM, § 18 (AM. LAW. INST. 2010).

18. *Potts v. Uap-Ga Ag Chem, Inc.*, 567 S.E.2d 316, 321 (Ga. Ct. App. 2002).

19. Winifred Weitsen Boyle, *There’s No Smoking Gun: Cities Should Not Sue the Firearm Industry*, 25 U. DAYTON L. REV. 215, 231 n. 96 (2000)

20. *Cipollone v. Liggett Group*, 505 U.S. 504, 524 (1992).

instructions or warnings by the seller or other distributor ... and the omission of the instructions or warnings renders the product not reasonably safe.”<sup>21</sup> In regard to guidance aimed specifically at the special liability of drug manufacturers, comment k to Restatement § 402A effectively illustrates the quintessential importance of adequate warnings, explaining that that a dangerous but useful medication that is “properly prepared[] and accompanied by proper directions and warning, is not defective nor is it unreasonably dangerous.”<sup>22</sup>

Without question, the tripartite defect model effectively governed drug manufacturer liability while the market consisted largely of name-brand producers.<sup>23</sup> As the pharmaceutical marketplace has grown more diverse, tensions have begun to arise due to influential shifts in the controlling market dynamics.<sup>24</sup> Many scholars have debated the arduous Food and Drug Administration’s (hereinafter “FDA”) “new drug” approval process,<sup>25</sup> with critics alleging that the threat of litigation created by tort liability has contributed to the development of excessively burdensome approval procedures.<sup>26</sup> Critics highlight how product defect liability plays a large role in the growing costs associated with earning FDA approval and securing health care provider insurance, which are passed on to consumers through soaring medication prices and insurance premiums.<sup>27</sup> In opposition to those critics, proponents of name-brand manufacturer liability argue that holding name-brand companies responsible for harm they cause is essential for ensuring adequate consumer protections.<sup>28</sup>

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21. Martin A. Kotler, *Reconceptualizing Strict Liability in Tort: An Overview*, 50 VAND. L. REV. 555, 596 (1997) (citing the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(c)).

22. RESTATEMENT (SECOND) OF TORTS §402A cmt. k (AM. LAW INST. 1979).

23. Name-brand producers are companies that first bring medications to market by completing lengthy and expensive Food and Drug Administration (“FDA”) approval processes. Generic drug producers are the companies that market medicine which is equivalent to a name-brand product in dosage, strength, route of administration, quality, performance and intended use, but does not carry the brand name. *Generic Drug Facts*, FDA (June 4, 2018), <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm167991.htm>.

24. Maura Calsyn & Thomas Huelskoetter, *The FDA Is Not the Problem: Why Undermining the Drug Approval Process Is Not The Answer to High Drug Prices*, CTR. FOR AM. PROGRESS (Mar. 9, 2016), <https://www.americanprogress.org/issues/healthcare/reports/2016/03/09/132850/fda-is-not-the-problem/>.

25. *Id.*

26. Nina J. Crimm, *A Tax Proposal to Promote Pharmacologic Research, to Encourage Conventional Prescription Drug Innovation and Improvement, and to Reduce Product Liability Claims*, 29 WAKE FOREST L. REV. 1007 (1994); 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 Effect*, 81 FORDHAM L. REV. 1835 (2013).

27. *Id.*

28. George Mason Law and Economics Center, *Congressional Civil Justice Academy Debate: Inventing New Liability? Who Should We Blame When Generic Drugs Harm Patients?*, VIMEO (Feb. 9, 2018), <https://vimeo.com/255119753> (highlighting arguments regarding how to maintain reasonable consumer protections in the drug manufacturer context).

Regardless of any impact that tort liability has had, due to the significant time commitment and financial resources required to bring medicine to market, name-brand medications are inherently sold at steep prices.<sup>29</sup> High medication purchase prices allow name-brand companies to compensate for the large upfront costs they shoulder developing medicine for public use.<sup>30</sup> While these prices manifest sound economics for name-brand manufacturers, they can make it difficult for average and low-income individuals that are lacking adequate insurance coverage for prescription drugs to purchase necessary medication.<sup>31</sup>

To alleviate supply-side deficiencies and unreasonable medication costs, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Amendments.<sup>32</sup> The purpose of this law was to make medications more affordable and accessible.<sup>33</sup> Congress sought to bring down medication prices by modifying the approval process required for generic versions of FDA approved medication and allowing for “Abbreviated New Drug Applications” (hereinafter “ANDA”).<sup>34</sup> Under Hatch-Waxman, a generic medication may be approved for use without completing the onerous New Drug Application process<sup>35</sup> (hereinafter “NDA”) that name-brand manufacturers must finish, provided the generic drug is bioequivalent to an FDA approved name-brand drug.<sup>36</sup> Hatch-Waxman prohibits generic drug manufacturers from using different active ingredients or altering the warning label that the FDA approved for the name-brand medication.<sup>37</sup> On the whole, the benefits that Hatch-Waxman provides for generic companies has helped address price discrimination problems in a plethora of ways. Generic companies may

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29. Aaron Kesselheim et al., *The High Cost of Prescription Drugs in the United States Origins and Prospects for Reform*, 316 JAMA 858–71 (August 23/30, 2016), <https://phhp-bahealthscience-new.sites.medinfo.ufl.edu/files/2016/09/jsc1600151.pdf>.

30. Rick Mullin, *Cost to Develop New Pharmaceutical Drug Not Exceeds \$2.5B*, SCI. AM., (Nov. 24, 2014), <https://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/>; Jim Logan, *The Economics of Drug Pricing*, THE UC SANTA BARBARA CURRENT (Nov. 23, 2015), <http://www.news.ucsb.edu/2015/016151/science-drug-pricing>.

31. TOPHER SPIRO ET AL., CTR FOR AM. PROGRESS, ENOUGH IS ENOUGH: THE TIME HAS COME TO ADDRESS SKY-HIGH DRUG PRICES, 1, 18–19 (Sept. 2015), <https://cdn.americanprogress.org/wp-content/uploads/2015/09/15131852/DrugPricingReforms-report1.pdf>; AM.’S HEALTH INS. PLANS, HIGH PRICES OF PRESCRIPTION DRUGS INCREASE COSTS FOR EVERYONE, [https://www.ahip.org/wp-content/uploads/2015/05/High-Cost\\_Drugs\\_Slide\\_Deck.pdf](https://www.ahip.org/wp-content/uploads/2015/05/High-Cost_Drugs_Slide_Deck.pdf).

32. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585 (1984); S. REP. NO. 98–547 at 1585 (1984); Allen Sokal & Bart A. Gerstenblith, *The Hatch-Waxman Act: Encouraging Innovation and Generic Drug Competition*, FINNEGAN CURRENT TOPICS IN MEDICINAL CHEMISTRY (Winter 2010), <https://www.finnegan.com/en/insights/the-hatch-waxman-act-encouraging-innovation-and-generic-drug.html>.

33. *Id.*

34. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585 (1984).

35. *Id.* at 1585–86.

36. *Id.* at 1585–91.

37. *Id.*

now sell medications initially developed by name-brand companies without going through the same expensive research and development phase.<sup>38</sup> This allows generic drug companies to sell their medication at significantly reduced prices which, in turn, makes the generic medication accessible to a broader market of people.<sup>39</sup>

Before diving into cases that shape the issues related to generic medication failure to warn claims, it is important to briefly review preemption and the broader manufacturer liability landscape. Federal preemption is derived from the Supremacy Clause of the United States Constitution,<sup>40</sup> which establishes that state laws contrary to or interfering with the laws of Congress are invalid.<sup>41</sup> Federal preemption comes in three main flavors: express preemption, conflict preemption, and field preemption.<sup>42</sup> The aspects of preemption that are of particular import for inadequate warning label suits are conflict and field preemption.<sup>43</sup> Conflict preemption occurs when a state and federal law conflict in a way that makes it impossible to comply with both simultaneously, or because the state law interferes with the core purpose of the federal law.<sup>44</sup> Field preemption occurs when the extent of federal regulation is so extensive that it fully occupies the chosen field.<sup>45</sup> To prove field preemption, it must be demonstrated that the federal law was intended to occupy a field in a manner that leaves no room for any additional state regulation.<sup>46</sup>

Those who oppose allowing inadequate generic medication warning claims to proceed against name-brand manufacturers argue that either one or both of the aforementioned forms of preemption apply to actions based on harms stemming from faulty generic medication warnings.<sup>47</sup> Proponents for allowing such claims to proceed against name-brand manufacturers counter with a two-fold argument that federal regulation of medication does not preempt state tort claims.<sup>48</sup> As the

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38. Donald Dietz, White Paper: *Generic Drug Pricing: Understanding the Impact*, 1, 2 (2015), <http://www.wolterskluwer CDI.com/sites/default/files/documents/white-papers/ms-generic-pricing-info.pdf>.

39. *Id.*

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

41. *See infra* Part III.

42. *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472, 479–80, 512 (explaining the various forms of federal preemption).

43. *See infra* note 161.

44. Amanda G. Lewis, *Federal Preemption of State and Local Laws: State and Local Efforts to Impose Sanctions on employers of Unauthorized Aliens*, 1, 6 (May 2008), <https://web.law.columbia.edu/sites/default/files/microsites/career-services/Federal%20Preemption%20of%20State%20and%20Local%20Laws.pdf>.

45. *Id.* at 7.

46. *Id.*

47. Wolfman & King, *supra* note 1.

48. *Id.*

Court reiterated in *Wyeth v. Levine*,<sup>49</sup> there are “two cornerstones of our preemption jurisprudence” that control issues regarding federally regulated medication manufacturers: Congressional intent and federal recognition of police powers reserved by the states.<sup>50</sup> As the controlling medication labeling laws do not expressly preempt tort claims, and there is a presumption against interfering with state police powers, the cornerstones of preemption indicate that pursuit of failure to warn claims resulting from inadequate generic medication labels are viable.

Two early cases that had meaningful impacts on the expansion of manufacturer liability were *Henningsen v. Bloomfield Motors, Inc.*<sup>51</sup> and *Greenman v. Yuba Power Products, Inc.*<sup>52</sup> These precedents provided for strict liability in both contract and tort law, yet ultimately established that tort law principles, not contract law principles, should govern claims regarding defective products.<sup>53</sup> *Henningsen* involved the development of strict liability as a function of contract law, rather than tort law.<sup>54</sup> In that case, the Supreme Court of New Jersey, for all intents and purposes, created strict liability through enforcing an implied warranty of merchantability without a privity requirement.<sup>55</sup> This decision was followed by holdings across most jurisdictions which “adopted a tort version of strict liability independent of warranty theory.”<sup>56</sup> The shift towards tort law strict liability was exemplified by *Greenman*, a case decided by the Supreme Court of California, which definitively positioned tort law as the proper grounds for analyzing product defect personal injury claims.<sup>57</sup> These cases set the stage for modern developments in manufacturer liability tort common law.

A more recent manufacturer liability case is *Cipollone v. Liggett Group*.<sup>58</sup> This preminent case centered around whether injured cigarette smokers could hold cigarette companies liable for labeling their product in a manner that did not adequately warn of the dangers associated with smoking.<sup>59</sup> While the case ultimately resulted in a byzantine holding, it addressed many facets of

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49. 555 U.S. 555 (2009).

50. *Id.* at 565.

51. 161 A.2d 69 (N.J. 1960) (involving plaintiffs who were injured in a car accident that was caused by a steering defect in their Plymouth Plaza 6 Club Sedan ten days after delivery).

52. 377 P.2d 897 (Cal. 1963) (involving a plaintiff who sustained a head injury while using a Shopsmith combination saw, drill, and wood lathe tool in accordance with the instructions for that machine).

53. DAVID G. OWEN & MARY J. DAVIS, PRODUCTS LIABILITY AND SAFETY CASES AND MATERIALS, 153–60 (7th ed. 2015).

54. SHULMAN ET AL., *supra* note 12, at 583–86.

55. OWEN & DAVIS, *supra* at 53; *Henningsen*, 161 A.2d 69 (N.J. 1960).

56. SHULMAN ET AL., *supra* note 12, at 583–87.

57. OWEN & DAVIS, *supra* at 53; *Greenman*, 377 P.2d 897 (Cal. 1963).

58. 505 U.S. 504 (1992).

59. *Id.*



preemption and misrepresentation that help illuminate the failure to warn issue. Importantly, *Cipollone* supports the argument that misrepresentations are not necessarily preempted in the same way that other tortious actions are.<sup>60</sup> In reaching its decision the Court emphasized the importance of the presumption against preemption of state police powers, that federal warning label regulations do not automatically preempt the entire regulatory field or foreclose obligations imposed under state law, and that there is no general inherent conflict between federal regulation of warning labels and the continued vitality of state common law tort claims.<sup>61</sup> The underpinning of this holding was grounded in “the state law duty not to make false statements of material facts.”<sup>62</sup> The court held that the manufacturer’s duty was not predicated on any specific provision of the federal regulation, but rather grounded in a more general duty to provide accurate and non-deceitful information.<sup>63</sup> The court determined that allowing for a breach of this duty to be actionable at the state level was conducive to the federal regulatory scheme, and that it did not create the feared “diverse, nonuniform, and confusing standards.”<sup>64</sup> This holding expressly allows for the avoidance of preemption in faulty labeling misrepresentation cases.<sup>65</sup> As preemption is one of the two main hurdles that need to be overcome to hold medication manufacturers liable, this approach can be particularly useful when attempting to reveal a theory of liability that alleviates the suffering of countless harmed generic drug consumers.

### III. ANALYSIS OF DECISIONAL LAW

This paper now advances by providing analysis of noteworthy cases related to issues facing harmed consumers of mislabeled generic medications. This section reviews two Supreme Court holdings that handicap consumers’ ability to recover from generic manufacturers, two significant state court decisions that may be used to support name-brand manufacturer liability, three recent divergent state court decisions that were entered between 2017 and 2018, and a landmark Maryland Court of Appeals failure to warn case that may provide a framework which could allow harmed consumers of mislabeled generic medications to recover from name-brand manufacturers. The section concludes by noting two contexts where innovative claims rooted in misrepresentation and failure to warn have been gaining popularity.

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60. *Id.* at 531.

61. *Id.* 531–32.

62. *Id.* at 529.

63. *Id.*

64. *Id.*

65. *Id.*

*A. Supreme Court Decisions*

*PLIVA, Inc. v. Mensing* consolidated claims from two plaintiffs and centered around the respective liability of generic and name-brand drug manufacturers.<sup>66</sup> Ms. Mensing and Ms. Demahy were prescribed Reglan<sup>67</sup> to combat diabetic gastroparesis in 2001 and 2002.<sup>68</sup> Instead of receiving the name-brand version of this drug from their pharmacists, they each received and consumed generic versions of metoclopramide.<sup>69</sup> After both women took this medication as prescribed for several years, they suffered severe side-effects that the medication label did not adequately warn about.<sup>70</sup> Specifically, testing had suggested that “long term use of metoclopramide carries a risk of [developing] tardive dyskinesia<sup>71</sup> far greater than that indicated on the label.”<sup>72</sup> The women developed tardive dyskinesia after their prolonged use of metoclopramide.<sup>73</sup> At the time of the lawsuit, studies demonstrated that up to twenty-nine percent of patients who took metoclopramide for several years developed this condition.<sup>74</sup>

In their suit against the generic drug manufacturers, Ms. Mensing and Ms. Demahy alleged wrongful omission and failure to warn about the potential side-effects.<sup>75</sup> The generic manufacturer defendants responded by arguing that they could not be held responsible for the warnings on the label because federal regulations afforded them no ability to modify the language of the labels on the generic medication.<sup>76</sup> FDA regulations required that generic drug manufacturers copy the labels and warnings provided by name-brand manufacturers.<sup>77</sup> The defendants asserted that “it was impossible to simultaneously comply with both federal law and any state tort-law duty that required them to use a different label” than the name-brand manufacturer.<sup>78</sup>

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66. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 608 (2011).

67. A name-brand metoclopramide, which, as defined by the Mayo Clinic, is a medication used to treat the symptoms of a certain type of stomach problem called gastroparesis in patients with diabetes. It works by increasing the movements or contractions of the stomach and intestines. *Drugs and Supplements: Metoclopramide (Oral Route)*, MAYO CLINIC, <https://www.mayoclinic.org/drugs-supplements/metoclopramide-oral-route/description/drg-20064784> (last updated Oct. 1, 2018).

68. *PLIVA*, 564 U.S. at 610.

69. *Id.*

70. *Id.*

71. David Daiomov, *Tardive Dyskinesia*, COLL. OF PSYCHIATRIC & NEUROLOGIC PHARMACISTS, (CPNP), <https://www.nami.org/Learn-More/Mental-Health-Conditions/Related-Conditions/Tardive-Dyskinesia> (last updated Jan. 2016) (explaining that this ailment is a severe neurological disorder that impairs movement).

72. *PLIVA*, 564 U.S. at 610

73. *Id.*

74. *Id.* at 609.

75. *Id.* at 611.

76. *Id.*

77. *Id.* at 610.

78. *Id.*

The United States Supreme Court agreed with the defendant manufacturer and held that generic drug makers cannot be held liable for a failure to warn when they have fully complied with FDA regulations.<sup>79</sup> In making this decision, the Court appeared weary of infringing on the rightful actions of co-equal branches of government. Justice Thomas stated that the Court deferred to the FDA's interpretation of its own "changes-being-affected"<sup>80</sup> and generic medication labeling regulations.<sup>81</sup> Although the Court specifically noted that the tort law and federal regulation pairing dealt *Mensing, Demahy, and others* similarly situated, an "unfortunate hand," it ultimately decided that holding generic drug manufacturers liable for doing exactly as they were required to do would be unreasonable and unfair.<sup>82</sup> In this case, federal preemption was dispositive for determining where liability could fall when evaluating whether generic manufacturers could be held liable for inadequate warning labels.

Importantly, the *PLIVA* decision was directed towards generic manufacturers and not name-brand manufacturers. The *PLIVA* holding restricted means by which injured consumers of generic medication could hold generic drug manufacturers liable for harms suffered as a result of the generic manufacturer's failure to warn. Shortly after this decision, another blow was struck at the federal level against generic drug consumers seeking to hold generic manufacturer's liable.

*Mutual Pharmaceutical Co. v. Bartlett*<sup>83</sup> began with Ms. Bartlett being prescribed and subsequently using Clinoril<sup>84</sup> to alleviate chronic shoulder pain.<sup>85</sup> Unbeknownst to her, Ms. Bartlett was subjected to the possibility of developing toxic epidermal necrolysis, a debilitating side-effect of the medication.<sup>86</sup> Unfortunately, soon after beginning to use Clinoril, Ms. Bartlett was plagued with an acute case of toxic epidermal necrolysis which resulted in sixty-percent of her skin being destroyed.<sup>87</sup>

Ms. Bartlett was left severely disfigured, almost blinded and struggling with physical disabilities.<sup>88</sup> She sued Mutual Pharmaceutical on failure to warn and design defect grounds, but the District Court dismissed the failure to warn claim

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79. *Id.* at 619–20.

80. A major change requires the submission of a supplement and approval by FDA prior to distribution of the drug product made using the change. This type of supplement is called, and should be clearly labeled, a Supplement - Changes Being Effectuated in 30 Days. 21 C.F.R. § 314.70 (c)(3) (2018).

81. *PLIVA*, 564 U.S. at 615–17.

82. *Id.* at 625–26.

83. 570 U.S. 472 (2013).

84. A generic version of the anti-inflammatory drug, Sulindac. Clinoril, DRUGS.COM (June 3, 2015), <https://www.drugs.com/cdi/clinoril.html>.

85. *Bartlett*, 570 U.S. at 477–78.

86. *Id.* at 477–78

87. *Id.*

88. *Id.* at 478.

based on her doctor's "admi[ssion] that he had not read the box label or insert."<sup>89</sup> The doctor failed to properly inform that plaintiff and the plaintiff did not read the label or the informative insert that was provided with the generic drug. Ultimately, only the design-defect claim was tried.<sup>90</sup> A jury found that Mutual was liable to the plaintiff for \$21 million.<sup>91</sup>

Mutual appealed the decision, but the Court of Appeals affirmed the district court's ruling, holding that the Food and Drug Administration's regulations did not preempt the state tort law design defect claims.<sup>92</sup> The court distinguished this case from *PLIVA, Inc. v. Mensing*, arguing that because the risks and side effects were known to the manufacturer, the generic producer could have elected to not manufacture and sell the drug at all, thereby complying with both federal and state law.<sup>93</sup> The case was subsequently appealed to the Supreme Court, which reversed the First Circuit decision, holding that state-law warning label defect claims are preempted by federal law.<sup>94</sup>

In a 5–4 opinion written by Justice Alito, the Court held that state law design-defect claims based on the adequacy of a medication's warnings are preempted by federal regulations that prohibit generic drug manufacturers from independently changing FDA approved medication labels.<sup>95</sup> The principal support for the Court's holding was the Supremacy Clause and the implied preemption arising thereunder when "it is impossible for a private party to comply with both state and federal requirements."<sup>96</sup> New Hampshire state law obligated manufacturers to place stronger warnings on the generic drug labels, a requirement that was impossible to satisfy in light of the federal labeling restriction requirements.<sup>97</sup> The New Hampshire law was preempted by the Supremacy Clause, which establishes that federal law supersedes that of the states.<sup>98</sup>

The *Bartlett* decision reinforced the argument that generic drug manufacturers cannot be held liable for inadequate medication labeling when federal pharmaceutical regulation preempts the underlying state law claim. As detailed in the opinions for both *PLIVA* and *Bartlett*, a clear indicator that a state claim against a generic drug manufacturer is ripe for federal preemption is when it is impossible for the generic manufacturer to meet both state and federal legal

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89. *Id.* at 479.

90. *Id.*

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.* at 476.

95. *Id.* at 475–76.

96. *Id.* at 475.

97. *Id.*

98. *See supra* notes 40 & 41.

obligations.<sup>99</sup> The key difference between *Bartlett* and its predecessor, *PLIVA*, was that *Bartlett* undermined the ability to levy a design defect claim against generic manufacturers while *PLIVA* attacked the viability of failure-to-warn claims against generic manufacturers.<sup>100</sup> The outcomes of these two cases force the hand of any attorney seeking to find redress for injured generic drug consumers to take aim at name-brand manufacturer's rather than generic companies.

Justices Ginsberg and Sotomayor dissented from the majority in *Bartlett*, arguing that state law should not be preempted without evidence that Congress intended to supersede state law, especially in fields historically dominated by states.<sup>101</sup> Justice Sotomayor argued that Congress' objective in creating the law prohibiting alterations to generic medication labels was to improve consumer protection and that disallowing additional state tort protections does not further the consumer protection goal.<sup>102</sup> In fact, "[t]racing the history of federal drug regulation from the Federal Food and Drugs Act of 1906,<sup>103</sup> up to the Food Drug and Cosmetic Act and its major amendments,<sup>104</sup> the Court explained that federal drug law and state common-law liability have long been understood to operate in tandem to promote consumer safety."<sup>105</sup> It follows that state law requiring adequate warnings on labels does not frustrate the protection purpose, rather, it complements it. Accordingly, the New Hampshire design-defect laws effectively acted as an incentive to avoid strict-liability, not a mandate that product labels must be altered, and therefore the law should not have been struck down. The two dissenting Justices articulated that state laws which protect consumers by requiring adequate medication warnings are not irreconcilable with federal laws that provide guidelines for generic drug production and labeling.<sup>106</sup> While this reasoning is from a dissent, the concept of cooperative federal and state consumer protections is widely recognized.<sup>107</sup>

These Supreme Court rulings largely prevented injured generic drug consumers from holding generic manufacturers liable for harmful mislabeled medication. In reaching their decisions, the Justice's legal analysis centered on

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99. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 619–20 (2011); *Bartlett*, 570 U.S. at 501.

100. Wolfman & King, *supra* note 1, at 5.

101. *Bartlett*, 570 U.S. at 498.

102. *Id.* at 517.

103. Pure Food and Drug Act., 59 Pub. L. No. 59–384, 34 Stat.768 (1906).

104. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585 (1984).

105. *Bartlett*, 570 U.S. at 498; *Wyeth v. Levine*, 555 U.S. 555, 566–68 (2009).

106. *Bartlett*, 570 U.S. at 498.

107. Consumer Credit Protection Act, Pub. L. No. 90–321, 82 Stat. 146 (1968) (commonly referred to as the "Fair Credit Reporting Act"); Fair Debt Collection Practices Act, Pub. L. No. 95–109, 91 Stat. 874 (1977); *see generally* state adoptions of the Revised Uniform Deceptive Trade Practices Act, 75th HANDBOOK OF THE NAT'L CONFERENCE OF COMM'RS ON UNIFORM STATE LAWS AND PROCEEDINGS OF THE ANNUAL CONFERENCE MEETING 298, 315 (1966).

the liability of the generic company, rather than that of the name-brand manufacturer.<sup>108</sup> In turning to the state court holdings, it becomes clear that while there are limited ways to find a generic manufacturer liable, avenues which could provide redress for injured consumers of generic medications lead towards name-brand manufacturer liability.

### *B. Early State Court Decisions*

*Huck v. Wyeth, Inc.*,<sup>109</sup> a recent Iowa case, addressed the generic manufacturer versus name-brand manufacturer liability issue head-on.<sup>110</sup> As in *PLIVA*, the plaintiff in this case suffered serious side effects after taking a generic version of Reglan for several years.<sup>111</sup> She claimed the warning on the label was insufficient in relation to the potential harm, therefore the generic drug company had failed to adequately warn customers about the side effects associated with using their medication.<sup>112</sup> The primary issue in this case was that the generic manufacturer had not strengthened its warning label in accordance with changes made to the name-brand label in 2004.<sup>113</sup> Since the generic medication's label was not correctly updated with the proper "changes being affected," many consumers of the generic drug were unaware of the medication's significant risks.<sup>114</sup>

While *Huck* was pending, the United States Supreme Court decided *PLIVA*.<sup>115</sup> Relying on *PLIVA* and an earlier Iowa case, *Mulcahy v. Eli Lilly*,<sup>116</sup> the *Huck* court analyzed whether claims against either the name-brand or generic manufacturer might be successful.<sup>117</sup> Applying the rules reiterated in *PLIVA* and *Mulcahy*, the Iowa district court dismissed Huck's claims against all manufacturers.<sup>118</sup> The Iowa Court of Appeals affirmed this dismissal.<sup>119</sup> The district court and court of appeals dismissed the plaintiff's claims against the name-brand manufacturer because, to satisfy the causation element, Iowa law required that the defendant's drug, not the defendant's warning label, be the cause of plaintiff's injury.<sup>120</sup> In this case, the generic drug maker manufactured the physical medication, not the brand name-brand company, therefore the court

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108. See generally *Bartlett*, 570 U.S. 472 (2013); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011).

109. 850 N.W.2d 353 (Iowa 2014).

110. *Id.*

111. *Id.* at 359.

112. *Id.* at 363–66.

113. *Id.*

114. *Id.*

115. See generally *PLIVA, Inc., v. Mensing*, 564 U.S. 604 (2011).

116. 386 N.W.2d 67, 76 (Iowa 1986).

117. *Huck*, 850 N.W.2d at 364–65, 370; *PLIVA*, 564 U.S. 604; *Mulcahy*, 386 N.W.2d at 76.

118. *Huck*, 850 N.W.2d at 356.

119. *Id.*

120. *Id.*

held the name-brand manufacturer could not be liable.<sup>121</sup> The lower courts held that the plaintiff's claims were preempted by federal law.<sup>122</sup> The Court of Appeal's decision was submitted, and accepted, for review by the Iowa Supreme Court.<sup>123</sup>

The Iowa Supreme Court reversed the decision in part, allowing some of the claims to proceed against the generic manufacturer.<sup>124</sup> The Iowa Supreme Court found a narrow path around the federal preemption argument.<sup>125</sup> The court referenced numerous federal decisions and regulations in concluding that common law tort claims against generic manufacturers based on inadequate warnings are not preempted to the extent that the generic manufacturer failed to implement stronger warnings approved by the FDA in 2004.<sup>126</sup>

Citing *Cipollone*, the *Huck* court found that "there is no general, inherent conflict between federal pre-emption [sic] of state warning requirements and the continued vitality of state common-law damages actions."<sup>127</sup> This contention enhanced the court's argument that it was permissible for tort law claims to proceed against negligent manufacturers even when there may be federal regulations related to the subject matter of the tort action. In reaching its decision, the court nimbly navigated through a web of preemption triggers to allow the generic manufacturer to be held liable. They reasoned:

If Huck's claims against PLIVA do not require the company to change its labeling to differ from that of the approved label, they are not preempted. [citation omitted] ("[O]ur task remains to identify whether [plaintiff's] claims are predicated upon labeling and packaging requirements in addition to and different from those required by [federal law].").<sup>128</sup>

Finding that because Huck's claim only required PLIVA, Inc. to conform its label to the most recently FDA approved label, the claims not only were valid, they supported the mission of the federal regulation.<sup>129</sup>

The court relied on *Wyeth v. Levine*<sup>130</sup> and *Fulgenzi v. PLIVA, Inc.*<sup>131</sup> in its analysis of how state tort claims should be able to proceed against drug manufacturers.<sup>132</sup> *Levine* recognized that Congress has not provided a federal

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121. *Id.*

122. *Id.*

123. *Id.*

124. *Id.*

125. *Id.* at 364–66.

126. *Id.*

127. *Huck*, 850 N.W.2d at 366 (quoting *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 518(1992)).

128. *Id.*

129. *Id.* at 364–65 (citing *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 584 (6th Cir. 2013), "[C]ompliance with federal and state duties was not just possible; it was required.").

130. 555 U.S. 555 (2009).

131. 711 F.3d 578.

132. *Huck*, 850 N.W.2d at 357–58.

remedy for consumers harmed by prescription drugs and, as such, “state law offers an additional, and important, layer of consumer protection that complements FDA regulation.”<sup>133</sup> The *Levine* court explained how state tort suits help reveal drug hazards and incentivize the prompt disclosure of discovered safety risks by drug manufacturers.<sup>134</sup> Additionally, these claims create a financial motivation for injured consumers to come forward with information about harms they sustained, thereby potentially helping address dangerous faulty labeling issues.<sup>135</sup> In emphasizing the importance of allowing tort claims that can hold manufacturers accountable, the court noted that “[f]ailure-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>136</sup> Notably, the Court in *Levine* clearly established that claims against name-brand manufacturers are not preempted by federal law.<sup>137</sup> The *Fulgenzi* court also grappled with the differences between name-brand and generic medication manufacturer liability.<sup>138</sup> In evaluating the main thrust of the FDCA, the court singled out increased usage of generic drugs and the attendant lessening of costs for consumers as “[t]he most easily identifiable policy.”<sup>139</sup> The court noted that “[p]ermitting state tort actions to go forward against generic-drug manufacturers [rather than brand manufacturers] . . . would increase costs and reduce usage,”<sup>140</sup> practically defeating the central purpose of generic alternatives to name-brand medications. Recognizing the need to ensure consumer protection, the *Fulgenzi* court referenced the *PLIVA* dissenters’ observation that “the inability to sue for inadequate warnings may actually reduce consumer demand.” That being said, the *Fulgenzi* court did not endorse a correct way to protect consumers of generic medication, rather it explained that “[t]his is an empirical question, and we should not affirmatively answer on the basis of mere speculation about Congressional purposes.”<sup>141</sup>

With the *Levine* and *Fulgenzi* holdings factoring into its analysis, the *Huck* court appeared to be divided regarding imposing liability on the name-brand manufacturer. The majority ultimately held that the name-brand manufacturer

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133. See *Levine*, 555 U.S. at 579 (noting additionally that, “[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption [sic] provision at some point during the FDCA’s 70-year history”); see also *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 451 (2005).

134. *Levine*, 555 U.S. at 579.

135. *Id.*

136. *Id.*

137. *Levine*, 555 U.S. at 581.

138. 711 F.3d 578 (6th Cir. 2013).

139. *Id.* at 585.

140. *Id.*

141. *Id.*



cannot be liable when the plaintiff only consumed the generic drug.<sup>142</sup> Citing back to *Mulcahy*, the court applied Iowa law which required that the plaintiff establish their injury was “caused by a product sold or supplied by the defendant.”<sup>143</sup> This long-standing requirement barred Ms. Huck’s recovery from the name-brand manufacturers of a medication she, in one sense, never used. Under Iowa law at the time of this decision, manufacturers only owed a duty to consumers that are harmed by use of that specific manufacturer’s products.<sup>144</sup> The court asserted that they would “not contort Iowa’s tort law in order to create liability for brand manufacturers” and that “the unfairness [to potential plaintiffs] resulting from *PLIVA* is best addressed by the Congress or FDA.”<sup>145</sup>

The court’s holding provided a narrow avenue allowing recovery against generic manufacturers that had not met the requisite FDCA standards.<sup>146</sup> As a result of the generic manufacturer’s failure to match its warning label to the label on the name-brand medication, the generic manufacturer was open to liability.<sup>147</sup> “Huck’s claims fit into a “narrow gap”: she [was] suing for conduct that violate[d] the FDCA, but she [was] not suing *because* the conduct violate[d] the FDCA.”<sup>148</sup> While a positive outcome for injured consumers in this unique situation, the holding in *Huck* did not provide a remedy generally for injured consumers of mislabeled generic medications when those medication warning labels satisfy the required federal drug regulations. The support *Huck* provides for holding name-brand manufacturers liable is similar to the backing provided by *Levine*, that being endorsement of the concept that state claims should be used in concert with federal regulations, not barred by them.<sup>149</sup>

The first case fully endorsing protection for injured consumers of mislabeled generic medications did not arise until three years after *Huck*. In 2014, the Alabama Supreme court decided *Wyeth, Inc. v. Weeks*,<sup>150</sup> ruling that under a breach of duty to warn theory, name-brand manufacturers can be liable for harm caused by generic versions of their medication.<sup>151</sup> Mr. Weeks brought suit against drug manufacturers for injuries he sustained due to his long-term use of a generic version of Reglan.<sup>152</sup> Mr. Weeks’ harm stemmed from inaccurate

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142. *Huck v. Wyeth*, 850 N.W.2d 353, 381–82 (Iowa 2014).

143. *Huck*, 850 N.W.2d at 381–82 (quoting *Mulcahy v. Eli Lilly, & Co.*, 386 N.W.2d 67, 69 (Iowa 1986)).

144. *Id.* at 371.

145. *Id.* at 381 (citing *PLIVA, Inc., v. Mensing*, 564 U.S. 604 (2011)).

146. *Id.* at 370.

147. *Id.*

148. *Id.* at 369 (citing *In re Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010)).

149. *Id.* at 357–58.

150. 159 So.3d 649 (2014).

151. *Id.*

152. *Id.* at 653.

labeling on a generic drug and an alleged misinformation campaign.<sup>153</sup> These two occurrences led to Mr. Weeks's physician prescribing medication without knowing the complete array of potential side-effects.<sup>154</sup> After using the generic medication, Mr. Weeks developed tardive dyskinesia, a permanent movement disorder.<sup>155</sup> Mr. Weeks alleged the name-brand manufacturer had knowledge the medication could significantly increase the likelihood that a patient would develop tardive dyskinesia and the manufacturer failed to adequately warn of this side-effect.<sup>156</sup>

The circumstances in this case gave rise to a consideration of whether name-brand manufacturers can be liable for harm caused by the combined use of labeling language it created and a product it did not manufacture.<sup>157</sup> The difficulty with this case, and other cases of this nature, is that the harm was caused by a misrepresentation regarding a generic medication, but that that misrepresentation was first authored by the name-brand manufacturer for its own medication.<sup>158</sup> The only reason the misrepresentation was on the generic label was because federal law required that the generic label contain the exact same information as the name-brand product label.<sup>159</sup> Plaintiff claimed that the name-brand manufacturer had breached its reasonable duty of care because it failed to warn Mr. Weeks or his physician of the potential dangers associated with the generic version of the name-brand medication.<sup>160</sup> This argument is a version of manufacturer liability, which is rooted in the idea that there is enough of a nexus between the name-brand manufacturer and the generic manufacturer to open the name-brand manufacturer up to liability.<sup>161</sup> The defendant companies claimed that this dispute should be judged under a product liability standard and under said standard plaintiffs could not present a *prima facie* case.<sup>162</sup> The defendant's primary arguments were that the plaintiffs (i) failed to affirmatively identify the name-brand product as the product that caused the harm and (ii) the name-brand

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153. *Id.*

154. *Id.* at 653–55.

155. *Id.* at 656.

156. *Id.*

157. *Id.* at 653–54.

158. *Id.*

159. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585 (1984).

160. *Weeks*, 159 So.3d at 656.

161. Victor E. Schwartz et al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs has Severe Side Effect*, 81 FORDHAM L. REV. 1835 (2013). Some critics of name-brand manufacturer liability cunningly have deemed this form of liability “innovator liability” to create a bias against holding those who first create medications liable. Victor E. Schwartz et al., *Deep Pocket Jurisprudence: Where Tort Law Should Draw the Line*, 70 OKLA. L. REV. 359, 360–61 (2018).

162. *Weeks*, 159 So.3d at 656.

manufacturers had no duty to warn consumers about the risks associated with ingestion of the generic version of their medication.<sup>163</sup>

The court applied existing Alabama law to determine whether the name-brand manufacturer could be held liable for false representations on the warning labels that it created, which were subsequently copied by generic companies.<sup>164</sup> The court asserted that state case law established “a duty to disclose may be owed to a person with whom the defendant has had no prior dealings, specifically, where there is a duty not to make a false representation to those members of a group or class that the defendant has special reason to expect to be influenced by the representation.”<sup>165</sup>

The Supreme Court of Alabama ruled against the name-brand manufacturer, finding that because of FDA regulations and the close relationship between name-brand and generic medications, it was foreseeable that generic medication consumers would have to rely on warnings drafted by name-brand manufacturers.<sup>166</sup> Due to the federal regulations on prescription-drugs, Wyeth had “special reason to expect” that the information presented on its metoclopramide labeling was “intended to reach and influence” users of both the name-brand and generic versions of the medication.<sup>167</sup>

This ruling also furthered the common public policy goal of reducing tortious conduct by creating a duty for name-brand manufacturers to ensure proper warnings are provided to consumers of both name-brand and generic medications.<sup>168</sup> This decision added an incentive for name-brand manufacturers operating in Alabama to adequately warn drug prescribers of the risks associated with the name-brand and generic medications, so that prescribers could accurately relay those risks to end-consumers.<sup>169</sup> Under this precedent, if name-brand manufacturers provide adequate warning to the prescribers of medication, then the manufacturer has likely satisfied its duty to the end users.<sup>170</sup> Conversely, if there is a failure to warn and the deficiencies, misrepresentations, or inadequate warnings were created by the name-brand manufacturer, that manufacturer can be held liable for the harm caused thereby.<sup>171</sup>

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163. *Id.* at 353–54.

164. *Id.* at 679.

165. *Id.*

166. *Id.* at 680.

167. *Id.* at 681.

168. *Id.* at 676–77.

169. *Id.* at 681–82.

170. *Id.* at 680–81.

171. *Id.*

*C. 2017-2018: Divided Times*

Providing an adequate remedy for consumers that are harmed by generic drugs remains a hot-topic in the tort law world. In the short time spanning between December 21, 2017 and May 11, 2018 there were three state court decisions addressing this conundrum.<sup>172</sup> Fortunately for consumers, two of the three courts, the Supreme Court of California and the Supreme Judicial Court of Massachusetts, recognized name-brand manufacturer liability.<sup>173</sup> Accepting the defendant's policy argument, the Supreme Court of Appeals of West Virginia did not adopt name-brand manufacturer liability,<sup>174</sup> and seemingly gave little regard to the central tort principle that the party responsible for causing harm should be liable for the suffering they created.<sup>175</sup>

*T.H. v. Novartis* arose from birth defects caused by a mother's use of mislabeled medication and sustained by children in utero.<sup>176</sup> In arriving at its decision to hold name-brand manufacturer's liable when the inadequate labeling they created injured a consumer of the generic product, the *T.H.* court identified a number of key facts that guided its reasoning.<sup>177</sup> The court noted:

Federal law explicitly conveys to the brand-name manufacturer—and only that manufacturer—the responsibility to provide an adequate warning label for both the [generic medication] and its brand-name equivalent... Only the brand-name manufacturer has unilateral authority to modify the drug's label... Generic drug manufacturers are required to follow the brand-name manufacturer's label to the letter. Accordingly the [name-brand manufacturer] controlled both the form and content of the [ ] warning label.<sup>178</sup>

Recognizing that within the pharmaceutical marketplace name-brand manufacturer's control the medication labeling, the court found the plaintiff's reliance on the RESTATEMENT SECOND OF TORTS § 311,<sup>179</sup> persuasive.

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172. See *T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18 (Cal. 2017); *Rafferty v. Merck & Co.*, 92 N.E.3d 1205 (Mass. 2018); *McNair v. Johnson & Johnson*, 818 S.E.2d 862 (W.Va. 2018).

173. *T.H.*, 407 P.3d at 47–48; *Rafferty*, 92 N.E.3d at 1219–20.

174. *McNair*, 818 S.E.2d at 856, 861.

175. George Mason Law and Economics Center, *Congressional Civil Justice Academy Debate: Inventing New Liability? Who Should We Blame When Generic Drugs Harm Patients?*, VIMEO (Feb. 9, 2018), <https://vimeo.com/255119753>. Leslie A. Brueckner, a senior attorney at Public Justice and lead counsel in the *T.H.* case, noted that the argument in favor of innovator liability is founded upon the fundamental principle that those responsible for injuring others should be held responsible.

176. *T.H.*, 407 P.3d at 22.

177. *Id.* at 28–29.

178. *Id.* at 22.

179. RESTATEMENT (SECOND) OF TORTS, §311 (AM. LAW INST. 1979) provides that “[o]ne who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results to the other or to such third persons as the actor should expect to be put in peril by the action taken.” Comment b to §311 explains that this section “finds particular application where it is a part of the actor's business or profession to give information upon which the safety of the recipient or a third persons depends.” See also Prosser,

Importantly, the Court's analysis provides significant insight regarding the impact of foreseeability in inadequately labeled medication cases.<sup>180</sup> In California, as in many other jurisdictions, foreseeability of physical harm is the most important factor in determining the appropriate duty of care.<sup>181</sup> The court found that, since only name-brand manufacturers have a federally imposed duty to update the warning labels, name-brand manufacturers know to a legal certainty that "any deficiencies in the label for its drug will be perpetuated in the label for its generic bioequivalent."<sup>182</sup> The court determined that this knowledge, paired with often required substitution practices,<sup>183</sup> made it entirely foreseeable that the warnings included or not included on the name-brand drug label would influence the administration of the generic drug.<sup>184</sup> A combined application of the court's interpretation of the federal regulations, California precedent and long-recognized tort principles led the Supreme Court of California to find that "brand-name drug manufacturers have a duty to use ordinary care in warning about the safety risks of their drugs, regardless of whether the injured party (in reliance on the brand-name manufacturer's warning) was dispensed the brand name or generic version of the drug."<sup>185</sup>

Endorsement of name-brand manufacturer liability on the East Coast was provided by the *Rafferty* court, which found consumers "may bring a common-law recklessness claim against [a] brand-name manufacturer if it failed to update the label on its drug, knowing or having reason to know of an unreasonable risk of death or grave bodily injury associated with its use."<sup>186</sup> This case arose from injurious side effects related to a generic medication that was used to treat enlarged prostates.<sup>187</sup> While the court reiterated that "brand-name manufacturers are in the best position...to prevent an injury arising from the inaccurate or inadequate warning on a generic drug,"<sup>188</sup> it provided a slightly limited application of name-brand liability, allowing claims to proceed for recklessness, rather than garden-variety negligence.<sup>189</sup> The court's reasoning for this decision

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*Misrepresentation and Third Persons* (1966) 19. VAND. L.REV. 231, 254 (explaining that individuals have a duty to refrain from making false statements to "[t]hose to whom a public duty is found to have been created by statute, or pursuant to a statute. . . [and to] [t]hose members of a group or class whom he has special reason to expect to be influenced by the misrepresentation.").

180. *T.H.*, 407 P.3d at 29.

181. *Id.*

182. *Id.*

183. Substitution regulations generally are either legal statutory requirements or insurance company procedures that result in the generic drug being provided by the pharmacist in lieu of the name-brand drug. *T.H.*, 407 P.3d at 29–30.

184. *Id.*

185. *Id.* at 47.

186. *Rafferty v. Merck & Co.*, 92 N.E.3d 1205, 1209 (Mass. 2018).

187. *Id.* at 1211–12.

188. *Id.* at 1217.

189. *Id.* at 1217–18.

largely centered upon policy implications and societal risk-benefit analysis.<sup>190</sup> The court held that “public policy is not served if generic drug consumers have no remedy for the failure of a brand-name manufacturer to warn in cases where such failure exceeds ordinary negligence, and rises to the level of recklessness.”<sup>191</sup> Now, under Massachusetts law, consumers can hold name-brand manufacturers liable when they intentionally fail to “update the label on its drug to warn of an unreasonable risk of death or grave bodily injury, where the manufacturer knows of this risk or knows of facts that would disclose this risk to any reasonable person.”<sup>192</sup> The approach employed in *Rafferty* is agreeable with the balance struck in the Hatch-Waxman amendments, provides only a slight threat of increased litigation to pharmaceutical companies and could be a happy medium for jurisdictions that are not yet comfortable adopting a negligence-based theory for recovery against name-brand manufacturers for inadequate medication warning labels.

Contrary to the two decisions detailed immediately above, the *McNair* holding rejected name-brand manufacturer liability and held fast to a restrictive mislabeled generic medication analysis.<sup>193</sup> *McNair* arose from the plaintiff’s development of acute respiratory distress after taking a generic medication. This controversy came before the court on order of the United States Court of Appeals for the Fourth Circuit certifying the following question:

Whether West Virginia law permits a claim of failure to warn and negligent misrepresentation against a branded drug manufacturer when the drug ingested was produced by a generic manufacturer.<sup>194</sup>

The court answered this question in the negative.<sup>195</sup> The *McNair* decision, without including significant discussion of foreseeability or the responsibility of the name-brand manufacturer to update warning labels, hinged on the basic idea that liability is usually premised on the defendant being the manufacturer or seller of the product in question.<sup>196</sup> Inexplicably, in reaching this conclusion, the *McNair* court cited to Maryland law without regard to recent developments in Maryland precedent.<sup>197</sup> The *McNair* court did not heed the holding in *May v. Air & Liquid Systems Corporation*, as explained below, which allowed a manufacturer to be held liable for harm arising from the combined used of the manufacturer’s inadequate warning and another product.<sup>198</sup> Furthermore, the

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190. *Id.* at 1215–18.

191. *Id.* at 1215–19.

192. *Id.* at 1220.

193. *McNair v. Johnson & Johnson*, 818 S.E.2d 852, 861 (W.Va. 2018).

194. *Id.* at 856.

195. *Id.*

196. *Id.* at 859–60.

197. *Id.* at 864–65.

198. *See infra* note 202 and accompanying text.

West Virginia decision reviewed how the medication label and underlying product are inherently different items, but dismissed the ability to separate the two in regard to where liability should fall.<sup>199</sup> Where the legal foundation appeared unsound, the court relied on popular judicial sentiment to bolster its position, citing multiple times to the fact that the majority of states had not yet adopted name-brand manufacturer liability.<sup>200</sup> The *McNair* court ultimately held that there is not a cause of action in West Virginia for failure to warn and negligent misrepresentation against name-brand manufacturers when the ingested drug was a generic.<sup>201</sup>

#### D. The Home Front

Facing down a what appears to be an evolving, yet stubborn swath of precedent leaving injured generic consumers without redress, I now turn to *May v. Liquid Air Systems*, a decision that identified scenarios where manufacturers can be held liable for harm caused by the combined use of their inadequate warning and another product.<sup>202</sup> In *May*, the Maryland Court of Appeal's application of widely-accepted tort rules pertaining to duty and causation allow plaintiffs to hold manufacturers to a necessary and reasonable standard.<sup>203</sup> The crux of this holding is grounded in the traditional tort concept that liability should fall on the party that is responsible for the harm, best positioned to make the plaintiff whole and most able to prevent future injury.<sup>204</sup> Similar to the consumer-friendly decision in *Weeks*, the court in this case also recognized the importance of foreseeability in determining when a duty is owed by a manufacturer to an injured plaintiff.<sup>205</sup>

The *May v. Liquid Air Systems* court emphasized that in strict liability and negligence actions involving personal injury, the principal determinant of duty is foreseeability.<sup>206</sup> Although this decision involved harms created by asbestos-containing products,<sup>207</sup> the court's legal analysis framework can be applied to other tort claims, such as pharmaceutical negligent failure to warn and strict liability design defect actions. A brief review of the *May* decision provides context for the application of its framework in other situations.

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199. *McNair*, 818 S.E.2d at 861.

200. *Id.* at 863–65.

201. *Id.* at 867.

202. 129 A.3d 984 (Md. 2015).

203. *Id.*

204. SHULMAN ET AL., *supra* note 12, at 573–609.

205. *Compare* *Wyeth, Inc. v. Weeks*, 159 So.3d 649 (Ala. 2014) *with* *May v. Air & Liquid Systems*, 129 A.3d 984 (Md. 2015).

206. *May*, 129 A.3d at 994 (citing *Doe v. Pharmacia & Upjohn Co., Inc.*, 388 Md. 407, 416 (2005) and *Jacques v. First Nat'l Bank of Md.*, 307 Md. 527, 534–35 (Md. 1986)).

207. *May*, 129 A.3d at 986–87.

In *May*, replacement asbestos-containing gaskets were necessary for the proper functioning of the manufacturer's product.<sup>208</sup> Repairmen needed to replace those gaskets multiple times, and each time they did so they were exposed to asbestos.<sup>209</sup> One of the repairmen who subsequently suffered from asbestos-related disease brought suit against the original system manufacturers for their failure to warn of the dangers associated with replacement gaskets, even though the original manufacturers did not make the replacement parts that directly exposed Mr. May to asbestos.<sup>210</sup>

The court reasoned that the foreseeability of harm to workers servicing pumps with asbestos gaskets and packing was especially strong where a manufacturer knew or should have known that those components were necessary to the proper functioning of its product and must be replaced periodically.<sup>211</sup> The court proceeded by evaluating seven factors to determine whether their collective weight favored imposing a duty.<sup>212</sup> Those factors were:

1. Foreseeability;
2. Degree of certainty that the plaintiff suffered harm;
3. The closeness of the connection between the defendant's conduct and the injury suffered;
4. The extent of the burden to the defendant and the consequences to the community of imposing a duty to exercise care;
5. Moral blame;
6. The policy of preventing future harm;
7. The availability, cost and prevalence of insurance.

As Maryland law reflects that the foreseeability of harm factor is a significant determinant of whether or not a duty exists, and it favored imposing a duty in this case, there was a compelling argument in favor of finding that a

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208. *Id.* at 994–95.

209. *Id.* at 986–90.

210. *Id.* at 986–87.

211. *Id.* at 994.

212. *Id.* at 989–94; *see also* Rowland v. Christian, 443 P.2d 561, 567 (Cal. 1968) (providing a clear application of the factors that can be used to determine when a duty is owed by a tortfeasor and plaintiff); Dillon v. Legg, 441 P.2d 912, 919 (Cal. 1968) (demonstrating that foreseeability is the primary factor in determining whether a duty existed); Tarasoff v. Regents of the Univ. of Cal., 551 P.2d 334, 342, 344 (Cal. 1976) (demonstrating an application of the Rowland analysis, and establishing that a special relationship between two parties that are sufficiently involved can create a duty for one party “to assume some responsibility” to the other party in the relationship or third parties that may be harmed). In California, this factor-based analysis is applied when the defendant is acting affirmatively, while in Maryland the factor-based approach has been applied in many different contexts and has not been circumscribed to limited situations, as illustrated in Patton v. U.S. Rugby Football, 851 A.2d 566, 571 (Md. 2004) (citing Ashburn v. Anne Arundel Cty., 510 A.2d 1078, 1083 (Md. 1986)).



duty existed.<sup>213</sup> When the court balanced the subsidiary factors along with the predominant foreseeability factor, finding a duty was the appropriate choice.<sup>214</sup> Thus, the court decided that manufacturers sometimes have a duty to provide adequate warnings for products that the manufacturer did not produce and failure to do so may result in liability.<sup>215</sup>

Having identified that manufacturers can have a duty to warn about defective products that they did not place into the stream of commerce, the *May* court next addressed what is required to prove factual causation and impose liability in these scenarios. Utilizing the language provided by the Supreme Court of California in *O'Neil v. Crane Co.*,<sup>216</sup> the Maryland Court of Appeals reasoned that a product manufacturer may be held liable in strict liability or negligence for harm caused by another manufacturer's product when the defendant's own product contributed substantially to the harm, or the defendant participated substantially in creating a harmful combined use of the products.<sup>217</sup>

In *May*, it was undisputed that the defendant had sold asbestos laden component parts to the Navy and that those parts would be used by the Navy in mechanical pumps.<sup>218</sup> The employment record demonstrated that the plaintiff, as a mechanic who worked for the Navy, performed maintenance on the mechanical pumps, was required to handle replacements for the original manufacturer's defective component parts and relied on the associated instruction manuals for the products that the component parts were incorporated in.<sup>219</sup> Significantly, the defendant manufacturer did not refute the allegation that it knew the asbestos pumps were dangerous and that they would need to be replaced periodically, rather the defendants claimed that the needs of the war effort should excuse their conduct.<sup>220</sup> Mr. May made clear that he would have relied on warnings related to asbestos had they been in the instruction manual, as he always conducted maintenance in accordance with the instruction manual.<sup>221</sup> Therefore had the instruction manuals contained adequate warnings, Mr. May would have been able to minimize exposure to asbestos and prevent the injury he suffered.<sup>222</sup> The court held that there was sufficient factual support to demonstrate causation as it pertained to a negligent failure to warn claim.<sup>223</sup> Additionally, "[b]ecause of the intersections between strict liability and negligent failure to warn claims," the

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213. *May*, 129 A.3d at 994.

214. *Id.* at 1000.

215. *Id.*

216. 266 P.3d 987 (Cal. 2012).

217. *May*, 129 A.3d at 995 (citing *O'Neil v. Crane Co.*, 266 P.3d 987, 991 (Cal. 2012)).

218. *Id.* at 986.

219. *Id.* at 986-87.

220. *Id.* at 993.

221. *Id.* at 986-87.

222. *Id.*

223. *Id.* at 996.

May court also concluded “that a manufacturer has a duty to warn of asbestos-containing replacement components that it has not placed into the stream of commerce in strict liability in the same narrow circumstances as in negligence.”<sup>224</sup> The manufacturer had a duty to warn the plaintiff about the dangers associated with the asbestos gasket replacement process and the manufacturer breached that duty when they failed to supply adequate warnings. This case illustrates a manner by which manufacturers can cause harm by supplying an inadequate warning and be held accountable for the harm arising from that failure to warn.

Utilizing the duty and causation analysis applied by the Maryland Court of Appeals could provide injured consumers of generic drugs a way to hold name-brand manufacturers liable. While some may critique this form of liability because it holds parties liable that have recently been able to escape responsibility, it is merely a function of widely accepted tort principles.<sup>225</sup> By using well-settled law in a nuanced combination,<sup>226</sup> this theory allows courts to place liability on tortfeasors that bear responsibility for creating an inadequate warning regarding another manufacturer’s product, even when the tortfeasor was not privy to the final product purchase transaction. Before demonstrating that analysis, we will briefly review two contexts that already allow duty and causation to be established in a similar manner.

#### *E. Liability Without Privity: Architects*

In addition to the *May* holding, there have been other courts that found parties liable even though they were not privy to the transaction giving rise to harm. Construction professionals are one such group that has been found liable in the absence of privity. *Ossining Union Free School Dist. v. Anderson*,<sup>227</sup> is a case that demonstrates how courts hold parties liable for harm they have caused through misrepresentation.<sup>228</sup> While not all aspects of this case are directly applicable to mislabeled generic medication lawsuits, components of the legal analysis are directly transferrable.

In *Ossining*, a consulting engineer who was hired by a head project architect was sued by the project owner for negligent misrepresentation.<sup>229</sup> The court posed the question whether “in negligent misrepresentation cases . . . is privity of contract required in order for plaintiff to state a cause of action?”<sup>230</sup> The court responded that bringing a valid action required the underlying relationship

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224. *Id.* at 998.

225. RESTATEMENT (SECOND) OF TORTS §§ 18, 282, 283, 388, 402A, 402B (AM. LAW. INST. 1965).

226. *See infra* Part IV.

227. 539 N.E.2d 91 (N.Y. 1989).

228. *Id.*

229. *Id.* at 92.

230. *Id.* at 91.

between the parties to be one of “contract or the bond between them so close as to be the functional equivalent of contractual privity.”<sup>231</sup> The court defined privity of contract “as a means of fixing fair manageable bounds of liability.”<sup>232</sup> The court adhered to the long-standing rule for recovery of pecuniary loss for negligent misrepresentation that requires privity or “a relationship so close as to approach that of privity.”<sup>233</sup>

In finding that the project owner’s intended reliance created the sufficient “bond,” even though there was no semblance of a contract or traditional privity, the court determined that liability may arise when there is awareness that information is to be used for a particular purpose, there is reliance by a party in furtherance of that purpose and there is some conduct by the defendants linking them to the reliant party and evincing defendant’s understanding of the reliant party’s reliance.”<sup>234</sup> The court held that the facts alleged by the owner against the consultants satisfied these criteria.<sup>235</sup> Through direct contact with plaintiffs, information transmitted by the contracting architect and the notice of work, the consultants “could not have possibly failed to know that the plaintiff would receive and use the engineering report.”<sup>236</sup>

The two important takeaways from this precedent are that (i) a party’s intended reliance on the representations of a tortfeasor can create grounds for establishing a duty in tort cases and (ii) that it is permissible to hold a tortfeasor liable for causing harm to a plaintiff through the tortfeasor’s acts or omissions, even when the harm stems strictly from inaccurate representations or warnings provided by the tortfeasor.<sup>237</sup> Although there is more than mere pecuniary loss involved in our mislabeled generic medication cases, the principle that reliance by party “Y” on party “Z” can create a bond or nexus which allows for a defendant party to be found liable may be applicable in the inadequate medication label context.<sup>238</sup> One can identify how the principles applied in *Ossining* could also be used in generic medication failure to warn actions when plaintiffs are attempting to hold a name-brand manufacturer liable. The modified application could take the following form:

Under this theory, name-brand manufactures may be liable for a generic consumers’ harm when the (i) the name-brand manufacturers have an awareness that their advertisements and warnings reach prescribers and consumers when decisions are made about using a generic medication; (ii) there is reliance by

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231. *Id.*

232. *Id.*

233. *Id.* at 94.

234. *Id.* at 95; *Credit Alliance Corp. v. Andersen & Co.*, 493 N.Y.S.2d 435, 443 (N.Y. 1985).

235. *Ossining Union Free School Dist.*, 539 N.E.2d at 95.

236. *Id.*

237. *Id.*

238. *Id.*

prescribers and consumers on the name-brand warnings and information campaigns; and (iii) the name-brand manufacturer's assertions and conduct evidence the name-brand manufacturer's understanding that the prescribers and consumers of generic drugs would rely on their representations.

A presiding judge could find that the facts alleged by generic consumers against name-brand manufacturers satisfy these criteria. Based on direct contact with generic consumer plaintiffs via advertisements, removed contact through warning information transmitted by information campaigns, and compliance with the federal medication labeling regulations, it is foreseeable to name brand-manufacturers that generic consumers receive and rely on name-brand manufacturer medication warnings. This foreseeability should give rise to a duty that would be breached if the name-brand manufacturer failed to provide an adequate warning, which subsequently causes harm to the end consumer that relied on the inadequate warning.

#### *F. Leaving the Door Open*

There have been additional carveouts introduced by courts across the country that allow manufacturers to be held liable for products they did not create. California is one such jurisdiction that, even before its 2018 adoption of name-brand manufacturer liability, provided an avenue for holding manufacturers liable for harm caused by the combined use of their inadequate warning labels with another manufacturer's product.<sup>239</sup> *O'Neil v. Crane Co.* demonstrates how California courts left the door open for harmed consumers to redress their injuries.<sup>240</sup> This wrongful death case arose from a death that was allegedly caused by asbestos released from third party products that were added to the defendant's product post-sale.<sup>241</sup> It differs from the *May* decision in that the original product produced by the defendant did not contain asbestos.<sup>242</sup>

The California Supreme Court explicitly held that "a product manufacturer may not be held liable in strict liability or negligence for harm caused by another manufacturer's product unless the defendant's own product contributed substantially to the harm."<sup>243</sup> The court determined that when a defendant participated substantially in creating a harmful combined use of the products, as the manufactures did in *May*, the original manufacturer, can be held liable.<sup>244</sup> The *O'Neil* court thus recognized that a manufacturer is generally not liable for component parts it did not touch, but can be liable in certain circumstances.<sup>245</sup>

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239. *O'Neil v. Crane Co.*, 266 P.3d 987 (Cal. 2012).

240. *Id.*

241. *Id.* at 991.

242. Compare *May v. Air & Liquid Systems*, 129 A.3d 984 (Md. 2015) with *O'Neil*, 266 P.3d 987.

243. *O'Neil*, 266 P.3d at 991.

244. *Id.* at 1005.

245. *Id.*

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The provision that allows for liability when the original manufacturer participated substantially in the harmful combined use of the products could be applicable in the generic medication mislabeling context.

#### IV. TACKLING THE TWO KEY ISSUES

Having reviewed the guiding precedent, this paper now connects legal theories that may allow injured consumers of mislabeled generic drugs to be made whole. Addressing this problem involves overcoming the two primary issues that permeate the case law above: (i) establishing there was both a duty owed and causation and (ii) escaping the effects of federal preemption. This paper addresses each in turn.

##### *A. Establishing the Elements of Duty and Causation*

Of the two primary legal obstacles, this section first addresses the imposition of a duty and how to prove causation. Fortunately for injured consumers, case law demonstrates that proving breach and damages in inadequate warning label claims usually is achieved without significant challenges.<sup>246</sup> Therefore this section does not provide further review of those elements, rather it delivers extensive analysis of the two problematic elements—duty and causation. From the reasoning in *May*, *Weeks*, *Ossining*, *Novartis* and *Rafferty* one can derive ample support for establishing duty and causation as they pertain to harm suffered by generic medication consumers that stems from inadequate warnings from name-brand manufacturers.

##### *i. Imposing a Duty*

A logical starting point for a plaintiff that was injured because of reliance on an inadequate medication warning label would be to apply the factor-based analysis set forth in *May* to establish that they were owed a duty by the name-brand manufacturer.

##### *1. Foreseeability*

The foreseeability of harm to a consumer of generic medication who must rely on inadequate medication warning information created by a name-brand manufacturer weighs heavily in favor of imposing a duty on name-brand manufacturers to provide adequate warnings to consumers of generic medication. As a result of federal regulations that require generic labels to match name-brand labels, there can be no doubt that name-brand manufacturers have notice that their actions will reach and influence consumers of the generic version of their

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246. See discussion *supra* Section III.C, III.D.

medication.<sup>247</sup> These facts support a contention that the foreseeability of harm factor weighs in favor of imposing a duty on the name-brand manufacturer.

*2. Degree of certainty that the plaintiff suffered harm*

The “degree of certainty that the plaintiff suffered the injury” also weighs in favor of imposing a duty on name-brand manufacturers in inadequate medication labeling cases. Name-brand drug manufacturers cannot effectively contest that injured consumers of mislabeled generic medication suffered as a result of their failure to warn. Only name-brand manufacturers can change what is on the labels that warn consumers of both generic and name-brand versions of a medication.<sup>248</sup> When a serious side-effect is not warned about and a consumer is injured, the potential plaintiff has, by definition, suffered harm. In these cases, the harm suffered is usually not minor.<sup>249</sup> The injuries can range from severe movement disorders to the destruction of large portions of consumers’ skin.<sup>250</sup> This factor favors imposing a duty.

*3. The closeness of the connection between the defendant’s conduct and the injury suffered*

This factor also weighs in favor of holding the name-brand manufacturer liable. The name-brand manufacturer did all the drug testing, explained the dangers of the medication to the prescriber, and printed the warning labels that the generic manufacturers had to copy (which the generic consumer was forced to rely on).<sup>251</sup> But for the failure to warn by the name-brand manufacturers, consumers of mislabeled generic drugs would not have been harmed. Furthermore, a duty to warn may arise if the manufacturer knows that its product will be interchanged with the generic medication and that the two will be represented as being essentially the same product.<sup>252</sup> Given that federal medication labeling laws and many state “substitution” laws provide notice that name-brand products and generic products can be interchanged, name-brand manufacturers either are aware or should be aware that their goods and generics will be represented as essentially the same product.<sup>253</sup>

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247. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585 (1984).

248. *Id.*; *T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18, 22 (Cal. 2017).

249. *See* discussion *supra* Sections III.A, III.B.

250. *See* discussion *supra* Sections III.A, III.B.

251. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585 (1984); *T.H.*, 407 P.3d 22–23.

252. *See generally* *Wyeth, Inc. v. Weeks*, 159 So.3d 649 (2014).

253. *See supra* note 183 and accompanying text.

*4. The extent of the burden to the defendant and the consequences to the community of imposing a duty to exercise care*

This factor can go either way based on how a court analyzes it. The burden on the manufacturer of adding a few words to the label it prints is negligible, especially in comparison to the harm that consumers may suffer in the event that the label is not updated, and the consumers are unaware of potential risks. If that is the only burden considered, this factor would favor imposing a duty and possibly liability. If the burden includes a significant amount of costly additional testing that would need to be completed to identify new issues, this factor could result in a finding that favors manufacturers instead of consumers. Where there is large amount of expensive testing required to improve the label and the potential harm is slight, then this factor may favor not imposing a burden and liability.

*5. Moral blame*

This factor likely goes against imposing a duty and liability. Since the name-brand manufacturer likely did not knowingly keep information off the label, it is difficult to assign moral blame to their actions.<sup>254</sup> This factor could become radically more influential in the event that either the generic or name-brand manufacturer actively ensured that negative information about its medication was hidden from the public domain.<sup>255</sup> If that was the case, and as a result harm befell consumers, there would be a more effective argument for assigning moral blame.

*6. The policy of preventing future harm*

This factor is in favor of imposing a duty and liability. If there is a medication that has harmful side effects that are not accounted for on the label, then adding the additional warnings will help reduce future harm. Since only the name-brand manufacturer can rightfully change the label,<sup>256</sup> they should be the ones held liable when the label does appropriately reflect the potential harms of a medication. Generic manufacturers are not allowed to independently change the medication warning labels,<sup>257</sup> so they should not be held liable for injuries related to inadequate labeling. In fact, the only ability that generic companies have to affect change is to bring concerns to the FDA and name-brand company

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254. If the manufacturer knowingly kept information off the label, the plaintiffs would not need to pursue a negligence claim, rather they could levy charges for recklessness (as provided for in *Rafferty*) or fraud. *Rafferty v. Merck & Co.*, 92 N.E.3d 1205, 1209 (Mass. 2018).

255. *Id.*

256. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

257. *Id.*; see also *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011); *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013).

in hopes that the name-brand company may act.<sup>258</sup> It is the name-brand company that has the authority, ability, and legal duty to change the labels so that they provide sufficient warnings to potential consumers.<sup>259</sup> Providing an incentive for name-brand manufacturer's to better inform consumers furthers the policy goal of preventing future harm.

#### *7. The availability, cost and prevalence of insurance*

This is a neutral factor as the name brand and generic manufacturers likely both have insurance, so there likely would be no further analysis of which company would be better shielded from potential loses. The one clear point is that the consumers should not be forced to deal with these injuries alone as they are likely in the worst position to address the financial challenges created by treating their harm. Loss distribution principles play a meaningful, but not dispositive, role in this portion of the analysis and they support imposing a duty.

#### *8. Balancing the Factors*

As noted by the Maryland Court of Appeals in *May*, in negligence and strict liability actions involving personal injury, the principal determinant of duty is foreseeability.<sup>260</sup> The foreseeability of harm to consumers that rely on inaccurate warning information for generic medications is especially strong when name-brand manufacturers know or should know that the consumers of the generic versions will rely on the name-brand manufacturer's representations for the equivalent generic product.<sup>261</sup> Given that there is a high degree of foreseeability, this predominant factor supports holding name-brand manufacturer's liable for harm created by their inadequate warning labels. Evaluating the subsidiary factors, it appears that three or four of the remaining six also favor imposing a duty. This analysis results in a majority of the factors, including the most influential one, supporting imposing a duty and an obligation to bear liability. Under *May*, it appears clear that a duty exists for name-brand manufacturers to provide accurate warnings for consumers of both name-brand and generic versions of the medication.

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258. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

259. *Id.*

260. *See supra* note 206.

261. *See May v. Air & Liquid Systems*, 129 A.3d 984 (Md. 2015); *Wyeth, Inc. v. Weeks*, 159 So.3d 649 (2014); George Mason Law & Economics Center, *Congressional Civil Justice Academy Debate: Inventing New Liability? Who Should We Blame When Generic Drugs Harm Patients?*, VIMEO (Feb. 9, 2018), <https://vimeo.com/255119753> (illustrating that even Phil Goldberg, an esteemed critic of name-brand manufacturer liability, admits that consumers will often rely on representations made by the name-brand manufacturer).



*ii. Showing Factual Causation*

Having established that name-brand manufacturers owe a duty to the consumers of generic drugs, the next issue to address is factual causation. Generally speaking, the most feverishly debated issue regarding name-brand manufacturer liability is whether causation can be established when the drug consumed was a generic.<sup>262</sup> Critics claim that it cannot be, as the medication ingested closest to the time that harm is recognized is a generic, not a name-brand product.<sup>263</sup> This theory, although accepted by a number of courts, fails to address the fact that the inadequate warning is a cause of the harm, not merely the medication itself.<sup>264</sup> All medications have side-effects, and based on the severity of those side-effects compared to the ailment that a medication is being used to treat, a consumer must decide whether to use the medication in question.<sup>265</sup> When an inadequate medication warning is created by the name-brand manufacturer, generic consumers are forced to rely on that same warning in deciding to use the associated generic medication. If that consumer then suffers from a side-effect that was not properly warned of, the flawed warning played a role in inducing use and causing the consumer's harm. When name-brand manufacturer's breach the duty they owe to generic consumers by providing inadequate medication warning labels, that failure can cause injury. As reiterated in *May*, a defendant manufacturer can cause harm to a consumer through that consumer's use of another manufacturer's product when the defendant manufacturer's own product contributed substantially to the harm, or the defendant manufacturer participated substantially in creating a harmful combined use of the products.<sup>266</sup>

In the inadequately labeled generic medication context, name-brand manufacturers contribute substantially to both the direct harm suffered by generic consumers and to the combined use of lacking name-brand label warnings with generic medication.<sup>267</sup> The inadequate warning instructions authored by the name-brand manufacturers cause harm to generic consumers, as those warnings are printed on generic medications and do not provide sufficient insight regarding the potential risks associated with either the name-brand or

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262. George Mason Law & Economics Center, *supra* note 261; Wolfman & King, *supra* note 1, at 9–10; *see also* Mutual Pharmaceutical Co. v. Bartlett, 570 U.S. 472 (2013); PLIVA, Inc. v. Mensing, 564 U.S. 604 (2011).

263. *Weeks*, 159 So.3d at 684–708 (Murdock, J. dissenting) (citing cases throughout the twelve circuits where courts have refused to find name-brand manufacturer liability when the plaintiff ingested the generic drug).

264. *Id.*

265. *Id.*

266. *May v. Air & Liquid Sys. Corp.*, 129 A.3d 984, 995 (Md. 2015).

267. *Bartlett*, 570 U.S. 472; *PLIVA*, 564 U.S. 604; *Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014); *Weeks*, 159 So.3d 649.

generic medication.<sup>268</sup> The provision of insufficient warnings can directly cause the consumer's harm by inducing the generic consumer to use a medication and experience unexpected side-effects, satisfying the first means by which liability can be assessed against a name-brand manufacturer.<sup>269</sup> The second liability theory, which is grounded in combined use, can be satisfied through the name-brand manufacturer's publishing of advertisements and commercials directly to the public. Through the use of direct marketing to consumers via various media sources and information campaigns, the name-brand manufacturers are participating substantially in the combined use of the generic medications (which will be associated with name-brand products) and the warnings provided through media regarding the name-brand products.

The aforementioned direct harm and combined use liability theories, first set forth by the California Supreme Court and subsequently adopted in Maryland, can readily be applied to instances that involve injuries caused by inadequate name-brand warning labels.<sup>270</sup> But for the name-brand manufacturer's proliferation of flawed medication warning labels and instructions, the generic medications would not have contained inaccurate information. Therefore, absent the name-brand manufacturer's provision of inadequate warnings, the consumers of generic medications would not have been induced by those same inadequate warnings to use a medication that had severe side-effects. When generic medication consumers are injured by inadequate labels provided by name-brand manufacturers, there should be sufficient facts to show factual causation. Fundamental tenets of tort law support imposing liability on name-brand manufacturers that cause harm to generic medication consumers by providing inadequate side-effect warnings.<sup>271</sup>

### *iii. Weaving Together the Duty and Causation Analysis*

Principles set forth in *Wyeth, Inc. v. Weeks*, *Ossining Union Free School Dist. v. Anderson*, *T.H. v. Novartis*, *Rafferty v. Merck* and *O'Neal v. Crane Co.* bolster an argument in favor of name-brand manufacturer liability. The *Ossining* duty and causation analysis appears to be transferrable to the generic drug consumer context.<sup>272</sup> The federally mandated reliance by generic producers on the representations of name-brand producers aids in the creation of a close nexus between name-brand manufacturers and generic manufacturers.<sup>273</sup> Since the

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268. *T.H. v. Novartis Pharmaceuticals Corp.*, 407 P.3d 18 (Cal. 2017); Wolfman & King, *supra* note 1, at 17.

269. *T.H.*, 407 P.3d at 47.

270. *T.H.*, 407 P.3d 18; *May*, 129 A.3d 984.

271. RESTATEMENT (SECOND) OF TORTS §§ 18, 282, 283, 388, 402A, 402B (AM. LAW. INST. 1965).

272. *Ossining Union Free School Dist. v. Anderson*, 539 N.E.2d 91 (N.Y. 1989).

273. *Id.*; Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

name-brand manufacturers are provided clear notice that their representations will be recreated on generic medication warning labels, it is foreseeable that consumers of the generic medications will rely on the name-brand manufacturer's representations. The substantial degree of reliance by consumers of generic medications suggests a nexus between those consumers and the name-brand manufacturer on whom they rely, establishing a duty owed by the name-brand manufacturers to the generic consumers.<sup>274</sup> When a name-brand manufacturer provides a defective label, which is subsequently replicated by generic manufacturers, harm to generic consumers caused by their reliance on the defective warnings can satisfy the causation element for a claim against the name-brand manufacturer. Even though the name-brand manufacturer does not directly supply the medication, it does create the injury-causing inadequate warning.

Similarly, under the *Weeks* and *T.H.* precedent, the significant level of foreseeability creates a "special reason" for the name brand manufacturer to expect that its representations will "reach and effect" not only consumers of the name-brand medication, but the generic version as well.<sup>275</sup> The "special reasons" name-brand manufacturers have to know that their representations will influence generic medication consumers is grounded in the inherent combined use of the medication warnings provided for the name-brand and generic versions of the medicine.<sup>276</sup> As noted in *O'Neal v. Crane, Co.*, when a manufacturer participates substantially in creating harmful combined usage, that manufacturer can be held liable for harm to the end consumer.<sup>277</sup> In the pharmaceutical market context, the warning labels for name-brand medications are inherently used in combination with the warnings provided on generic labels.<sup>278</sup> In fact, the generic and name-brand labels are the exact same.<sup>279</sup>

Medications are not reasonably safe due to inadequate instructions or warnings if reasonable warnings regarding foreseeable risks of harm are not provided with the medication.<sup>280</sup> This rule emphasizes how important it is that the consumers of both name-brand and generic medication be adequately informed of the risks associated with that product.<sup>281</sup> When name-brand manufacturers do not provide adequate warnings about a medication, this can cause injury to consumers that are harmed by their uninformed use of name-

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274. *Id.*

275. *Weeks*, 159 So.3d at 676; *T.H.*, 407 P.3d at 27.

276. *Weeks*, 159 So.3d at 676–77.

277. 266 P.3d 987, 991 (Cal. 2012).

278. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585 (1984).

279. *Id.*

280. OWEN & DAVIS, *supra* at note 53, at 326–31.

281. *Id.* at 326.

brand and generic medications.<sup>282</sup> Therefore, because name-brand manufacturers can cause harm to generic consumers through inadequate warnings and this harm is foreseeable, the duty and causation requirements for claims against name-brand manufacturers can be satisfied for failure to warn claims stemming from injurious inadequate warnings.

### B. Escaping Preemption

After proving duty and causation, the next step in levying a strong claim against name-brand manufacturers for harms arising from a mislabeled generic drug would require the plaintiff to demonstrate why federal preemption does not bar their suit.<sup>283</sup> Fortunately, the road to recovery for injured consumers attempting to hold name-brand manufacturers liable is much less treacherous than the footpaths plaintiffs must follow when trying to hold generic manufacturers responsible. *Wyeth v. Levine* controls this issue, as the United States Supreme Court held in that case that state law tort duties do not obstruct FDA drug regulations.<sup>284</sup> Specifically, the court ruled that claims against name-brand manufacturers are not preempted by federal law as there is zero indication that Congress intended to bar such tort claims in regard to inadequate medication warning instructions.<sup>285</sup> The reasoning underlying the perpetuation of state tort claims is detailed below. The discussion that follows takes on enhanced significance because of the current posture of the Supreme Court. As our highest court's bench has recently welcomed two conservative Justices,<sup>286</sup> there is a possibility that *Levine* could be overturned.<sup>287</sup> In the event *Levine* is nullified, a plaintiff would need to fall back on traditional tort principles to overcome the defendant name-brand manufacturer's preemption defense.

Under the governing statutory law, the FDCA and Hatch-Waxman Amendments do not use language to expressly preempt state law, nor is there any conflict preemption or material indication that Congress intended to preempt

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282. *Id.*

283. *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014); *Wyeth, Inc. v. Weeks*, 159 So.3d 649 (Ala. 2014).

284. *Wyeth v. Levine*, 555 U.S. 555, 581 (2009).

285. *Levine*, 555 U.S. at 574–75.

286. Leigh Ann Caldwell, *Neil Gorsuch Confirmed to Supreme Court After Senate Uses 'Nuclear Option'*, NBC NEWS (April 7, 2017 11:57 AM), <https://www.nbcnews.com/politics/congress/neil-gorsuch-confirmed-supreme-court-after-senate-uses-nuclear-option-n743766>; Clare Foran and Stephen Collinson, Brett Kavanaugh sworn in as Supreme Court justice, CNN politics (Oct. 6, 2018 8:02 PM), <https://www.cnn.com/2018/10/06/politics/kavanaugh-final-confirmation-vote/index.html>.

287. Richard Wolf, *Justice Gorsuch confirms conservatives' hopes, liberals' fears in first year on Supreme Court*, USA TODAY – NEWS (April 8, 2018 12:30 PM), <https://www.usatoday.com/story/news/politics/2018/04/08/justice-gorsuch-confirms-conservatives-hopes-liberals-fears-first-year-supreme-court/486630002/>.

state claims pertaining to this field.<sup>288</sup> As Congressional intent is the “ultimate touchstone” for preemption analysis,<sup>289</sup> the lack of clear Congressional intent to preempt mislabeling state law actions indicates that there should be no federal preemption in these instances.<sup>290</sup> Additionally, as evidenced by multiple cases, the language of the federal regulations provide means by which state tort claims can be successfully brought against name-brand medication manufacturers.<sup>291</sup> As it is challenging to discern any sign that Congress intended to preempt state claims, under traditional canons of construction,<sup>292</sup> it is appropriate to argue that Congress lacked such intention.

Second, the history surrounding regulation of medication demonstrates that state and federal rules have long been used in tandem to further promote consumer safety.<sup>293</sup> Almost equally important as Congressional intent is the presumption against federal preemption when Congress legislates in a field that has traditionally been occupied by the states.<sup>294</sup> When there are decades of precedent demonstrating that state tort claims help to further the federal goal of protecting medication consumers, there is an added indicia in favor of allowing such tort claims to remain in effect.<sup>295</sup> It has been common practice to allow state claims as they “necessarily perform an important remedial role in compensating accident victims.”<sup>296</sup> Apparently understanding the important role that tort claims play, Congress drafted the FDCA and its amendments in a manner that does not offend the traditional means of judicial remedy.<sup>297</sup> Congress did not establish a federal cause of action for damages, ostensibly because state tort law claims already provide injured consumers an opportunity to hold manufacturers of harmful medications liable.<sup>298</sup> This conduct by Congress further demonstrates that it had no intention of preempting state claims that effectuate state police powers and have long been the primary remedy for injured defective medication consumers.

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288. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984); S. Rep. No. 98-529 (1984).

289. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (citing *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)).

290. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1518 (1984); S. REP. NO. 98-5529 (1984); *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013).

291. See generally *Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649 (Ala. 2014).

292. Macey & Miller, *The Canons of Statutory Construction and Judicial Preferences*, 45 YALE L. SCH. FAC. SCHOLARSHIP SERIES, 647–72, (1992).

293. *Bartlett*, 570 U.S. at 498 (Sotomayor, J., dissenting); *Levine*, 555 U.S. at 566–68, 574.

294. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *Lohr*, 518 U.S. at 485.

295. *Bartlett*, 570 U.S. at 496 (Sotomayor, J., dissenting).

296. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002).

297. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

298. *Bartlett*, 570 U.S. at 501 (citing *Levine*, 555 U.S. at 574–75).

As noted in *Cipollone*, the most viable claim in cases dealing with inadequate warning labels is misrepresentation, particularly when there is some degree of fraud or concealment involved.<sup>299</sup> The Court determined that allowing mislabeling and misrepresentation claims to be actionable at the state level helped effectuate the goals of federal regulatory consumer protections.<sup>300</sup> By utilizing the approach recommended in this paper, which embodies a small portion of the *Cipollone* reasoning, courts will permit the continuance of a venerable alliance between federal and state consumer protections. Additionally, applying longstanding case law, the high court in Alabama also recognized the importance of providing both federal and state protections for consumers of medication.<sup>301</sup> Although subsequently abridged by legislative action, the *Weeks* decision valuably emphasized that instead of inhibiting federal regulations, state tort claims can be utilized along with federal regulations to improve consumer safety, aid in establishing a cooperative relationship between name-brand manufacturers and generic manufacturers, and clarify the connection between name-brand manufacturers and the consumers of generic medication.<sup>302</sup>

#### V. EFFECT ON POLICY

As with any change in the legal system, there are policy implications that surround whether name-brand manufacturers should be held liable for harms suffered by consumers of mislabeled generic medication.<sup>303</sup> The main thrust of the argument for name-brand manufacturer liability is focused on protecting people who, at the moment, have no way to protect themselves.<sup>304</sup> The contrary argument is that name-brand manufacturer liability should not be permitted because allowing such liability would have negative effects on the pharmaceutical supply market and that plaintiffs cannot establish that the defendant's actions were the cause of the plaintiff's injuries, therefore the court has no authority to impose liability.<sup>305</sup> This argument is fallible because in cases involving inadequate medication warning labels, it is the misrepresentation by the name-brand manufacturer, not solely the medication itself, that is a factual cause of the plaintiff's harm. Therefore, because the name-brand manufacturer does indeed cause the harm in inadequate warning cases, there would be authority for a court to impose liability.

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299. 505 U.S. at 529 (concluding that “the phrase ‘based on smoking and health’ fairly but narrowly construed does not encompass the more general duty not to make fraudulent statements. Accordingly, petitioner’s claim based on allegedly fraudulent statements made in respondents’ advertisements is not pre-empted by § 5(b) of the 1969 Act).

300. *Id.*

301. *Wyeth, Inc. v. Weeks*, 159 So.3d 649, 676 (Ala. 2014).

302. *Id.* at 661, 677.

303. George Mason Law & Economics Center, *supra* note 261.

304. *Id.*

305. *Id.*; Wolfman & King, *supra* note 1.

Allowing for name-brand manufacturer liability will have a meaningful impact in terms of both loss distribution and loss minimization.<sup>306</sup> Loss distribution involves assigning liability, within the constraints of the governing legal framework, on the party that is responsible for the harm and most able to shoulder the financial burden.<sup>307</sup> As the law stands now, the party that must pay the heavy price of harmful inadequate generic medications are the injured consumers.<sup>308</sup> This result offends notions of loss distribution, as the harmed consumers are neither the party responsible for causing the injury nor are they best positioned to address the economic challenges associated with the pecuniary loss.<sup>309</sup> While assessing liability on the generic manufacturer would demonstrate sound loss distribution principles, doing so is impermissible.<sup>310</sup> In cases involving mislabeled medications, federal regulations disallow generic manufacturer liability due to impossibility preemption.<sup>311</sup> This leaves only name-brand manufacturers as viable candidates to assume the liability burden. They are in the best position to know the dangers associated with the medication, monitor the labeling process, correct faulty labels, and purchase insurance to protect against tort liability.<sup>312</sup>

There are also significant positive loss minimization effects that this form of tort liability would provide. Loss minimization involves introducing incentives that help to minimize the general risk of harm and loss to society.<sup>313</sup> Knowing they will be on-the-hook for harms to generic consumers, name-brand manufacturers would be incentivized to take additional precautions to ensure that consumers are properly informed of the potential risks associated with a medication. Taking such precautionary measures likely would not constitute an excessive burden for the name-brand manufacturers.<sup>314</sup> To minimize liability risk, they would merely need to update labels whenever a new dangerous side effect is identified and purchase adequate insurance for occasions when they fail to identify an issue before it causes harm.<sup>315</sup> Due to federal regulation, the generic manufactures would then be required to adjust their labels to match the name-

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306. SHULMAN ET AL., *supra* note 12, at 18.

307. *Id.*

308. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

309. SHULMAN ET AL., *supra* note 12, at 121.

310. *Id.*; *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014); *Wyeth, Inc. v. Weeks*, 159 So.3d 649 (Ala. 2014).

311. *See generally Bartlett*, 570 U.S. 472; *PLIVA*, 564 U.S. 604; *Huck*, 850 N.W.2d 353; *Weeks*, 159 So.3d 649.

312. *T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18 (Cal. 2017).

313. SHULMAN ET AL., *supra* note 12, at 17.

314. *See infra* text accompanying note 292.

315. *See supra* Part III (detailing how manufacturers were found liable and what could have prevented such liability).

brand warning language.<sup>316</sup> Even if the costs are significant, the name-brand manufacturers are most prepared to complete the necessary testing, updating, and re-labeling of the name-brand product.<sup>317</sup> As name-brand manufacturers already have the knowledge, procedures and capital required for testing, they are best positioned to address any need for additional research on potential negative side-effects and understand what type of insurance will be most appropriate to protect against potential liabilities. This approach also creates an additional incentive for name-brand manufacturers to provide comprehensive warnings that allow consumers to make informed decisions about whether they will use a medication.<sup>318</sup> If forced to bear this burden, name-brand manufacturers will surely take steps to minimize their liability exposure, thereby reducing risks to all consumers and aiding with loss minimization. While inconvenient for the well-insulated name-brand manufacturers, this form of liability is the clearest way to apply existing tort principles in a fashion that provides access to justice for consumers injured by inadequate warnings on generic medication.

Critics will argue that this form of liability could cripple the pharmaceutical market, which directly frustrates the purpose of the FDCA and its amendments.<sup>319</sup> The primary fear would be that name-brand manufacturers may exit the pharmaceutical market due to the increase in potential liability.<sup>320</sup> While increased liability risk could reduce potential profits, and reduced financial gain can cause a company to leave a given industry, the earnings in Big Pharma<sup>321</sup> don't reflect a legitimate concern of vanishing profits.<sup>322</sup> In fact, federal regulatory penalties and law suit awards in the multi-billion dollar range have not deterred companies from remaining in the medication marketplace.<sup>323</sup> While the drug approval process is time consuming, pharmaceutical companies are handsomely rewarded for their efforts.<sup>324</sup> It seems unreasonable to suppose that

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316. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

317. *Ossining Union Free School Dist. v. Anderson*, 539 N.E.2d 91 (N.Y. 1989).

318. The incentive being the ability to reduce potential litigation risks and the related costs of litigation.

319. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

320. George Mason Law & Economics Center, *supra* npte 261.

321. *Big Pharma*, MERRIAM-WEBSTER ONLINE DICTIONARY (August 1, 2018) (providing the following definition for Big Pharma: "meaning large pharmaceutical companies considered especially as a politically influential group").

322. Lindsey Plant, *Big Pharma Has Higher Profit Margins Than Any Other Industry*, ANDRUS|WAGSTAFF ATTORNEYS AT LAW (2018), <https://www.andruswagstaff.com/blog/big-pharma-has-higher-profit-margins-than-any-other-industry/>.

323. *Id.*

324. *Top 10 global pharmaceutical and biotech companies based on total revenue in 2017 (in billion U.S. dollars)*, HEALTH AND PHARMACEUTICALS BLOG (2018), <https://www.statista.com/statistics/272720/top-global-biotech-and-pharmaceutical-companies-based-on-net-income/>.



the relatively insignificant costs of ensuring name-brand manufacturer's own labels are accurate will force companies that are experiencing near record-high profits to shut down.<sup>325</sup> Importantly, as explained in *Huck*, if the name-brand company did update their labels, but the generic company failed to follow suit, the name-brand company would be protected from liability because injured generic medication consumers would be able to levy a claim directly against the generic manufacturer.<sup>326</sup> While it is clear that updating labels will involve a number of additional costs, these costs likely will only amount to a "drop in the bucket" compared to the massive returns that companies realize from good investments in pharmaceuticals.<sup>327</sup>

As it is vitally important that pharmaceutical companies stay engaged in the furtherance of modern medicine, name-brand manufacturer liability is not aimed at damaging the pharmaceutical market.<sup>328</sup> The effect of this legal theory is to hold those responsible for harm liable for damages they have caused. The added level of corporate responsibility and safeguards may actually lead to greater consumer demand for medications, as consumers will know that they are adequately protected.<sup>329</sup> Presently, the party left worse-off in these cases is the consumer who is injured by incorrect medication warnings that do not contain ample information about side-effects.<sup>330</sup> Up to this point, consumers have largely only been able to recover for their suffering if they ingested the name-brand version.<sup>331</sup> In most jurisdictions today, if a consumer is harmed by inadequate warnings for a generic medication, they are almost certainly without a legal remedy.<sup>332</sup> This is the case even though it is not the consumer who creates the contents of the label, nor is it the generic manufacturer.<sup>333</sup> The only party that has creative control over the contents of the warning labels in these instances is

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325. See *supra* notes at 321 and 322.

326. See *supra* discussion of *Huck v. Wyeth* in Section III.B (explaining the state tort claim that can be brought against a generic manufacturer when it fails to update its label to the most recent FDA approved name-brand label).

327. RICK CLAYPOOL, PUBLIC CITIZEN, PHARMACEUTICAL INDUSTRY PROFITS EXCEED INDUSTRY'S SELF-REPORTED R&D COSTS, 1-4 (2017), <https://www.citizen.org/sites/default/files/pharma-profits-and-r-and-d-report.pdf>.

328. MICHAEL J. BRIEN, ET AL., PHARM. RESEARCH & MANUFACTURERS OF AM., QUANTIFYING IMPROVEMENTS IN LIFE QUALITY OF INDIVIDUALS WITH COMPLEX CHRONIC MEDICAL CONDITIONS OVER THE PAST DECADE (2016) <http://phrma-docs.phrma.org/files/dmfile/Study—Quality-of-Life-Improvements-Over-the-Past-Decade—March-2016.pdf> (explaining how medical innovation has been a significant tool for improving people's quality of life, reducing pain, and extending lifespans).

329. Consumers may be more willing to purchase products when they have assurances about quality control.

330. *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011).

331. See *supra* Part I, II.

332. See *supra* Part I, II.

333. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

the name-brand manufacturer.<sup>334</sup> While the name-brand manufacturer has been responsible for creating the harms suffered, only the generic drug consumer has been forced to grapple with the painful side-effects of inadequate warning labels.

#### VI. CONCLUSION

While potentially uncomfortable for name-brand manufacturers, this combined application of the well-settled tort principles applied in *May*, *Levine*, *Cipollone*, *T.H.*, *Rafferty*, and *Weeks* provides a means by which countless plaintiffs can receive the redress they so desperately need. Although this form of liability may affront stalwart defenders of Big Pharma, it should be given credence. This approach is novel in that it simultaneously (i) asserts foreseeability's prime importance in determining when a duty is owed, (ii) demonstrates how a name-brand manufacturer can cause harm to a generic consumer through providing inadequate warnings, (iii) argues that federal and state consumer protections should act in unison, (iv) dutifully abides by the cornerstones of preemption; Congressional intent and recognition of the importance that state police powers are not infringed upon, and (v) reiterates that misrepresentation claims are not preempted by federal regulation. While not often used in this combination, these principles have found support at almost every level of the judicial system and can now be applied jointly to address a very real need. Courts can comfortably apply this framework knowing that it is grounded in well-settled tort law principles that have been recognized and reaffirmed for decades. Hopefully, this approach will ease the debilitating symptoms of evolving tort liability.

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334. *Id.*; see *supra* text accompanying note 10.