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## "A Distinction Without a Difference"?: *Bartlett* Going Forward

Steven A. Schwartz

*Fordham University School of Law*

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# **“A DISTINCTION WITHOUT A DIFFERENCE”?: BARTLETT GOING FORWARD**

*Steven A. Schwartz\**

*This Note addresses the question of whether federal law preempts state design defect claims against generic drug manufacturers regardless of which test state law uses to determine whether a drug is defective. This issue, arising out of the U.S. Supreme Court’s interpretation of preemption jurisprudence and fundamental tort law as stated in Mutual Pharmaceutical Co. v. Bartlett, is significant because it plays a large role in determining to what extent generic drug manufacturers are immune to civil liability arising out of injuries caused by their generic drugs. In an age of rising medical costs and jury awards, both plaintiff and defendant, and the political arena, are considerable stakeholders.*

*First, this Note provides an overview of the battle over the Food and Drug Administration’s (FDA) regulatory authority, preemption jurisprudence (highlighting physical impossibility preemption), design defect law, and relevant Supreme Court jurisprudence. Second, this Note introduces the conflict among the lower courts as to whether the type of test a jurisdiction uses to determine a product’s defectiveness plays any role in an analysis of applicable FDA regulations’ preemptory effect on state design defect law. Finally, this Note concludes that after Bartlett, so long as state design defect law adheres to strict liability principles, federal law preempts state design defect causes of action against generic drug manufacturers.*

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\* J.D. Candidate, 2016, Fordham University School of Law; B.A., Economics, Political Science, and Philosophy, Politics, and Law, 2013, Binghamton University. I would like to thank Professor Benjamin Zipursky for his assistance throughout this process.

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#### INTRODUCTION

In November 2006, Denise Neeley was prescribed the prescription drug Reglan to treat her gastroesophageal reflux disease<sup>1</sup> (GERD). GERD, which is essentially severe or chronic acid reflux disease or heartburn,<sup>2</sup> is a common ailment that affects approximately 5 to 7 percent of the population.<sup>3</sup> Although Neeley's prescription called for her to receive the brand name version of the drug, she was provided with, and ultimately only ingested, metoclopramide (MCP), a generic version produced by various drug manufacturers.<sup>4</sup> In April 2010, Neeley was diagnosed with the disease tardive dyskinesia, allegedly due to ingesting MCP.<sup>5</sup> Tardive dyskinesia is a disease commonly associated with involuntary movements in the face.<sup>6</sup> Neeley allegedly experienced abnormal and inadvertent body movements, pain, breathing issues, and weight loss.<sup>7</sup>

Following her injuries, Neeley sued the generic drug manufacturers that produced MCP, alleging that MCP had a design defect.<sup>8</sup> The generic drug manufacturers, however, argued that federal law preempted state design defect claims against generic drug manufacturers.<sup>9</sup> The Eastern District of Missouri held that federal law *did not* preempt these claims and hence Neeley's design defect suit against the generic manufacturers could

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1. See *Neeley v. Wolters Kluwer Health, Inc.*, No. 4:11-CV-325 JAR, 2013 WL 3929059, at \*1 (E.D. Mo. July 29, 2013).

2. *Heartburn/GERD Health Center*, WEBMD, <http://www.webmd.com/heartburn-gerd/guide/heartburn-gerd-basic-information-causes> (last visited Sept. 27, 2015) [<http://perma.cc/QB8P-CCQY>].

3. Press Release, Int'l Found. for Functional Gastrointestinal Disorders, GERD Costs America Nearly \$2 Billion Each Week in Lost Productivity (Nov. 2005), <http://www.iffgd.org/site/news-events/press-releases/2005-1125-gerd-costs> [<http://perma.cc/UPU7-G9EY>].

4. See *Neeley*, 2013 WL 3929059, at \*1.

5. See *id.*; Second Amended Complaint at 19 ¶ 99, *Neeley*, 2013 WL 3929059 (No. 4:11-CV-325).

6. *Tardive dyskinesia*, STEDMAN'S MEDICAL DICTIONARY (27th ed. 2000).

7. See Second Amended Complaint, *supra* note 5, at 16 ¶ 82.

8. See *id.* at 23 ¶ 123.

9. See *Neeley*, 2013 WL 3929059, at \*7.

proceed.<sup>10</sup> Therefore, Neeley could have her claims adjudicated and potentially receive a sizeable settlement or jury award to compensate her for her injuries.<sup>11</sup>

This result lies in sharp contrast with the experience of Lirlene Gardley-Starks, who was prescribed and ingested MCP, just like Neeley.<sup>12</sup> She too claimed to have developed tardive dyskinesia.<sup>13</sup> She then sued various drug manufacturers, including four generic drug manufacturers, alleging they produced a drug with a design defect.<sup>14</sup>

Despite the striking similarities between Neeley's and Gardley-Starks's claims, the Northern District of Mississippi held that federal law *did* preempt Gardley-Starks's design defect claim.<sup>15</sup> Even though Neeley and Gardley-Starks alleged that they took the same generic drug and it caused the same ailment, Gardley-Starks had no opportunity to receive a jury award or settlement, while Neeley did.

In reaching these disparate results, both courts relied on the U.S. Supreme Court's decision in *Mutual Pharmaceutical Co. v. Bartlett*,<sup>16</sup> which held that federal law preempted design defect claims under New Hampshire law pursuant to the doctrine of physical impossibility because it would be impossible for generic drug manufacturers to both comply with state requirements and federal requirements.<sup>17</sup> Since *Bartlett*, some lower courts, such as those in Neeley's and Gardley-Starks's cases, have disagreed over whether the test that state design defect law uses to determine if a product is defective should affect the analysis of whether the Food and Drug Administration (FDA) regulations preempt state design defect law.<sup>18</sup> In *Bartlett*, the Court evaluated New Hampshire's design defect law, which applies the risk-utility test to determine whether a product is defective.<sup>19</sup> However, not all jurisdictions use the risk-utility test; some jurisdictions apply the consumer expectations test.<sup>20</sup> Furthermore, even those jurisdictions that do use the risk-utility test do not always apply it the same way that New Hampshire does.<sup>21</sup> Instead, some courts apply slight variations of the risk-utility test.<sup>22</sup> These variations evaluate different

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10. *See id.* at \*10.

11. *See, e.g.,* *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466, 2474 (2013) (awarding plaintiff twenty-one million dollars in compensatory damages by jury for design defect lawsuit against generic drug manufacturer).

12. *See* *Gardley-Starks v. Pfizer, Inc.*, 917 F. Supp. 2d 597, 600 (N.D. Miss. 2013), *aff'd* No. 4:10-CV-099-SA-JMV, 2013 WL 5423951 (N.D. Miss. Sept. 26, 2013).

13. *See id.*

14. *See id.* at 599–601, 611.

15. *See* *Gardley-Starks*, 2013 WL 5423951, at \*3.

16. 133 S. Ct. 2466 (2013).

17. *See id.* at 2473.

18. *See infra* Part II.A–B.

19. *See* *Bartlett*, 133 S. Ct. at 2474–75.

20. *See infra* Part I.C.1 (discussing development and use of consumer expectations test).

21. *See infra* Part I.C.3 (discussing development and use of variations of the risk-utility test).

22. *See infra* Part I.C.3.

factors<sup>23</sup> and consider the knowledge that the manufacturer will be assumed to have known.<sup>24</sup>

After *Bartlett*, if a state's design defect test *does not* make a difference, FDA regulations—which constitute federal law<sup>25</sup>—preempt state design defect lawsuits against generic drug manufacturers by injured consumers, severely inhibiting the injured consumer's ability to recover monetary damages for injuries.<sup>26</sup> If a state's design defect test *does* make a difference, the consumer's ability to recover monetary damages perhaps will not be as bleak.<sup>27</sup>

The majority of the courts that have addressed this issue hold that federal law preempts state design defect lawsuits against generic drug manufacturers regardless of the test that the jurisdiction uses to determine defectiveness of a drug.<sup>28</sup> These courts hold, as stated by the Southern District of Illinois, that the characteristics of the different design defect tests are a “distinction without a difference.”<sup>29</sup>

This result, however, has not been unanimous. The Eighth Circuit, the Eastern District of Missouri, the Illinois Appellate Court, and the Pennsylvania Superior Court have each found that the differences between the design defect test used creates a distinction that may preclude FDA regulations from preempting design defect suits against generic drug manufacturers.<sup>30</sup>

This Note analyzes the various design defect regimes within the impossibility preemption framework expanded upon by *Bartlett* and determines whether there really is a “distinction without a difference.” Part I provides an overview of the current state of the FDA's authority, federal preemption jurisprudence (ultimately highlighting impossibility preemption), the various tests that jurisdictions use to determine whether a product is defective, and, finally, the Supreme Court cases *Wyeth v. Levine*,<sup>31</sup> *PLIVA, Inc. v. Mensing*,<sup>32</sup> and *Mutual Pharmaceutical Co. v. Bartlett*.<sup>33</sup> Part II describes the division in the lower courts stemming from

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23. See *infra* Part I.C.3.a (discussing alternative design requirement); *infra* Part I.C.3.c (discussing *Restatement (Third): Products Liability*'s version of the risk-utility test).

24. See *infra* Part I.C.3.b (discussing prudent manufacturer test).

25. See *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466, 2476 (2013).

26. See *infra* Part II.B. But see *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 929–30 (6th Cir. 2014) (discussing “parallel misbranding” theory); *Conte v. Wyeth*, 168 Cal. App. 4th 89, 109–11 (Cal. Ct. App. 2008) (adopting “pioneer liability”).

27. See *infra* Part II.A (discussing cases in which FDA regulations were found not to preempt state design defect law).

28. See *infra* Part II.B (discussing cases in which FDA regulations were found to preempt state design defect law).

29. *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Pracs. & Prods. Liab. Litig.*, No. 3:13-cv-10143-DRH-PMF, 2014 WL 1632149, at \*9 (S.D. Ill. Apr. 24, 2014).

30. See *infra* Part II.A.

31. 555 U.S. 555 (2009).

32. 131 S. Ct. 2567 (2011).

33. 133 U.S. 2466 (2013). In 2013, following *Bartlett*, the FDA proposed new generic drug labeling rules. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985 (proposed Nov. 13, 2013) (to be

*Bartlett*'s treatment of New Hampshire's design defect regime. Part II then introduces commentary regarding this lower court split. Part III resolves this conflict by analyzing the doctrinal interaction between strict liability and preemption in light of the Supreme Court's decision in *Bartlett* and general tort law principles. Lastly, Part III concludes by discussing the ramifications of this analysis.

#### I. PREEMPTION AND DESIGN DEFECT TESTS

Part I of this Note provides background on the legal principles involved in *Bartlett*. Part I.A tracks the FDA's recent battle over preemption. Part I.B discusses the fundamentals of preemption law, highlighting physical impossibility conflict preemption. Part I.C discusses design defect law. Finally, Part I.D examines two important cases leading up to *Bartlett*—*Levine* and *Mensing*—and then *Bartlett* itself.

##### A. *The Political Background of the FDA's Authority over the State*

At a 2002 symposium hosted by the Food and Drug Law Institute, Daniel Troy suggested that because the FDA holds "broad authority" to regulate drug labeling under the Food, Drug & Cosmetic Act (FDCA), this dual layer of coverage created the risk of parties having inconsistent obligations under the FDCA and state law.<sup>34</sup> In December 2003, at a drug and medical device litigation conference, Troy told the audience to recommend lawsuits in which the FDA might be able to intervene—make them "sound like a Hollywood pitch."<sup>35</sup> What made Troy's actions significant was his occupation: Chief Counsel of the FDA.<sup>36</sup>

Around this time, the FDA filed unsolicited amicus briefs in various cases, expressing the view that the FDA impliedly preempted state law.<sup>37</sup> One of these briefs, for example, argued "the prospect of hundreds of individual juries determining the propriety of particular device approvals, or the appropriate standards to apply to those approvals, is the antithesis of the orderly scheme Congress put in place and charged FDA with implementing."<sup>38</sup>

The FDA's position in these briefs was contrary to its position just a few years earlier. Previously, then-FDA Chief Counsel Margaret Jane Porter indicated that the "FDA's view is that FDA product approval and state tort

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codified at 21 C.F.R. pts. 314 and 601). The implications of the potential adoption of these rules are outside the scope of this Note. As of the date of publication, these rules have not been approved.

34. Margaret H. Clune, *Stealth Tort Reform: How the Bush Administration's Aggressive Use of the Preemption Doctrine Hurts Consumers*, CTR. FOR PROGRESSIVE REFORM 2 (Oct. 2004), <http://www.progressivereform.org/articles/preemption.pdf> [<http://perma.cc/EH72-77D3>].

35. *Id.*

36. *See id.* at 1–2.

37. *See id.* at 4–7.

38. Statement of Interest of the United States of America, *Murphree v. Pacesetter*, No. 005429-00-3 (Tenn. Cir. Ct. Dec. 12, 2003), *cited and quoted in* *Horn v. Thoratec Corp.*, 376 F.3d 163, 171 n.13, 178 (3d Cir. 2004); *see* Clune, *supra* note 34, at 4.

liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection.”<sup>39</sup> This view was similarly posited in an FDA amicus brief in 1996.<sup>40</sup>

The administration of President George W. Bush justified the FDA’s changing view on a new cost-benefit analysis.<sup>41</sup> The FDA argued that it was now properly calculating for the risk added by the FDA’s regulatory measures, in addition to the actual risk associated with the devices.<sup>42</sup> Tort reform was a policy goal of President Bush.<sup>43</sup> As Governor of Texas, President Bush helped to enact seven tort reform bills, one of which made it more difficult for plaintiffs to receive punitive damages by increasing the burden of proof and reducing punitive damage liability.<sup>44</sup> President Bush argued that product liability tort lawsuits increase prices in the healthcare sector and thus burden the economy as a whole.<sup>45</sup>

This policy followed Bush into the White House and would become one of the goals of his administration.<sup>46</sup> President Bush attempted to achieve this goal through federal legislation<sup>47</sup> and by having the government submit amicus briefs in medical drug and device litigation, to mixed success.<sup>48</sup>

In 2006, the FDA published a formal statement in the Federal Register discussing the extent of the FDA’s preemptive reach.<sup>49</sup> In particular, this statement stated that it was necessary for FDA regulations to preempt state products liability lawsuits in order to ensure that state tort lawsuits did not

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39. Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 11 (1997).

40. Brief for the United States as Amicus Curiae, *Smith Indus. Med. Sys., Inc. v. Kernats*, No. 96-1405, 1997 WL 33561767 (1997); see Clune, *supra* note 34, at 2.

41. See Clune, *supra* note 34, at 7.

42. See *id.* at 7–8.

43. See *id.* at 8.

44. See *id.*

45. See *id.*; Jordyn K. McAfee, *Medical Malpractice Crisis Factional or Fictional?: An Overview of the GAO Report as Interpreted by the Proponents and Opponents of Tort Reform*, 9 J. MED. & L. 161, 166 (2005) (“President Bush maintains that the high costs of medical malpractice premiums are due to excessive damage awards . . . . [I]f there are caps that disallow high damage awards it would lead to a decrease of medical malpractice premiums.”).

46. See Michele E. Gilman, *Presidents, Preemption, and the States*, 26 CONST. COMMENT. 339, 351 (2010).

47. See McAfee, *supra* note 45, at 164–66 (discussing Bush’s then-proposed federal legislation); see also BRADLEY M. JONES & MARY BYRNE FLETCHER, MEAGHER & GEER PLLP, *HOW THE LITIGATION CLIMATE IN THE USA HAS CHANGED SINCE OBAMA BECAME PRESIDENT AND THE DEMOCRATS TOOK CONTROL OF CONGRESS* 9 (2009), <http://www.meagher.com/files/upload/acb.pdf> (arguing that the only significant Bush tort reform legislation was the Class Action Fairness Act, and the Bush Administration’s tort reform successes derived from state legislation and federal court rulings) [<http://perma.cc/7BBB-NTDG>].

48. See James M. Beck, *Federal Preemption in FDA-Regulated Product-Liability Litigation: Where We Are and Where We Might Be Headed*, 32 HAMLINE L. REV. 657, 683 (2009).

49. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3933–36 (Jan. 24, 2006) [hereinafter Requirements on Content and Format]; see Beck, *supra* note 48, at 684.



interfere with the FDA's labeling determinations.<sup>50</sup> The crux of the FDA's argument was based on concerns of "defensive labeling."<sup>51</sup> Under this theory, the prospect of state litigation can add pressure on manufacturers to warn consumers about risks that may be speculative, which in turn discourages the safe and effective use of products and encourages second-guessing of FDA determinations in litigation.<sup>52</sup>

In May 2009, President Obama fought back against FDA preemption.<sup>53</sup> In a memorandum directed to executive department and agency heads, President Obama provided instructions for all agencies regarding preemption determinations.<sup>54</sup> President Obama's memorandum directed departments and agencies not to rely upon uncodified preemption preamble provisions, to review whether preemption regulations are still justified under traditional preemption principles every ten years, and to refrain from codifying preemption provisions when not justified under traditional preemption principles and Executive Order 13,132.<sup>55</sup> In response to President Obama's memorandum, in October 2011, the FDA issued notice that it had in fact reviewed its preemption preambles and codifications from the past ten years and deemed that three of its preemption preambles were not legally justified.<sup>56</sup>

As one commentator notes, the Obama Administration, despite its earlier efforts to limit FDA preemption, actually *supported* the generic drug manufacturer's preemption claim in *Bartlett*.<sup>57</sup> The government even submitted an amicus brief to the Court indicating this view.<sup>58</sup> Unlike other cases,<sup>59</sup> *Bartlett* "directly challenge[d] the FDA's very authority to approve a product in the first place" and initiated concerns over the future of biomedical innovation.<sup>60</sup> Because other support for preemption

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50. Requirements on Content and Format, *supra* note 49, at 3967; *see* Beck, *supra* note 48, at 684–85.

51. Requirements on Content and Format, *supra* note 49, at 3935; *see* Beck, *supra* note 48, at 686.

52. Beck, *supra* note 48, at 685–86.

53. *See* Victor E. Schwartz & Cary Silverman, *Preemption of State Common Law by Federal Agency Action: Striking the Appropriate Balance That Protects Public Safety*, 84 TUL. L. REV. 1203, 1219 (2010).

54. Memorandum from the Administration of Barack Obama, Memorandum Regarding Preemption (May 20, 2009), <https://www.whitehouse.gov/the-press-office/2009/05/20/20090520-preemption> [http://perma.cc/HB7T-XTLW]; *see* Schwartz & Silverman, *supra* note 53, at 1219–20.

55. Memorandum from the Administration of Barack Obama, *supra* note 54; *see* Schwartz & Silverman, *supra* note 53, at 1220; *see also* Exec. Order No. 13,132, 64 Fed. Reg. 43,255, 43,255 (Aug. 4, 1999) (ensuring "the principles of federalism established by the Framers guide the executive departments and agencies in the formulation and implementation of policies").

56. Preemption Review, 76 Fed. Reg. 61,565, 61,565–66 (Oct. 5, 2011).

57. Tevi Troy, *The Best Prescription for Pre-emption*, WALL STREET. J. (Mar. 18, 2013 7:11 PM), <http://www.wsj.com/articles/SB10001424127887323869604578368080602288500> [http://perma.cc/574M-7HSB].

58. Brief for the United States as Amicus Curiae Supporting Petitioner, Mutual Pharmaceutical Co. v. Bartlett, 133 S. Ct. 2466 (2013) (No. 12-142), 2013 WL 314460.

59. *See infra* Part I.D.1 (discussing Wyeth v. Levine and PLIVA, Inc. v. Mensing).

60. *See* Troy, *supra* note 57.

unsurprisingly came from pharmaceutical companies, this created a situation of “strange bedfellows.”<sup>61</sup>

### B. Federal Preemption

The doctrine of preemption is rooted in the U.S. Constitution’s Supremacy Clause.<sup>62</sup> Under this doctrine, courts are handed the task of determining whether federal law has the effect of nullifying state law.<sup>63</sup> The Court has applied preemption under three different theories: express, field, and conflict preemption.<sup>64</sup>

#### 1. Express Preemption

Express preemption analysis occurs when federal legislation explicitly states federal law’s effect on state law<sup>65</sup> or enumerates the state laws that Congress *does not* want the statute to nullify.<sup>66</sup> Ultimately, when engaging in an express preemption analysis, a court must ascertain what the clause itself means and determine from its meaning whether the clause nullifies state law.<sup>67</sup>

#### 2. Field Preemption

Another type of preemption is “field preemption.”<sup>68</sup> A court will find field preemption occurs when it concludes, “that Congress has intended

61. SCOTT GOTTLIEB, AM. ENTERPRISE INST., COURT CASE COULD UNDERMINE DRUG APPROVAL PROCESS (2013), <https://www.aei.org/publication/court-case-could-undermine-drug-approval-process/>; see THOMAS MCGARITY, CENT. FOR PROGRESSIVE REFORM, ANOTHER SKIRMISH IN THE PREEMPTION WAR: DOES FDA APPROVAL TRUMP STRICT LIABILITY? (2013), <http://www.progressivereform.org/CPRBlog.cfm?idBlog=5F199697-B315-8C86-A26F5A4D15C6FCA3> (arguing the content of the amicus brief is inconsistent with President Obama’s memorandum on preemption) [<http://perma.cc/H9SH-X847>]; Rich Samp, *DOJ/FDA Brief in SCOTUS Generic Drug Preemption Case Hands Plaintiffs New Liability Theories*, FORBES (Jan. 30, 2013, 12:21 PM), <http://www.forbes.com/sites/wlf/2013/01/30/doj-fda-brief-in-scotus-generic-drug-preemption-case-hands-plaintiffs-new-liability-theories/2/> (noting that in its amicus brief, the government “went out of its way to propose a brand new cause of action that, in the federal government’s view, would survive preemption”) [<http://perma.cc/A8VP-PV8F>].

62. See, e.g., *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466, 2470 (2013) (“Under the Supremacy Clause, state laws that require a private party to violate federal law are pre-empted and, thus, are ‘without effect.’” (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981))); see also U.S. CONST. art. VI, § 2 (“This Constitution and the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”).

63. See Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 226 (2000).

64. See *id.*

65. See *id.*; see e.g., *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77–84 (2008) (applying an express preemption analysis).

66. See Nelson, *supra* note 63, at 226–27; see, e.g., 49 U.S.C. § 30103(e) (2012) (“Compliance with any Federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law.”).

67. See Nelson, *supra* note 63, at 227.

68. See *id.*

federal law to be the exclusive law in a certain area of regulation.”<sup>69</sup> Unlike express preemption, field preemption allows a court to find that federal law preempts state law without a direct conflict.<sup>70</sup> Courts can infer this occurs when the “‘federal regulatory scheme’ may be ‘so pervasive’” as to make reasonable the inference that “Congress left no room for the States to supplement it.”<sup>71</sup> Additionally, courts infer preemption where “‘the federal interest’ in the field that a federal statute addresses may be ‘so dominant’ that federal law ‘will be assumed to preclude enforcement of state laws on the same subject.’”<sup>72</sup>

### 3. Conflict Preemption

Federal law also may preempt state law under the doctrine of “conflict preemption.”<sup>73</sup> Conflict preemption is divided into two categories: “obstacle” and “physical impossibility.”<sup>74</sup>

Under obstacle preemption, federal law preempts state law if the state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”<sup>75</sup> Under “physical impossibility” preemption, the theory of preemption that the *Bartlett* majority analyzed,<sup>76</sup> a court will examine the feasibility of the actions required by state law with respect to those actions required by federal law.<sup>77</sup> Where federal law and state law each impose different obligations via statute on the same subject matter, a court determines whether it would be “literally impossible for someone to comply with both statutes.”<sup>78</sup> When two statutes impose contradictory positive requirements, federal law preempts state law.<sup>79</sup> For example, if a federal law states that one must drive on the right side of the road, and a state law states that one must drive on the left side of the road, the federal law will be upheld.<sup>80</sup> However, for federal law to preempt state law, the physical impossibility doctrine requires that the state law *require* an activity that federal law *prohibits*, or vice versa.<sup>81</sup> For example, in

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69. Christopher H. Schroeder, *Supreme Court Preemption Doctrine*, in PREEMPTION CHOICE 125 (William W. Buzbee ed., 2009).

70. *See id.* at 126.

71. Nelson, *supra* note 63, at 227 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

72. *Id.* at 227 (quoting *Rice*, 331 U.S. at 230).

73. *See id.* at 227–28.

74. *See* Schroeder, *supra* note 69, at 131.

75. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); *see* Schroeder, *supra* note 69, at 132; *see, e.g., Geier v. Am. Motor Co.*, 529 U.S. 861, 881 (2000) (finding design defect claim against car manufacturer for failure to equip car with airbag preempted under obstacle preemption because it “would have stood as an obstacle to the gradual passive restraint phase-in that the [Department of Transportation] regulation deliberately imposed”).

76. *See infra* note 183 and accompanying text.

77. *See* Schroeder, *supra* note 69, at 131.

78. *Id.*

79. *See generally* Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132 (1963).

80. *See* Transcript of Oral Argument at 45, *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013) (No. 12-142) (Alito, J.).

81. *See* Erika Fisher Lietzan & Sarah E. Pitlyk, *Thoughts on Preemption in the Wake of the Levine Decision*, 13 J. HEALTH CARE L. & POL’Y 225, 227 (2010).

*Michigan Cannery & Freezers Ass'n v. Agricultural Marketing & Bargaining Board*,<sup>82</sup> the Court held that federal law did not preempt state law because the state law was “permissive” rather than “mandatory.”<sup>83</sup>

Physical impossibility preemption gets considerably murkier where federal law has enacted a positive requirement that is seemingly contrary to common law as opposed to a statute.<sup>84</sup> Since *Cipollone v. Liggett Group, Inc.*,<sup>85</sup> the Court has engaged in a debate as to whether common law truly creates a “requirement” imposed by state law.<sup>86</sup> The question is whether state common law creates a positive duty upon parties due to its regulatory effect on human behavior, or whether it is not a “requirement,” but merely a cost that the manufacturer must internalize.<sup>87</sup>

### C. Determining Defect

As stated in section 402A, comment a of the Restatement (Second) of Torts (“Restatement (Second)”), “[t]he rule [of design defect] is one of strict liability, making the seller subject to liability to the user or consumer even though he has exercised all possible care in the preparation and sale of the product.”<sup>88</sup> As implemented in section 402A of the Restatement (Second), following Judge Traynor’s opinions in the Supreme Court of California cases *Escola v. Coca Cola Bottling Co. of Fresno*<sup>89</sup> and *Greenman v. Yuba Power Products*,<sup>90</sup> strict liability is concerned with the status of the product itself—that is, whether the product sold is “defective.”<sup>91</sup>

Section 402A of the Restatement (Second) endorses the following test for strict products liability:

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
  - (a) the seller is engaged in the business of selling such a product, and

82. 467 U.S. 461 (1984).

83. *Id.* at 478 n.21.

84. See Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 459–71 (2008) (discussing the Supreme Court’s “tort as regulation” and “tort as compensation” jurisprudence).

85. 505 U.S. 504 (1992).

86. See Sharkey, *supra* note 84, at 459–71.

87. See *id.*

88. RESTATEMENT (SECOND) OF TORTS § 402A cmt. a (AM. LAW INST. 1965).

89. 150 P.2d 436, 441 (Cal. 1944) (Traynor, J., concurring).

90. 377 P.2d 897 (Cal. 1963). The opinions of Judge Richard Traynor are traditionally viewed as establishing the doctrine of strict liability. See, e.g., *Tellez v. Dole Food Co., Inc.*, No. BC 312 852, 2008 WL 744052, at \*9 (Cal. Super. Ct. Mar. 7, 2008) (“[T]he doctrine of strict liability was created by *Greenman* . . .”).

91. See DAVID G. OWEN, *PRODUCTS LIABILITY LAW* 290 (2005). While section 402A actually refers to this as “defective condition unreasonably dangerous,” courts have not applied the term any differently when referred to as “defective,” “unreasonably dangerous,” “defective condition unreasonably dangerous,” or similar terms. See *id.* at 263–64.

- (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
- (2) The rule stated in Subsection (1) applies although
  - (a) the seller has exercised all possible care in the preparation and sale of his product, and
  - (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.<sup>92</sup>

In order to be found liable, the manufacturer must produce a product that is “defective” or “unreasonably dangerous.”<sup>93</sup> This raises an important question: When do we want “defect” or “unreasonable danger” to be found?<sup>94</sup> Courts and academics have formulated different answers to this question.<sup>95</sup>

The following sections discuss the different tests that courts use to determine defect. Part I.C.1 discusses the consumer expectations test. Part I.C.2 discusses the traditional risk-utility test. Part I.C.3 discusses variations of the risk-utility test. Part I.C.4 discusses variations that merge the consumer expectations and risk-utility tests. Finally, Part I.C.5 discusses true absolute liability.

### 1. The Modern-Day Minority: Consumer Expectations Test

When courts were first handed the task of determining the meaning of “defect” or “unreasonable danger” within section 402A of the Restatement (Second), they initially looked to the Restatement’s comments for guidance.<sup>96</sup> The Restatement (Second) contained two relevant comments which offered the courts guidance: comment g and comment i.<sup>97</sup> Both of these comments state that a determination of “defect” should ultimately be based upon the expectations of consumers.<sup>98</sup> As a result, in the 1960s and 1970s following the publication of the Restatement (Second), this was the majority view of courts.<sup>99</sup> A typical formulation of the test would ask a jury whether “the manufacturer’s product failed to perform as safely as an ordinary consumer would expect.”<sup>100</sup>

92. RESTATEMENT (SECOND) OF TORTS § 402A.

93. *See id.*

94. *See OWEN, supra* note 91, at 290.

95. *See infra* Part I.C.1–2.

96. *See OWEN, supra* note 91, at 292.

97. *See id.* at 292–93.

98. *See id.*; *see also* RESTATEMENT (SECOND) OF TORTS § 402A cmt. g (AM. LAW INST. 1965) (“The rule stated in this Section applies only where the product is, at the time it leaves the seller’s hands, in a condition not contemplated by the ultimate consumer, which will be unreasonable to him.”); *id.* cmt. i (“The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.”).

99. *See OWEN, supra* note 91, at 293.

100. *Soule v. Gen. Motors Corp.*, 882 P.2d 298, 303 (Cal. 1994); *see also* *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 352 (Ill. 2008) (“The jury is asked to make a single determination: whether the product is unsafe when put to a use that is reasonably foreseeable considering its nature and function . . . . No evidence of ordinary consumer expectations is required, because the members of the jury may rely on their own experiences to determine what an ordinary consumer would expect.” (citation omitted)).

Although various commentators have pointed out the several flaws in the consumer expectations test,<sup>101</sup> some courts have continued to apply it and reject any alternative.<sup>102</sup>

## 2. The Risk-Utility Test

Realizing the problems associated with application of the consumer expectations test, courts presently tend to measure defectiveness of design in the form of a risk-utility test.<sup>103</sup> Furthermore, this is the approach presently adopted by the Restatement (Third) of Torts: Products Liability (“Restatement (Third)”)<sup>104</sup>

Generally, the risk-utility test involves “a balancing of the probability and seriousness of harm against the costs of taking precautions.”<sup>105</sup> Under this rule, liability may not be found when the costs of avoiding a hazard are deemed to be foreseeably greater than the resulting benefits.<sup>106</sup> Conversely, liability may be found where the benefits from preventing such a danger exceed or outweigh any costs associated with it.<sup>107</sup>

Different jurisdictions may consider different factors when performing this cost-benefit analysis.<sup>108</sup> While some jurisdictions have taken a more expansive approach,<sup>109</sup> courts will generally refer to the factors recommended by Dean John Wade.<sup>110</sup> Under the “Wade Factors,” a court will direct a jury to look to (1) the usefulness and desirability of the product, (2) the product’s safety aspects, (3) the availability of a substitute

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101. First, the consumer expectations test inhibits injured parties from recovering damages for injuries caused by obvious dangers. *See* David G. Owen, *Design Defect Ghosts*, 74 BROOK. L. REV. 927, 942 (2009). Second, it prevents injured bystanders from recovering damages. *See* Gomulka v. Yavapai Mach. & Auto Parts, Inc., 745 P.2d 986, 989 (Ariz. Ct. App. 1987) (“The consumer expectation test does not apply to bystanders, at least in design defect cases, because a person who . . . is not using the product may be entirely ignorant of its properties and of how safe it could be made.”). Third, it has been criticized as too vague for juries to properly apply. *See* Horst v. Deere & Co., 2009 WI App 75, ¶ 95, 319 Wis. 2d 147, 769 N.W.2d 536, 558; James A. Henderson, Jr. & Aaron D. Twerski, *Achieving Consensus on Defective Product Design*, 83 CORNELL L. REV. 867, 882 (1998) (calling the consumer expectations test “so vague as to be lawless”).

102. *See* OWEN, *supra* note 91, at 296.

103. *See id.* at 301.

104. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. d (AM. LAW INST. 1998) (“[T]he test is whether a reasonable alternative design would, at reasonable cost, have reduced the foreseeable risks of harm posed by the product and, if so, whether the omission of the alternative design by the seller or a predecessor in the distributive chain rendered the product not reasonably safe.”).

105. OWEN, *supra* note 91, at 303 (quoting *Raney v. Honeywell, Inc.*, 540 F.2d 932, 935 (8th Cir. 1976)).

106. *See id.* at 303–04.

107. *See id.*

108. *See id.* at 499–504.

109. *See id.* at 499; *see, e.g.*, *Banks v. ICI Ams., Inc.*, 450 S.E.2d 671, 675 (Ga. 1994) (“[N]o finite set of factors can be considered comprehensive or applicable under every factual circumstance, since such matters must necessarily vary according to the unique facts of each case.”).

110. *See* OWEN, *supra* note 91, at 500–01; *see also* John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825, 837–38 (1973) (proposing the Wade Factors).

product that would serve the same function in a safer manner, (4) the manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility, (5) the user's ability to avoid danger by the exercise of care in the use of the product, (6) the user's ability to anticipate awareness of the dangers inherent in the product and their avoidability, and (7) the feasibility on the part of the manufacturer of spreading the loss.<sup>111</sup>

### 3. Modifications and Reformulations of the Risk-Utility Test

While the risk-utility test is the most commonly used test to determine defect, different jurisdictions employ different variations of it. This section explores these variations. Part I.C.1.a discusses the alternative design requirement. Part I.C.2.b discusses the prudent manufacturer test. Finally, Part I.C.3.c discusses the Restatement (Third)'s variation.

#### *a. Alternative Design*

One of the Wade Factors requires a jury to consider and evaluate the feasibility and reasonableness of an alternative design.<sup>112</sup> The Restatement (Third) suggests that this should be a *requirement*, not merely one factor for a jury to consider.<sup>113</sup> Similarly, many jurisdictions *require* proof of a feasible alternative design to prove defectiveness under the risk-utility test.<sup>114</sup> Normally, the injured plaintiff will hold the burden of proof on the issue of alternative design.<sup>115</sup> Other states, however, while not *requiring* the proof of an alternative design, will allow it to be considered in the process.<sup>116</sup> Finally, some states have completely rejected a jury's consideration of an alternative design due to the high cost plaintiffs endure to prove it and the alternative design requirement's perceived low value.<sup>117</sup>

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111. See *Akee v. Dow Chem. Co.*, 272 F. Supp. 2d 1112, 1132 (D. Haw. 2003); Wade, *supra* note 110, at 837–38.

112. See *supra* note 111 and accompanying text.

113. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(b) (AM. LAW INST. 1998). James A. Henderson, Jr. & Aaron D. Twerski argue that this is the “consensus view” and that the minority jurisdictions may accept it “given time for reflection.” Henderson & Twerski, *supra* note 101, at 920.

114. See *OWEN*, *supra* note 91, at 506; see, e.g., *General Motors Corp. v. Edwards*, 482 So.2d 1176, 1191 (Ala. 1985), *overruled on other grounds by Schwartz v. Volvo N. Am. Corp.*, 554 So.2d 927 (Ala. 1989).

115. See *OWEN*, *supra* note 91, at 506–07.

116. See *id.* at 507.

117. See *id.*; see also *Vautour v. Body Masters Sports Indus.*, 784 A.2d 1178, 1183 (N.H. 2001). One commentator argues that it ignores the complexity of modern day products, increases the expense of lawsuits, assumes that consumers are insured, is contrary to strict liability's purpose in making lawsuits and recovery by plaintiffs easier, will prevent certain lawsuits from being brought that will increase hazards of dangerous products, and fails to bear the inherent costs on the manufacturer. See Frank J. Vandall, *The Restatement (Third) of Torts: Products Liability Section 2(b): The Reasonable Alternative Design Requirement*, 61 TENN. L. REV. 1407, 1423–24 (1994). Another commentator sees the Restatement (Third)'s inclusion of this requirement as a result of special interest advocates manipulating caselaw. See Patrick Lavelle, *Crashing into Proof of a Reasonable Alternative Design: The*

*b. The Prudent Manufacturer Test*

The prudent manufacturer test, also commonly referred to as the “hindsight test” or the “Wade-Keeton test,” is applied in some jurisdictions.<sup>118</sup> Under this test, a jury is instructed to impute knowledge regarding the products’ condition to the manufacturer.<sup>119</sup>

As stated in *Dorsey v. Yoder Co.*,<sup>120</sup> under the prudent manufacturer test, “the proper test of ‘unreasonable danger’ is whether a reasonable manufacturer would continue to market his product in the same condition as he sold it to the plaintiff *with* knowledge of the potential dangerous consequences the trial just revealed.”<sup>121</sup> This test allows jurors to account for information about a product’s risk that may have been revealed after the time of the design, or even after the accident itself.<sup>122</sup> Despite the disassociation or repudiation of the test by both of its original proponents, Dean John Wade and W. Page Keeton,<sup>123</sup> some jurisdictions continue to adhere to the hindsight test.<sup>124</sup>

The prudent manufacturer test is not a unique test in and of itself, like the consumer expectations test, but rather a version of the risk-utility test where knowledge developed from the record is imputed upon the manufacturer.<sup>125</sup> Jurisdictions that do support the viability of the prudent manufacturer test apply it along with the risk-utility test, as it is a version of the risk-utility test.<sup>126</sup>

For example, in *Golonka v. General Motors Corp.*,<sup>127</sup> in a design defect action against an automobile manufacturer, the Court of Appeals of Arizona analyzed how a jury should determine defectiveness under this test.<sup>128</sup> The

*Fallacy of the Restatement (Third) of Torts: Products Liability*, 38 DUQ. L. REV. 1059, 1101 (2000).

118. See OWEN, *supra* note 91, at 532; see also Ray *ex rel.* Holman v. BIC Corp., 925 S.W.2d 527, 533 (Tenn. 1996) (“Wade-Keeton” test); Dart v. Wiebe Mfg., 709 P.2d 876, 881 (Ariz. 1985) (“hindsight test” and “prudent manufacturer test”).

119. See OWEN, *supra* note 91, at 531.

120. 331 F. Supp. 753 (E.D. Pa. 1971).

121. *Id.* at 759–60.

122. See JOHN C. P. GOLDBERG ET AL., TORT LAW: RESPONSIBILITY AND REDRESS 959 (3d ed. 2012).

123. See OWEN, *supra* note 91, at 533. They had both argued for the application of this test *independently* in a series of articles. See *id.* at 530–31.

124. See *id.* at 533–54 (citing a state statute in Tennessee, and courts in Arizona, New York, Maryland, Pennsylvania, Montana, and Mississippi, that continue to adhere to the hindsight test).

125. See Privette v. CSX Transp. Inc., No. 02-5312, 2003 WL 22514347, at \*9 (6th Cir. Nov. 4, 2003) (“To prevail under the prudent manufacturer test, a plaintiff must establish that [sic] ‘that the product because of its dangerous condition would not be put on the market by a reasonably prudent manufacturer or seller, assuming that the manufacturer or seller knew of its dangerous condition.’ . . . This determination involves a risk-utility analysis . . .”); Dominick Vetri, *Order Out of Chaos: Products Liability Design-Defect Law*, 43 U. RICH. L. REV. 1373, 1395 (2009) (“The [prudent manufacturer test] . . . generally relies on risk-utility evidence and analysis, but frames the jury question in terms of what a reasonable manufacturer would have done in the circumstances.”).

126. See Vetri, *supra* note 125, at 1395–98.

127. 65 P.3d 956 (Ariz. Ct. App. 2003).

128. See *id.* at 963.



court found that the information that the trial revealed should be imputed to the manufacturer, and then the risk-utility factors should be applied in “hindsight” to decide whether it was reasonable for the manufacturer to put the product on the market.<sup>129</sup> Thus, the court demonstrated how the aspect of hindsight can be applied alongside the risk-utility test.

*c. The Restatement (Third)’s Reformulation*

The Restatement (Third) contains arguably one of the more defendant-friendly formulations of the test for design.<sup>130</sup> Section 6(c) of the Restatement (Third) states:

A prescription drug . . . is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug . . . for any class of patients.<sup>131</sup>

While this standard has been highly criticized,<sup>132</sup> recently some courts have been willing to accept the Restatement (Third)’s design defect analysis.<sup>133</sup> For example, in *Haffner v. Stryker Corp.*,<sup>134</sup> the Colorado District Court determined whether a plaintiff stated a plausible claim regarding his design defect suit against the manufacturer of a knee replacement system.<sup>135</sup> The plaintiff claimed that the knee replacement system was defectively designed because it contained substances, nickel and cobalt, to which 19 percent of the population is allergic or sensitive, despite there being hypoallergenic alternatives available.<sup>136</sup> The court

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129. *See id.*; *see also* Sternhagen v. Dow Co., 935 P.2d 1139, 1147 (Mont. 1997) (“[W]e conclude that, in a strict products liability case, knowledge of any undiscovered or undiscoverable dangers should be imputed to the manufacturer.”).

130. *See generally* James A. Henderson, Jr., *Prescription Drug Design Liability Under the Proposed Restatement (Third) of Torts: A Reporter’s Perspective*, 48 RUTGERS L. REV. 471 (1996).

131. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(C) (AM. LAW INST. 1998).

132. *See* Freeman v. Hoffman-La Roche, Inc., 618 N.W.2d 827, 838–40 (Neb. 2000) (arguing that the test misstates the law, is difficult to apply, is inflexible, and cannot be defeated easily by an expert witness); George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 YALE L.J. 1087, 1133 (2000) (“The process of selecting a design should be informed by the knowledge that the designer someday may have to justify the particular balance it chose between risk and utility. Such thoughtful consideration of the need to justify design choices ultimately will result in better, safer products.”); Richard L. Cupp, Jr., *Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach*, 63 GEO. WASH. L. REV. 76, 76 (1994) (“[A] near-immunity standard provides too much protection for manufacturers and too little protection for consumers.”).

133. *See* ANDREW SOLOW ET AL., KAYE SCHOLER LLP, THE EVER-SHIFTING LANDSCAPE IN PRESCRIPTION DRUG DESIGN DEFECT LITIGATION 7 (2014), [http://www.kayescholer.com/in-the-market/publications/articles/20140204-shifting-landscape-in-prescription-drug-design-defect-litigation-product-liability/\\_res/id=sa\\_File1/solow-anziska-meyers-product-liability-article.pdf](http://www.kayescholer.com/in-the-market/publications/articles/20140204-shifting-landscape-in-prescription-drug-design-defect-litigation-product-liability/_res/id=sa_File1/solow-anziska-meyers-product-liability-article.pdf) [<http://perma.cc/WB4G-KMT8>].

134. No. 14-CV-00186-RBJ, 2014 WL 4821107 (D. Colo. Sept. 29, 2014).

135. *See id.* at \*1.

136. *See id.* at \*3.

dismissed these claims, citing the Restatement (Third), and held that “medical devices can be safe for certain patient populations and not others without their risk outweighing their utility.”<sup>137</sup>

#### 4. Consumer Expectations and Risk-Utility Come Together

While certain jurisdictions consider the consumer expectations and risk-utility tests to be mutually exclusive, several jurisdictions have abandoned that approach and accommodate each test in different circumstances.<sup>138</sup> First, some jurisdictions allow *either* of these tests to be proven to hold a manufacturer liable for design defect.<sup>139</sup> Under the jurisdictions that apply the “two-pronged approach,” a plaintiff may establish design defect through either the consumer expectations test or the risk-utility test.<sup>140</sup> For example, in *Barker v. Lull Engineering Co.*,<sup>141</sup> the Supreme Court of California held that a product may be deemed defective

(1) if the plaintiff demonstrates that the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, *or* (2) if the plaintiff proves that the product’s design proximately caused his injury and the defendant fails to prove, in light of the relevant factors . . . that on balance the benefits of the challenged design outweigh the risk of danger inherent in such design.<sup>142</sup>

Second, some jurisdictions will apply the tests in different situations.<sup>143</sup> For example, in *Halliday v. Sturm, Ruger & Co.*,<sup>144</sup> the Maryland Court of Appeals held that the consumer expectations test applies to design defect cases unless the product malfunctions, in which case the risk-utility test applies.<sup>145</sup>

Third, some jurisdictions may use one test as part of the other test, effectively combining the two tests into one.<sup>146</sup> For example, in *Potter v. Chicago Pneumatic Tool Co.*,<sup>147</sup> the Supreme Court of Connecticut held that one of the factors that may be considered *within* the consumer expectations test applied by the state may be the risk-utility factors.<sup>148</sup>

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137. *Id.*

138. See David G. Owen, *Design Defects*, 73 MO. L. REV. 291, 336–64 (2008).

139. See *id.* at 341.

140. See *id.* at 341–42.

141. 573 P.2d 443 (Cal. 1978).

142. *Id.* at 457–58 (emphasis added).

143. See Owen, *supra* note 138, at 346–53.

144. 792 A.2d 1145, 1153 (Md. 2002).

145. See *id.*

146. See Owen, *supra* note 138, at 335–41.

147. 694 A.2d 1319, 1333 (Conn. 1997).

148. See *id.* (“[A] consumer’s expectations may be viewed in light of various factors that balance the utility of the product’s design with the magnitude of its risks.”); see also *Delaney v. Deere & Co.*, 999 P.2d 930, 944 (Kan. 2000) (“[W]e . . . recognize the validity of risk/utility analysis as a guide in determining the expectations of consumers in complex cases.”).

### 5. No Test for Defect: True Absolute Liability

In a true absolute liability regime,<sup>149</sup> in order to make a prima facie claim, a court does not need to find that the defendant was at “fault.”<sup>150</sup> Rather, a plaintiff’s injury must merely be causally related to the product, regardless of whether the defendant took the utmost care *and* whether there was a defect in the product.<sup>151</sup>

True “absolute liability” and “strict liability” in tort are distinct concepts despite some commentators’ and courts’ willingness to use these terms interchangeably.<sup>152</sup> True absolute liability means that there is no excuse that will prevent liability so long as it was actually the defendant that caused the injury.<sup>153</sup> Meanwhile, strict liability does not create as broad an assumption of liability.<sup>154</sup> Rather, in strict liability, the defendant is only liable if a jury finds that the product that caused the injury was defective.<sup>155</sup> Unlike true absolute liability, strict liability requires a court to determine that a product was defective before liability can be found.<sup>156</sup>

The Supreme Court of Oregon identified this distinction in *Phillips v. Kimwood Machine Co.*<sup>157</sup> When the *Phillips* court determined the correct standard for determining defect, it noted that “[t]he problem with strict liability of products has been one of limitation. No one wants absolute liability where all the article has to do is to cause injury.”<sup>158</sup> The court then explained how this limitation, in products liability law, is found: “To impose liability [in true absolute liability] there has to be something about the article which makes it dangerously defective without regard to whether the manufacturer was or was not at fault for such condition. A test for unreasonable danger is therefore vital.”<sup>159</sup>

Presently, however, there are no jurisdictions that impose a true absolute liability design defect on drug manufacturers; in other words, no jurisdictions impose liability upon the manufacturer regardless of whether

149. This Note uses the terminology “true absolute liability” due to the tendency of courts and commentators to interchangeably use the terms “strict liability” and “absolute liability” despite their different meanings. See OWEN, *supra* note 91, at 290; Robert C. Baker III, *Requiem for a Remedy: The Law and Economics of Mutual Pharmaceutical v. Bartlett’s Over-Preemption*, 74 MD. L. REV. ENDNOTES 81, 97–98 (2015). When used by a court in this Note however, the term remains unaltered.

150. See OWEN, *supra* note 91, at 290.

151. See *id.*

152. See *id.*; *supra* note 149.

153. See OWEN, *supra* note 91, at 290.

154. See *id.*

155. See *id.* at 260–61.

156. See *id.* at 290; Gerald F. Tietz, *Strict Products Liability, Design Defects and Corporate Decision-Making: Greater Deterrence Through Stricter Process*, 38 VILL. L. REV. 1361, 1430–31 n.339 (1993) (“Although liability may be imposed without fault—e.g., when a manufacturer knowingly places a dangerous product into the stream of commerce—the liability is not absolute because it is created only when the product is found to be more dangerous than is reasonable under the circumstances . . .”).

157. 525 P.2d 1033 (Or. 1974).

158. *Id.* at 1036.

159. *Id.*

the product is defective.<sup>160</sup> Rather, all jurisdictions presently impose some sort of fault determination, i.e., strict liability, by finding liability when the product is in fact defective.<sup>161</sup>

#### D. Wyeth, Mensing & Bartlett

This section discusses the three major U.S. Supreme Court cases that led to the lower court split following *Bartlett*. Part I.D.1 discusses the two Supreme Court cases that set the stage for *Bartlett*. Then, Part I.D.2 discusses *Bartlett* itself.

##### 1. *Wyeth v. Levine* and *PLIVA, Inc. v. Mensing*: Setting the Stage for Generic Drug Manufacturer Design Defect Preemption

In *Wyeth v. Levine*,<sup>162</sup> the Court addressed whether FDA regulations preempted a plaintiff's failure-to-warn lawsuit under state law against a brand name drug manufacturer.<sup>163</sup> As to impossibility preemption, the Court held that it was possible for a brand name drug manufacturer to comply with both state duties under failure-to-warn common law and federal statutory law.<sup>164</sup> In *Wyeth*, the Court determined that federal law allowed brand name drug companies to unilaterally strengthen its drug warnings and therefore, federal law does not prohibit a brand name drug company from changing its label to properly warn of dangers associated with a drug.<sup>165</sup> Therefore, *Wyeth* held that because federal law allows the brand name drug company to change its labeling, there is no conflict between state and federal law.<sup>166</sup>

Two years later in *PLIVA, Inc. v. Mensing*,<sup>167</sup> the Court addressed whether FDA regulations preempted a similar failure-to-warn suit against a generic drug manufacturer.<sup>168</sup> In *Mensing*, the Court identified the state and federal duties.<sup>169</sup> First, they found that the applicable state law "require[s] a drug manufacturer that is or should be aware of its product's danger to label that product in a way that renders it reasonably safe."<sup>170</sup> Second, under federal law, the Court determined that FDA regulations allow generic drugs to receive approval "simply by showing equivalence to a reference listed drug that has already been approved by the FDA."<sup>171</sup>

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160. See JAMES L. GILBERT ET AL., *LITIGATING TORT CASES* § 59:60 (2014) ("[I]n no state is strict liability tantamount to absolute liability for injuries caused by a product."); Tietz, *supra* note 156, at 1430–31 n.339 (1993) ("[T]his author is aware of no decision that actually imposes an absolute liability standard."); Baker, *supra* note 149, at 97.

161. See *supra* note 160.

162. 555 U.S. 555 (2009).

163. See *id.* at 558.

164. See *id.* at 572–73.

165. See *id.*

166. See *id.*

167. 131 S. Ct. 2567 (2011).

168. See *id.* at 2572.

169. See *id.* at 2573.

170. *Id.*

171. *Id.* at 2574 (citing 21 U.S.C. § 355(j)(2)(A) (2006)).

However, FDA regulations prevented these drugs from “independently changing their generic drugs’ safety labels.”<sup>172</sup>

The Court held that federal law preempted these failure-to-warn claims against generic drug manufacturers under the doctrine of impossibility preemption.<sup>173</sup> The Court explained that if the generic drug manufacturer had independently changed its label to satisfy the state duty, then it would have violated FDA regulations which require “sameness” between a generic drug and its corresponding brand name drug’s labeling.<sup>174</sup> Therefore, after *Wyeth* and *Mensing*, an injured consumer’s ability to sue a drug manufacturer on a failure-to-warn theory is severely restricted.

## 2. *Mutual Pharmaceutical Co. v. Bartlett*

Two years after *Mensing*, the Court decided *Bartlett*. In 1978, the FDA approved the nonsteroidal anti-inflammatory drug “sulindac” under the brand name “clinoril.”<sup>175</sup> After its patent expired, several drug manufacturers—including Mutual Pharmaceutical Company (Mutual)—produced generic versions of clinoril.<sup>176</sup> Karen Bartlett was prescribed clinoril, but was ultimately given the generic version manufactured by Mutual and suffered from toxic epidermal necrolysis.<sup>177</sup> Toxic epidermal necrolysis is a syndrome characterized by skin peeling off in a manner similar to that of second-degree burns.<sup>178</sup>

Bartlett originally asserted failure-to-warn and design defect claims, but the New Hampshire District Court dismissed the failure-to-warn claim because Bartlett’s doctor admitted that he did not read the relevant warnings.<sup>179</sup> However, her design defect claim was successful and resulted in a twenty-one million dollar verdict in her favor.<sup>180</sup> Mutual appealed, arguing that FDCA and FDA regulations preempted the design defect claim, but the Court of Appeals affirmed the lower court’s decision.<sup>181</sup> The Supreme Court granted certiorari and heard the appeal.<sup>182</sup>

At issue in *Bartlett* was whether FDA regulations preempted Bartlett’s design defect claim against Mutual under the doctrine of impossibility preemption because it would be impossible for Mutual to comply with both federal and state requirements.<sup>183</sup> First, the Court determined the generic drug manufacturers’ duties under state law.<sup>184</sup> The Court recognized that

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172. *Id.* at 2577.

173. *See id.* at 2577–78.

174. *See id.*

175. *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013).

176. *See id.*

177. *See id.* at 2472.

178. *Toxic epidermal necrolysis*, STEDMAN’S MEDICAL DICTIONARY (27th ed. 2000).

179. *See Bartlett*, 133 S. Ct. at 2472.

180. *See id.*

181. *See id.*

182. *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 694 (2012); *see Bartlett*, 133 S. Ct. at 2472.

183. *See Bartlett*, 133 S. Ct. at 2470.

184. *See id.* at 2473.

New Hampshire adhered to design defect law as recommended by section 402A of the Restatement (Second).<sup>185</sup> Therefore,

[u]nder the Restatement—and consequently, under New Hampshire tort law—“[o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused” even though he “has exercised all possible care in the preparation and sale of the product.”<sup>186</sup>

The Court then addressed Mutual’s arguments that there is *no* state duty.<sup>187</sup> First, the Court rejected the respondent’s argument that because New Hampshire tort law is compensatory, and not regulatory, it did not create a duty.<sup>188</sup>

Second, the Court rejected respondent’s argument that New Hampshire law does not impose “strict liability,” but rather “absolute liability,” and thus, there are no state “requirements” because absolute liability does not impose a duty.<sup>189</sup> The Court rejected this argument because the argument failed to recognize the distinctions between jurisdictions that impose “strict liability” and “absolute liability.”<sup>190</sup> As stated by the Court in *Bartlett*, in strict liability, “liability does not depend on negligence, but still signals the breach of a duty,” while in absolute liability, “liability does not reflect the breach of any duties at all, but merely serves to spread risk.”<sup>191</sup>

The Court then proved that New Hampshire had not adopted an absolute liability regime, but rather a strict liability regime.<sup>192</sup> In support of this claim, the Court cited a series of New Hampshire Court of Appeals cases noting that 402(A) strict liability ultimately imposes a duty on the manufacturer that requires that they produce a safe product.<sup>193</sup>

Because the Court did not need to address whether an “absolute liability” regime could be preempted by the relevant FDA regulations, the Court, in a footnote, added: “[w]e can thus save for another day the question whether a true absolute-liability state-law system could give rise to impossibility preemption. As we have noted, most common-law causes of action for negligence and strict liability do not exist merely to spread risk, but rather impose affirmative duties.”<sup>194</sup>

The Court then determined the content of the duty New Hampshire law imposed.<sup>195</sup> The Court noted that under New Hampshire’s strict liability

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185. *See id.* (citing *Buttrick v. Arthur Lessard & Sons, Inc.*, 260 A.2d 111, 112–13 (1969)).

186. *Id.* (quoting RESTATEMENT (SECOND) OF TORTS § 402A (AM. LAW INST. 1965)) (second alteration in original).

187. *Id.*

188. *See id.*

189. *See id.*

190. *Id.*

191. *Id.*

192. *See id.* at 2473–74.

193. *See id.* (citations omitted).

194. *Id.* at 2474 n.1 (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323–24 (2008); *Cipollone v. Liggett Group*, 505 U.S. 504, 522 (1992)).

195. *See id.* at 2474.

law, courts apply the risk-utility test to determine whether the product is defective.<sup>196</sup> Under New Hampshire law, the risk-utility test requires a balancing of various factors, the most important being the product's usefulness and desirability, feasibility of the reduction of danger without significant affect on the product's effectiveness or manufacturing cost, and the presence and efficacy of a warning.<sup>197</sup>

The Court then analyzed the duty that federal law imposed.<sup>198</sup> The Court held that federal law prevented generic drug manufacturers from unilaterally changing their labels because FDCA rules required generic drugs to "have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based."<sup>199</sup> Second, the nature of sundilac's chemical composition precluded redesign because it was a one molecule drug.<sup>200</sup>

The Court then evaluated the state and federal duties and found that they conflicted.<sup>201</sup> The only way for Mutual to change its "risk utility profile" under state law and escape liability was to strengthen its warning label.<sup>202</sup> Because state law required Mutual to strengthen sundilac's warnings, and federal law prohibited Mutual from strengthening sundilac's warnings, they conflicted.<sup>203</sup>

The Court then addressed the so-called "stop selling alternative."<sup>204</sup> Under this theory, it is not impossible to comply with both federal and state requirements if the generic drug manufacturer simply refrains from selling the generic drug.<sup>205</sup> The Court rejected this argument because preemption does not require that a party, in order to satisfy both federal and state requirements, refrain from engaging in behavior altogether to avoid liability.<sup>206</sup> Rather, the Court held that such a holding would effectively eviscerate the entire doctrine of preemption.<sup>207</sup> The Court noted that *in*

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196. *See id.* (quoting *Vautour v. Body Masters Sports Indus.*, 784 A.2d 1178, 1181 (N.H. 2001); *Chellman v. Saab-Scania AB*, 138 A.2d 148, 150 (N.H. 1993)).

197. *Id.* at 2475 (quoting *Vautour*, 784 A.2d at 1182).

198. *See id.* at 2476.

199. *See id.* at 2475 (citing 21 U.S.C. §§ 355(j)(2)(A)(ii)-(v), (8)(B) (2012); 21 C.F.R. § 320.1(c) (2009)). The federal law that *Bartlett* analyzed was the Hatch-Waxman Act, which amended the FDCA and FDA regulations related to the Hatch-Waxman amendment. *See id.* at 2471; Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 417-19 (2011). The Hatch-Waxman Act sought to offer generic drugs an expedited approval process in order to allow pharmaceuticals to be more readily available to consumers. *See id.* at 417-18. Rather than undergoing a lengthy and expensive process to prove that a drug is safe and effective, generic drug manufacturers must merely submit an application demonstrating that a generic drug is equivalent to an FDA-approved brand name drug. *See id.* at 423. The FDA has approved over 10,000 generic drugs through this process. *See id.* at 418.

200. *See Bartlett*, 133 S. Ct. at 2475.

201. *See id.* at 2476-77.

202. *See id.* at 2475.

203. *See id.* at 2476-77.

204. *See id.* at 2477.

205. *See id.*

206. *See id.*

207. *Id.*

*every instance* where impossibility preemption had been found, there would not have been a conflict between state and federal law if the actor refrained from engaging in the activity completely.<sup>208</sup>

## II. THE LOWER COURTS DIVIDE

Lower courts have offered divergent theories regarding how *Bartlett* should be applied. Some jurisdictions see *Bartlett*'s holding as narrow and find room for design defects to maintain viability,<sup>209</sup> while others view *Bartlett*'s holding as broad and suggest that no design defect claim has continued viability after *Bartlett*.<sup>210</sup> Part II.A discusses cases that held (or suggested) that design defect claims against generic drug manufacturers can escape preemption even after *Bartlett*. Part II.B discusses cases holding that design defect claims against generic drug manufacturers cannot escape preemption after *Bartlett*.

### A. Courts Finding that Standard of Defectiveness Affects the Preemption Analysis

While in the minority, some lower courts have found that the state's test for defect *does* play a role in the preemption analysis after *Bartlett*.<sup>211</sup> The Eighth Circuit suggested it could<sup>212</sup> (although it recently backtracked partially),<sup>213</sup> the Eastern District of Missouri held that design defect claims against generic drug manufacturers are not preempted when the consumer expectations test is used,<sup>214</sup> the Illinois Appellate Court held design defect claims against generic drug manufacturers are not preempted when there is no alternative design that can be made,<sup>215</sup> and the Pennsylvania Superior Court has suggested that the "absolute liability" exception theorized in a *Bartlett* footnote has present applicability.<sup>216</sup>

#### 1. *Fullington v. Pfizer, Inc. (Fullington I)*

In *Fullington v. Pfizer, Inc.*<sup>217</sup> (*Fullington I*), the Eighth Circuit addressed whether federal law preempted a design defect claim against a generic drug manufacturer under Arkansas law.<sup>218</sup> In *Fullington I*, the appellant alleged that she developed tardive dyskinesia after ingesting MCP

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208. *See id.* But *see id.* at 2477 n.3 (noting an exception in "the rare case in which state or federal law actually requires a product to be pulled from the market—our pre-emption cases presume that a manufacturer's ability to stop selling does not turn impossibility into possibility." (citing *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 143 (1963))).

209. *See infra* Part II.A.

210. *See infra* Part II.B.

211. *See infra* Part II.A.1–4.

212. *See infra* Part II.A.1.

213. *See infra* Part II.B.2.c; *infra* note 285.

214. *See infra* Part II.A.2.

215. *See infra* Part II.A.4.

216. *See infra* Part II.A.3.

217. 720 F.3d 739 (8th Cir. 2013).

218. *See id.* at 745–47.



produced by a generic drug manufacturer from April 2008 to April 2009.<sup>219</sup> The Arkansas District Court originally granted the generic drug manufacturer's motion for summary judgment on the plaintiff's design defect claim against the generic drug manufacturer.<sup>220</sup>

In *Fullington I*, the Eighth Circuit distinguished the appellant's design defect claim from that in *Bartlett*.<sup>221</sup> The court noted that rather than using the risk-utility test, Arkansas applies the consumer expectations test to determine defect.<sup>222</sup> The court held that because of this difference, "it is not immediately clear whether Arkansas, unlike New Hampshire, offers generic drug manufacturers an opportunity, consistent with federal obligations, to somehow alter an otherwise unreasonably dangerous drug."<sup>223</sup> Rather than answering this question of law, the court reversed the district court's dismissal of the design defect claim and remanded the case back to the district court.<sup>224</sup>

### 2. *Neeley v. Wolters Kluwer Health, Inc.*

In *Neeley v. Wolters Kluwer Health, Inc.*,<sup>225</sup> the Eastern District of Missouri determined whether federal law preempted a design defect claim against a generic drug manufacturer under Kentucky law.<sup>226</sup> In *Neeley*, the court noted that Kentucky law, just like the Arkansas law discussed in *Fullington I*, required a court to apply to the consumer expectations test to determine defect.<sup>227</sup> Relying on *Fullington I*, the *Neeley* court stated that "it is not immediately clear whether [Kentucky] . . . offers generic drug manufacturers an opportunity, consistent with federal obligations, to somehow alter an otherwise unreasonably dangerous drug."<sup>228</sup> However, without even discussing how the consumer expectations test might affect the preemption analysis, the court denied the generic manufacturer's motion to dismiss.<sup>229</sup>

### 3. *Hassett v. Dafoe*

In *Hassett v. Dafoe*,<sup>230</sup> the Pennsylvania Superior Court determined whether federal law preempts a design defect claim against a generic drug

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219. *See id.* at 741.

220. *See id.* at 742.

221. *See id.* at 746.

222. *See id.*

223. *Id.*

224. *See id.* at 747. However, the district court did ultimately find that the claims were preempted. *See infra* Part II.B.1.c (discussing the case on remand).

225. No. 4:11-CV-325 JAR, 2013 WL 3929059 (E.D. Mo. July 29, 2013).

226. *See id.* at \*10. For the facts of *Neeley*, see *supra* notes 1-11 and accompanying text.

227. *See Neeley*, 2013 WL 3929059, at \*10.

228. *Id.* (quoting *Fullington*, 720 F.3d at 746) (alteration in original).

229. *See id.*

230. 74 A.3d 202 (Pa. Super. Ct. 2013).

manufacturer under Pennsylvania law.<sup>231</sup> In *Hassett*, the respondent alleged that he suffered tardive dyskinesia due to ingesting MCP.<sup>232</sup>

In *Hassett*, the court analyzed the holding in *Bartlett*.<sup>233</sup> The court stated that “[t]he *Bartlett* court concluded that New Hampshire’s version of § 402A liability did not impose absolute liability on manufacturers, but instead, a ‘duty to design [their products] reasonably safely for the uses which [they] can foresee.’”<sup>234</sup> However, the *Hassett* court further noted that “the Court expressly reserved ‘for another day the question whether a true absolute-liability state-law system could give rise to absolute-liability pre-emption.’”<sup>235</sup>

The court then criticized the “tsunami of cases” that the defendants had provided, arguing that these cases had failed to properly identify the “state law duties associated with various causes of action and a cogent analysis of how they conflict with federal law, which is the hallmark of an impossibility pre-emption determination.”<sup>236</sup> The court then further criticized the defendants, noting that they had not properly appreciated the nuance that preemption under *Bartlett* was “state-law specific.”<sup>237</sup> The court noted that because the case before the court “involv[ed] more than two thousand plaintiffs, many different states’ laws are potentially implicated.”<sup>238</sup>

The court then analyzed the claims that the plaintiffs asserted in their complaint.<sup>239</sup> The court stated that the plaintiffs asserted that the drug “has never been shown to be either efficacious or safe when used for long-term treatment,” “continued to [be] market[ed] . . . despite the fact that there were safer and less expensive alternatives available,” and “even when used as recommended and with appropriate warnings, was defective and unreasonably dangerous.”<sup>240</sup>

The *Hassett* court characterized the plaintiff’s claims as asserting *absolute liability*.<sup>241</sup> The court noted that regimes that impose absolute liability do not require a court to find that a duty was breached.<sup>242</sup> The court then noted that because there is no state duty for the federal duty to conflict with under an absolute liability regime, the “[d]efendants can comply with federal law, which does not permit them to unilaterally alter a drug’s design, and state law, which extends liability to a manufacturer of a

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231. *See id.* at 210–11.

232. *See id.* at 206.

233. *See id.* at 211.

234. *Id.* (quoting *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466, 2473 (2013)).

235. *Id.* (quoting *Bartlett*, 133 S. Ct. at 2474 n.1).

236. *Id.* at 211–12.

237. *Id.* at 212.

238. *Id.* at 212 n.6.

239. *See id.* at 212.

240. *Id.*

241. *See id.*

242. *See id.* (citing RESTATEMENT (SECOND) OF TORTS § 402A cmt. f (AM. LAW INST. 1965)).

defectively designed drug without regard to whether it may redesign its drug.”<sup>243</sup>

Judge William H. Platt filed an opinion concurring in part and dissenting in part.<sup>244</sup> In his dissent, Judge Platt argued that the majority failed to understand the differences between strict liability and absolute liability.<sup>245</sup> Furthermore, the dissent implied that the majority was hypocritical because, while they criticized the appellant for the failure to engage in a proper preemption analysis, the majority offered no case law or statutory law whatsoever that supported the assertion that the plaintiff’s design defect claim survived preemption.<sup>246</sup>

Judge Platt then suggested that the majority engaged in judicial activism by trying to find absolute liability where there was none.<sup>247</sup> Judge Platt argued that these claims were preempted despite the majority’s “eclectic exegesis” because Congress had regulated generic drugs in this manner.<sup>248</sup> The dissent then identified the majority’s failure to regard any precedent, even for persuasive value, that would have altered the outcome of the case.<sup>249</sup> The dissent continued by quoting *Bartlett*: “The dreadful injuries from which products liabilities cases arise often engender passionate responses. Today is no exception[.] But sympathy for [the injured party] does not relieve us of the responsibility of following the law.”<sup>250</sup>

#### 4. *Guvnoz v. Target Corp.*

In *Guvnoz v. Target Corp.*,<sup>251</sup> the Illinois Appellate Court determined whether federal law preempted a plaintiff’s design defect suit against a generic drug manufacturer under Illinois law.<sup>252</sup> In *Guvnoz*, the plaintiff alleged that the generic drug propoxyphene caused his cardiac arrest.<sup>253</sup> After summarizing the Supreme Court’s holdings in *Mensing* and *Bartlett*, the court stated that the facts of the case at bar were distinguishable because in those cases “the drug was safe for the vast majority of patients taking it, and only a ‘very small number of patients’ suffered an adverse and severe reaction,” while in the case at bar the “plaintiff alleges that there was no group of patients for whom the drug’s benefits outweighed its risks.”<sup>254</sup>

In *Guvnoz*, the drug at issue had been approved by the FDA, was ingested by the plaintiff while it was approved, and the plaintiff’s injuries

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243. *Id.*

244. *Id.* at 217 (Platt, J., concurring in part, dissenting in part).

245. *See id.* at 220 (citing *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466, 2474 n.1 (2013)).

246. *See id.* at 220–21.

247. *See id.*

248. *Id.* at 220.

249. *See id.* at 221.

250. *Id.* at 221 (quoting *Bartlett*, 133 S. Ct. at 2478) (first alteration in original).

251. 2015 IL App. (1st) 133940.

252. *See id.* ¶ 44.

253. *See id.* ¶ 10.

254. *Id.* ¶ 72 (quoting *Bartlett*, 133 S. Ct. at 2471).

occurred while it was approved.<sup>255</sup> However, afterwards, the FDA required manufacturers to withdraw any products containing propoxyphene due to safety studies showing the drug's adverse impact on electrical activity in the heart.<sup>256</sup> The court held that because the plaintiff alleged that the "drug was simply unsafe and should not have been sold at all" and that "since no remedy was possible," there is no "safe harbor" under *Bartlett*.<sup>257</sup> Because the plaintiff claimed that there was no improvement that could be made to the design or label that would have resolved the issue, there could not be a conflict with the generic drug manufacturer's requirement to have the same design and label as the brand name manufacturer.<sup>258</sup> The court noted that while Illinois courts use both the consumer expectations test and the risk-utility test, the result would be the same, as "[f]ederal law does not provide the drug companies with a 'safe harbor' to avoid liability for dangerous drugs, and there was no direct and positive conflict with their federal duty of sameness, when the drug should not have been sold."<sup>259</sup>

*B. Courts Finding That Standard of Defectiveness  
Does Not Affect the Preemption Analysis*

The more common trend is for courts to find that *Bartlett* stands for an across-the-board preemption of state design defect causes of action. Part II.B.1 discusses cases holding that federal law preempts design defect claims against generic drug manufacturers in jurisdictions applying the consumer expectations test. Part II.B.2 discusses cases holding that federal law preempts design defect claims against generic drug manufacturers in jurisdictions applying the risk-utility test.

1. Consumer Expectations Jurisdictions

Various courts after *Bartlett* have held that design defect claims are preempted under the consumer expectations test. The following cases offer a detailed explanation regarding this holding.<sup>260</sup>

*a. Drager v. PLIVA USA, Inc.*

In *Drager v. PLIVA USA, Inc.*,<sup>261</sup> the Fourth Circuit determined whether federal law preempted a plaintiff's design defect suit against a generic drug manufacturer under Maryland law.<sup>262</sup> In *Drager*, following the ten month

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255. *See id.* ¶¶ 14–18.

256. *See id.* ¶ 19.

257. *Id.* ¶ 73 (quoting *Bartlett*, 133 S. Ct. at 2479).

258. *See id.*

259. *Id.* ¶ 97 (quoting *Bartlett*, 133 S. Ct. at 2479).

260. The cases expanded upon below are not an exhaustive list of all courts that have held that *Bartlett* preempts consumer expectations design defect suits. This section limits its discussion to those cases that have addressed any argument that *Bartlett* does not apply to jurisdictions that do not apply the risk-utility test in the same manner that New Hampshire did in *Bartlett*.

261. 741 F.3d 470 (4th Cir. 2014).

262. *See id.* at 475.

use of the generic drug MCP, the appellant developed tardive dyskinesia and akathisia.<sup>263</sup>

The appellant argued that this case was distinguishable from *Bartlett* because Maryland law applies the consumer expectations test to determine “defect.”<sup>264</sup> The *Drager* court rejected this argument and held that the difference between the two tests with respect to the impossibility preemption analysis is “immaterial.”<sup>265</sup>

The court then elaborated by stating that ultimately, the *Bartlett* Court did not determine whether the New Hampshire design defect claim was preempted because New Hampshire determined “defect” using the risk-utility test; rather, “it concluded that there was no action that the defendant could take under that approach to increase the safety of its product without violating the restrictions of the FDCA.”<sup>266</sup> The court noted that Maryland also uses both the risk-utility and consumer expectations tests in different situations, and *Bartlett* applied to them similarly in both situations.<sup>267</sup> Under both tests, regardless of what factors make the product defective, there is still no action a generic drug manufacturer can take that would allow it to comply with both state and federal law.<sup>268</sup>

*b. In re Yasmin & Yaz (Drospirenone) Marketing,  
Sales Practices & Products Liability Litigation*

In *In re Yasmin & Yaz (Drospirenone) Marketing, Sales Practices & Products Liability Litigation*,<sup>269</sup> the Southern District of Illinois determined whether federal law preempted a plaintiff’s design defect suit under Illinois law.<sup>270</sup> In *In re Yasmin*, a plaintiff alleged that she suffered from an acute bilateral pulmonary embolus following the consumption of a generic version of the drug Yaz.<sup>271</sup>

The plaintiff argued that this case was distinguishable from *Bartlett* because Illinois, unlike New Hampshire, used the consumer expectations test to determine defect.<sup>272</sup> However, the court disagreed, holding “this is a distinction without a difference.”<sup>273</sup> The court stated that “the two tests are not separate theories of liability, but rather two different ways whereby a plaintiff can prove the same ground of liability—unreasonable

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263. *See id.* at 473. Akathisia is a disease characterized by feelings of restlessness and muscular quivering. *See Akathisia*, STEDMAN’S MEDICAL DICTIONARY (27th ed. 2000).

264. *See Drager*, 741 F.3d at 478.

265. *See id.*

266. *Id.*

267. *See id.*

268. *See id.*

269. No. 3:13-cv-10143-DRH-PMF, 2014 WL 1632149 (S.D. Ill. Apr. 24, 2014).

270. *See id.* at \*7–\*9.

271. *See id.* at \*1. Acute bilateral pulmonary embolus is a disease characterized by obstructions in the lung’s arteries. *See Pulmonary embolism*, STEDMAN’S MEDICAL DICTIONARY (27th ed. 2000).

272. *See In re Yasmin*, 2014 WL 1632149, at \*9.

273. *Id.*

dangerousness.”<sup>274</sup> The court held that whether the risk-utility or consumer expectations test is used does not change the content of the duty required under state law “because the two tests are simply alternative methods” of proving breach of duty, rather than the content of the duty.<sup>275</sup>

c. Fullington v. PLIVA, Inc. (Fullington II)

After the Eighth Circuit in *Fullington I* held it was uncertain whether design defect claims under Arkansas law were preempted after *Bartlett*,<sup>276</sup> on remand the Eastern District of Arkansas in *Fullington v. PLIVA, Inc.*<sup>277</sup> (*Fullington II*) determined whether federal law preempted a plaintiff’s design defect suit against a generic drug manufacturer under Arkansas law.<sup>278</sup>

In determining this issue, the court acknowledged the holding in *Drager* and emphasized that *Drager* held that the Court in *Bartlett* did not find that federal law preempted state law because it used the risk-utility test; rather, it held that federal law preempted state law because the defendant could not act in compliance with both state law and FDA regulations.<sup>279</sup> Following this acknowledgement, the court held that *Bartlett* is equally applicable under the risk-utility test and under Maryland’s consumer expectations test.<sup>280</sup> The court noted that the drug manufacturer cannot be forced to stop selling the product, but also cannot change the chemical composition of the product or the product’s labeling.<sup>281</sup> The court expanded this holding even further, claiming that *Bartlett*’s logic extends “[r]egardless of the way in which [a state] assesses the unreasonableness of a product’s risks.”<sup>282</sup> Ultimately, “a generic drug [must] have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug,” and thus the generic drug manufacturer cannot change the design; similarly, FDA rules prohibit the generic drug manufacturer from changing its label and leave market withdrawal, which *Bartlett* rejected, as the only option.<sup>283</sup> The court held as a result that it would be impossible for a generic drug manufacturer to comply with both state and federal law, and “[n]one of [the] reasoning depends on the distinction between the risk-utility approach and the consumer expectations approach.”<sup>284</sup>

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274. *Id.*

275. *Id.*

276. *See supra* Part II.A.1.

277. No. 4:10CV00236 JLH, 2014 WL 806149, \*1 (E.D. Ark. Feb. 28, 2014).

278. *See id.* at \*1.

279. *See id.* at \*3 (citing *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 478 (4th Cir. 2014)).

280. *See id.*

281. *See id.* (citing *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466, 2575–76 (2013)).

282. *Id.* (quoting *Drager*, 741 F.3d at 478).

283. *See id.* (citing *Bartlett*, 133 S. Ct. at 2475–78).

284. *See id.*

*d. Brinkley v. Pfizer, Inc.*

In December 2014, approximately one and a half years after their *Fullington I* decision, the Eighth Circuit once again spoke on preemption of design defect suits against generic drug manufacturers in *Brinkley v. Pfizer, Inc.*<sup>285</sup> In *Brinkley*, the court determined whether federal law preempted a design defect claim against a generic drug manufacturer under Missouri law.<sup>286</sup> The appellant alleged that she had suffered from tardive dyskinesia due to her consumption of generic MCP.<sup>287</sup>

The court noted that “Missouri courts have consistently refused to impose any judicial definition [of unreasonably dangerous] whether derived from consumer expectations, risk-utility, or otherwise.”<sup>288</sup> Rather, in Missouri, “the concept of unreasonable danger . . . is presented to the jury as an ultimate issue without further definition,” and the jury may define this term based upon the utility and risk of the product, the consumer’s expectations, “or any other theory of unreasonable dangerousness supported by the evidence.”<sup>289</sup> Due to this difference in approaches, the appellant argued that Missouri’s “open-ended approach” to determine if a product is defective distinguishes this claim from the claim preempted in *Bartlett*.<sup>290</sup>

However, the court rejected the appellant’s argument.<sup>291</sup> The court held that the appellant “place[d] too much weight on Missouri’s approach to determining unreasonable danger.”<sup>292</sup> Citing the Fourth Circuit in *Drager*, the court noted that *Bartlett* did not find the claim was preempted because state law applied the risk-utility test.<sup>293</sup> Rather, the court found that the claim was preempted because “there was no action that the defendant could take under that approach to increase the safety of its product without violating the restrictions of the FDCA.”<sup>294</sup> Therefore, it had “no trouble concluding that the same [wa]s true under either the risk-utility or the

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285. 772 F.3d 1133, 1139–40 (8th Cir. 2014). Even after *Brinkley*, *Fullington I* still appears to be good law. Within its preemption analysis, *Brinkley* does not specifically overturn, or even cite, *Fullington I*. See *id.* at 1139–40. Furthermore, the courts address federal preemption of different state laws: *Brinkley* addresses Missouri law, see *infra* note 286 and accompanying text, while *Fullington I* addresses Arkansas law, see *supra* note 218 and accompanying text. Finally, the *Brinkley* court stated its holding in narrow, rather than broad, language. See *Brinkley*, 772 F.3d at 1141 (“Because *Brinkley* fails to explain how Pliva could avoid liability under Missouri law for the alleged design defects without changing its product, changing its labeling, or leaving the market, *Brinkley*’s design defect claims—whether sounding in strict liability or negligence—are preempted by impossibility.”) (quoting *Drager*, 741 F.3d at 476–78)).

286. See *Brinkley*, 772 F.3d at 1140–41.

287. See *id.* at 1136.

288. *Id.* at 1140 (alteration in original) (quoting *Sappington v. Skyjack, Inc.*, 512 F.3d 440, 446 (8th Cir. 2008)).

289. *Id.* (en banc) (omission in original) (quoting *Nesselrode v. Exec. Beechcraft, Inc.*, 707 S.W.2d 371, 378 (Mo. 1986); *Sappington*, 512 F.3d at 446).

290. *Id.*

291. See *id.* at 1140–41.

292. *Id.* (citing *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 478 (4th Cir. 2014)).

293. See *id.* (citing *Drager*, 741 F.3d at 478).

294. *Id.* (quoting *Drager*, 741 F.3d at 478).

consumer-expectations approach.”<sup>295</sup> Furthermore, the court noted that the appellant had not proposed an action, short of stopping the sale of the product, that the generic drug manufacturer could have taken to create a different result.<sup>296</sup>

## 2. Risk-Utility Jurisdictions

Furthermore, courts have found federal law preempts design defect claims in jurisdictions that determine defect under different risk-utility tests than that used in New Hampshire. Part II.B.2.a discusses cases holding that federal law preempts a design defect suit against generic drug manufacturers where state law uses the risk-utility test with an alternative design requirement to determine defect. Part II.B.2.b discusses a case holding that federal law preempts a design defect suit against a generic drug manufacturer where state law uses the prudent manufacturer test to determine defect. Part II.B.2.c discusses a case holding that federal law preempts a design defect suit against generic drug manufacturers where state law uses the Restatement (Third)’s variation of the risk-utility test.

### a. *Safe or Safer Alternative Design*

This section discusses cases in which courts have found that federal law preempts design defect where defect is determined under a risk-utility test that requires proof of a safe or safer alternative design.

#### i. *Booker v. Johnson & Johnson*

In *Booker v. Johnson & Johnson*,<sup>297</sup> the Northern District of Ohio determined whether the federal law preempted a design defect claim under Georgia law.<sup>298</sup> In *Booker*, the plaintiff alleged that her daughter passed away as a result of a pulmonary embolism caused by use of a birth control patch.<sup>299</sup>

First, the court noted that “the essential inquiry” when determining if design defect actions are preempted is whether the state law requires an actor to engage in certain behavior.<sup>300</sup> The court noted that Georgia employs a risk-utility test that “emphasize[s] that the key factor to the risk-utility inquiry is whether ‘an alternative design would have made the product safer than the original design and was a marketable reality and technologically feasible.’”<sup>301</sup>

The court held that requiring a proof of an alternative design would mandate that the party change the drug’s composition, which federal law

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295. *Id.* at 1140–41 (alteration in original) (quoting *Drager*, 741 F.3d at 478).

296. *See id.* at 1141.

297. 54 F. Supp. 3d 868 (N.D. Ohio 2014).

298. *See id.* at 872–75.

299. *See id.* at 871.

300. *Id.* at 875.

301. *Id.* (quoting *Banks v. ICI Ams.*, 450 S.E.2d 671, 674–75 (Ga. 1994)).



prohibits.<sup>302</sup> Thus, federal law preempts the state design defect claim because the defendants could not comply with state law without violating FDA regulations.<sup>303</sup>

ii. *Davis v. Teva Pharmaceuticals USA, Inc.*

In *Davis v. Teva Pharmaceuticals USA, Inc.*,<sup>304</sup> the Eastern District of Louisiana determined whether federal law preempted a design defect claim against a generic drug manufacturer under Louisiana law.<sup>305</sup> In *Davis*, the plaintiff alleged that following the use of generic levonorgestrel and ethinyl estradiol, she developed a pulmonary embolism.<sup>306</sup>

The court first identified two prongs that a plaintiff must satisfy in order to state a claim under Louisiana law: “that (1) an alternative design exists, and (2) that plaintiff’s damage outweighs both the burden the manufacturer would suffer if it were to adopt the alternative and any adverse effect of the alternative on the product’s utility.”<sup>307</sup> The court held that because federal law requires the generic drug manufacturer to have the same composition and labeling as the brand name version of the drug, and Louisiana state law requires either additional labeling or an alternative design, federal law preempts the Louisiana state law.<sup>308</sup>

iii. *Johnson v. Teva Pharmaceuticals USA, Inc.*

In *Johnson v. Teva Pharmaceuticals USA, Inc.*,<sup>309</sup> the Fifth Circuit determined whether federal law preempted a design defect claim against a generic drug manufacturer under Louisiana law.<sup>310</sup> In *Johnson*, the appellant alleged that her use of generic MCP caused her to develop tardive dyskinesia.<sup>311</sup>

Like in *Davis*, after identifying Louisiana’s two-prong test, the court held that the state design law’s requirements that a generic drug manufacturer either change the drug’s composition or labeling conflicted with federal law, and therefore the federal law preempted the Louisiana state law.<sup>312</sup>

However, the appellant also argued that the state design defect suit was not preempted because Louisiana’s design defect test law requires that a “safer alternative product” exists and not just a “safer alternative design.”<sup>313</sup>

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302. *See id.* (citing *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466, 1479 (2013)).

303. *See id.*

304. No. 13–6365, 2014 WL 4450423 (E.D. La. Sept. 10, 2014).

305. *See id.* at \*3.

306. *See id.* at \*1.

307. *Id.* (citing LA. STAT. ANN § 9:2800.56 (1988); *Johnson v. Teva Pharmaceuticals USA, Inc.*, 758 F.3d 605, 612 (5th Cir. 2014)).

308. *See id.* at \*3.

309. 758 F.3d 605 (5th Cir. 2014).

310. *See id.* at 612–13.

311. *See id.* at 609.

312. *See id.* at 612–13.

313. *Id.* at 613.

However, the court refused to answer this claim because the appellant did make this allegation in her complaint.<sup>314</sup>

*b. The Prudent Manufacturer Test*

In *Strayhorn v. Wyeth Pharmaceuticals, Inc.*,<sup>315</sup> the Sixth Circuit determined whether federal law preempted a design defect claim under Tennessee law.<sup>316</sup> In *Strayhorn*, the appellants alleged that their use of generic MCP caused them to develop tardive dyskinesia.<sup>317</sup>

The court noted that under the prudent manufacturer test, a court engages in a risk-utility analysis.<sup>318</sup> The court then held that because the factors that a jury considers in a risk-utility test only enabled a generic drug manufacturer to avoid liability under state law by changing the drug's composition or warning, federal and state law conflicted.<sup>319</sup>

*c. Restatement (Third) Section 6(c): Products Liability*

On February 28, 2011, ninety-one different plaintiffs from twenty-eight different states filed a design defect suit in a Missouri state court, alleging in part that they suffered bone fractures from their use of generic alendronate sodium.<sup>320</sup> After removal to federal court, the U.S. Judicial Panel on Multidistrict Litigation “centralized the action with several other Fosamax[]-related lawsuits in a multi-district litigation” in the District Court of New Jersey, which found that federal law preempted the plaintiffs' claims.<sup>321</sup> The plaintiffs appealed to the Third Circuit.<sup>322</sup>

In *In re Fosamax (Alendronate Sodium) Products Liability Litigation (No. II)*, the Third Circuit determined whether federal law preempted these multi-district litigation design defect claims.<sup>323</sup> The appellants pled design defect claims under the risk-utility theory proposed in section 6(c) of the Restatement (Third).<sup>324</sup> The court held that because federal law prohibited the generic drug manufacturer from changing the drug's design or label, and because the appellants could not identify any other action that the defendants could take to comply with both state and federal duties, federal law preempted state design defect law.<sup>325</sup>

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314. *See id.*

315. 737 F.3d 378 (6th Cir. 2013).

316. *See id.* at 397.

317. *See id.* at 383.

318. *See id.* at 397 (quoting *Brown v. Crown Equip. Co.*, 181 S.W.2d 268, 282–83 (Tenn. 2005)).

319. *See id.* (citing *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466, 2475–76 (2013)).

320. *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 751 F.3d 150 (3d Cir. 2014).

321. *Id.* at 155.

322. *See id.* at 153.

323. *See id.* at 158–65.

324. *See id.* at 158 n.16.

325. *See id.* at 164.

The court also analyzed the respondents' argument that courts need to engage in a state-by-state analysis in light of *Bartlett*.<sup>326</sup> The court held that such an analysis would be unnecessary, as under the laws of the twenty-eight states at issue, the generic drug manufacturers' only options would be to change the labeling, change the design, or stop selling the product.<sup>327</sup>

### C. Commentary

The scholarship on this issue supports the claim that, in light of *Bartlett*, federal law preempts design defect lawsuits against generic drug manufacturers.

James Beck argues that theories that attempt to distinguish tests for defect are "red herring[s]."<sup>328</sup> He argues that there are no options allowed under federal law or the Supreme Court's jurisprudence that a generic drug manufacturer can take regardless of the test for defect that a jurisdiction uses.<sup>329</sup> He contends that a generic drug manufacturer may only avoid design defect liability by changing the drug's label or design, which federal law prohibits, or through withdrawing the drug from the market, which *Bartlett* rejected.<sup>330</sup> Because there are no further options available for a generic drug manufacturer to take, he argues that *all* design defect claims are preempted.<sup>331</sup>

Beck supports the reasoning in *Fullington II*, claiming that the court there "asked the right question": "[W]hat [could] the [generic drug manufacturers] . . . have done to comply with [state] law without violating federal law[?]"<sup>332</sup> Beck claims that because there is no positive answer, federal law preempts state design defect claims regardless of whether the test for defect is risk-utility with alternative design, risk-utility without alternative design, or consumer expectations.<sup>333</sup> "As long as any theory would require a change in design, [it is] preempted because that requires prior FDA approval."<sup>334</sup>

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326. *See id.*

327. *See id.* at 164 n.30.

328. James M. Beck, *Bullseye*, DRUG & DEVICE L. (Aug. 19, 2013, 1:20 PM), <http://druganddevicelaw.blogspot.com/2013/08/bullseye.html> [<http://perma.cc/C2N6-3GEK>].

329. *See id.*

330. *See id.* (citing *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466, 2471, 2477 (2013)).

331. *See id.*

332. James M. Beck, *Breaking News—Consumer Expectations Test Preempted*, DRUG & DEVICE L. (Mar. 4, 2014, 5:00 PM) (third alteration in original) (quoting *Fullington v. PLIVA, Inc.*, No. 4:10CV00236 JLH, 2014 WL 806149, \*4 (E.D. Ark. Feb. 28, 2014)), <http://druganddevicelaw.blogspot.com/2014/03/breaking-news-consumer-expectations.html> [<http://perma.cc/TME5-MGXZ>].

333. *See id.*; Beck, *supra* note 328.

334. Beck, *supra* note 332.

Beck similarly agrees with the court's analysis in *Drager*.<sup>335</sup> Beck called *Drager* "the first court of appeals to face this false distinction head on and identify this non-issue for what it is."<sup>336</sup> Beck argues that *Drager* correctly pointed out that "[i]f the result of a verdict is that, to avoid liability under state law, the defendant would have to violate FDA regulations requiring [a]gency pre-approval of any alteration of the product's design, then state law is preempted as 'impossible' to enforce in the face of supreme federal law."<sup>337</sup>

Futhermore, Beck agrees with the court's analysis in *In re Fosamax*.<sup>338</sup> Beck argues that the *In re Fosamax* court was correct because the appellants could not articulate a theory of liability that did not depend on the generic drug manufacturers changing the drug's warning, changing the drug's design, or stopping the sale of the product.<sup>339</sup>

Beck also rejects the court's analysis in *Hassett*.<sup>340</sup> Calling the result "jaw-dropping," Beck argues that the *Hassett* court erred in referring to absolute liability and strict liability interchangeably.<sup>341</sup> According to Beck, the dissent was correct to point out that the majority opinion "almost entirely lack[ed] in legal reasoning and violates the mandate that the courts 'must adhere to extant Supreme Court jurisprudence.'"<sup>342</sup>

Similarly, Beck rejects the court's analysis in *Neeley*.<sup>343</sup> Beck argues that *Neeley* wrongly distinguished strict liability consumer expectations claims from strict liability risk-utility claims in the preemption analysis because ultimately the generic drug manufacturer cannot change the design under federal law.<sup>344</sup>

Finally, Steve McConnell rejects the Illinois Appellate Court's analysis in *Guvnoz*.<sup>345</sup> Calling *Guvnoz* a clear case of "a court wearing its judicial

335. James M. Beck, *Progress on Design Defect Preemption*, DRUG & DEVICE L. (Jan. 31, 2014, 5:00 PM), <http://druganddevicelaw.blogspot.com/2014/01/progress-on-design-defect-preemption.html> [<http://perma.cc/E6FJ-VUBU>].

336. *Id.*

337. *Id.*

338. James M. Beck, *Breaking News—Third Circuit Holds Generic Fosamax Claims Preempted*, DRUG & DEVICE L. (Apr. 30, 2014, 1:11 PM), <http://druganddevicelaw.blogspot.com/2014/04/breaking-news-third-circuit-holds.html> [<http://perma.cc/X2VE-CXKU>].

339. *Id.*

340. James M. Beck, *Can't Blame Philadelphia for These*, DRUG & DEVICE L. (July 30, 2013, 5:01 PM) [hereinafter Beck, *Can't Blame Philadelphia*], <http://druganddevicelaw.blogspot.com/2013/07/cant-blame-philadelphia-for-these.html> [<http://perma.cc/44AL-C9BB>]; James M. Beck, *The Bad and the Ugly—The Worst Prescription Drug/Medical Device Decisions of 2013*, DRUG & DEVICE L. (Dec. 23, 2013, 8:16 AM) [hereinafter Beck, *The Bad and the Ugly*], [http://druganddevicelaw.blogspot.com/2013/12/the-bad-and-ugly-worst-prescription\\_23.html](http://druganddevicelaw.blogspot.com/2013/12/the-bad-and-ugly-worst-prescription_23.html) (ranking *Hassett* the fourth worst prescription drug/medical device case of 2013) [<http://perma.cc/3EWK-JVRE>].

341. Beck, *Can't Blame Philadelphia*, *supra* note 340.

342. Beck, *The Bad and the Ugly*, *supra* note 340 (quoting *Hassett v. Dafoe*, 74 A.3d 202, 218 (Pa. Super. Ct. 2013) (Platt, J., concurring in part, dissenting in part)).

343. *Id.*

344. *Id.*

345. Steve McConnell, *Illinois Appellate Court Misapplication of Bartlett Preemption: The Monster Case of the Week*, DRUG & DEVICE L. (Apr. 1, 2015, 7:30 AM),

heart on the sleeves of its judicial robes,” McConnell argues that the *Guvenoz* court’s attempt to distinguish that case from *Bartlett* ignored the preemption principles stated therein.<sup>346</sup>

### III. FEDERAL LAW REIGNS SUPREME

As the *Bartlett* majority explicitly recognized, the first step in determining whether the FDA regulations preempt a state design defect suit is to determine the content of the state duties.<sup>347</sup> However, courts have frequently failed to do so, possibly in an attempt to defy *Bartlett* and allow design defect claims against generic drug manufacturers to continue despite FDA regulation.<sup>348</sup> This determination of the content of the state duties is fundamental in determining whether there is a feasible possibility—besides changing a generic drug’s chemical composition, changing a generic drug’s labeling, or stopping the sale of the product altogether—that would allow the generic drug manufacturer to comply with both their federal and state duties.<sup>349</sup> Such a finding would prevent a court from concluding that the state design defect suit is preempted under physical impossibility conflict preemption.<sup>350</sup>

This part illustrates how federal law preempts state design defect claims against generic drug manufacturers regardless of the test the state court uses to determine defectiveness. First, Part III.A discusses the failure of courts to properly identify the content of the duties imposed by state design defect law after *Bartlett*. Then, Part III.B evaluates the content of state law duties under the various different design defect tests and discusses its ramifications, if any, on the subsequent physical impossibility analysis, as elaborated by *Bartlett*.

#### A. Identification of State Duties

This section identifies deficiencies in the approaches that the *Neeley*, *Hassett*, and *Guvenoz* courts have taken with respect to the identification of the content of state duties. Part III.A.1 argues that *Neeley* failed to evaluate the defendant’s duties under state law. Part III.A.2 argues that *Hassett* incorrectly engaged in its analysis of the state duties. Part III.A.3 argues that *Guvenoz* also incorrectly engaged in its analysis of the state duties.

##### 1. *Neeley* Failed to Undertake an Analysis of the State Duties

In *Neeley*, the court failed to properly identify the duties that Arkansas design defect law actually imposed upon a generic drug manufacturer. In *Neeley*, the District Court relied on the Eighth Circuit’s determination in

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<http://druganddevicelaw.blogspot.com/2015/04/illinois-appellate-court-misapplication.html> [<http://perma.cc/46Z4-4PNM>].

346. *Id.*

347. *See supra* notes 184–86 and accompanying text.

348. *See supra* Part II.A; *supra* notes 247–50 and accompanying text.

349. *See supra* notes 198–208 and accompanying text.

350. *See supra* notes 198–208 and accompanying text.

*Fullington I* that “it is not immediately clear” that federal law preempted Arkansas’s design defect law, which applies a consumer expectations test, because *Bartlett*’s preemption analysis was with respect to New Hampshire design defect law, which follows a risk-utility test.<sup>351</sup> While *Fullington I* ultimately remanded that determination to the District Court, *Neeley* merely cited *Fullington I* and engaged in no further analysis.<sup>352</sup>

This deference to *Fullington I* is defective for two reasons. First, the *Fullington I* court remanded the actual analysis of state duties to the district court; it was the district court in *Fullington II* that engaged in the state duties analysis.<sup>353</sup> Thus, the *Neeley* court had made this non-preemption determination without itself analyzing the state duties, or deferring to a court that had made such an analysis. Second, as shown below in Part III.B.1, jurisdictions determining defect under a consumer expectations analysis are preempted in light of the Court’s analysis in *Bartlett*.<sup>354</sup>

## 2. *Hassett* Improperly Engaged in an Analysis of the State Duties

In *Hassett*, the court failed to properly identify the duties that Pennsylvania design defect law actually imposed upon a generic drug manufacturer. The *Hassett* court found that federal law did not preempt the design defect claims because the state design defect law did not actually impose *any* duty upon the generic drug manufacturer.<sup>355</sup> However, this is an inaccurate portrayal of Pennsylvania law and strict liability.

*Hassett* correctly held that a claim imposing true absolute liability on generic drug manufacturers would not be preempted after *Bartlett*,<sup>356</sup> but incorrectly held that Pennsylvania design defect law imposed true absolute liability. Under true absolute liability, a court will not look to the condition of the product when determining whether the manufacturer is liable.<sup>357</sup> By contrast, under strict liability regimes, the evaluation of defectiveness, whether it be under a risk-utility test, a consumer expectations test, a hybrid, or any new derivation that should arise, is a determination of whether the generic drug manufacturer breached its duty under state law.<sup>358</sup> By requiring “defect” to be found before a defendant becomes liable, a court determines whether the manufacturer did in fact fail to adhere to a legal duty to design a product without “defect,” regardless of how “defect” may be defined or interpreted, so long as it requires the generic drug manufacturer not to produce a product in a certain non-conforming condition.<sup>359</sup> *Bartlett* has explicitly stated that this duty is to be viewed as a

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351. *See supra* notes 227–28 and accompanying text.

352. *See supra* notes 228–29 and accompanying text.

353. *See supra* notes 278–84 and accompanying text.

354. *See infra* Part III.B.1.

355. *See supra* notes 241–43 and accompanying text.

356. *See infra* Part III.B.5.

357. *See supra* notes 149–61 and accompanying text.

358. *See supra* notes 92–93, 155–56 and accompanying text.

359. *See supra* notes 92–93, 155–56 and accompanying text.

legal requirement.<sup>360</sup> Because this duty is a legal requirement, and because that requirement under state law makes it impossible for a generic drug manufacturer to comply with federal law, federal law must preempt state law.<sup>361</sup>

### 3. *Guvenoz* Improperly Engaged in an Analysis of the State Duties

In *Guvenoz*, the generic drug manufacturer had received FDA approval, but following new information, the FDA dropped its approval of the drug.<sup>362</sup> Based largely upon those facts, *Guvenoz* held that because the plaintiffs alleged that there was no way that the drug could have been altered to be safely produced, there was no requirement that conflicted with federal law.<sup>363</sup>

The *Guvenoz* court failed to properly engage in a state duties analysis because it looked to the content of the drug, rather than the content of state law. As shown in *Bartlett*, a court determines the content of the state duty by determining what actions the party must undertake in order to avoid liability.<sup>364</sup> However, the analysis does not look to whether an individual party can in fact comply with its state duty due to its own particular circumstances.<sup>365</sup> Impossibility preemption requires a court to determine what the law *requires* a party to do, not what is feasible for a party to do under its unique circumstances.<sup>366</sup>

#### B. *Physical Impossibility and Different Defect Tests*

As shown above, the determination that a product is defective is a determination of whether a state law duty has been breached.<sup>367</sup> Under *Bartlett*, federal law preempts state law under physical impossibility preemption when the state duty required by design defect law forces a behavior contrary to federal law's "sameness" requirement towards generic drug manufacturers and where the only option for the generic drug manufacturer to avoid liability is to stop the sale of the drug completely.<sup>368</sup> Any test for defect—whether it be through the risk-utility test's variations, the consumer expectations test, a hybrid, or any new variation—will still require the generic drug manufacturer to engage in behavior that leaves "stop selling" as the only viable alternative.<sup>369</sup> State design defect claims of any jurisdiction that require a finding of defectiveness, no matter the

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360. See *supra* notes 187–88 and accompanying text. This Note does not address the validity of this assumption.

361. See *supra* notes 187–88, 201–08 and accompanying text.

362. See *supra* notes 255–56 and accompanying text.

363. See *supra* notes 257–59 and accompanying text.

364. See *supra* notes 184–97 and accompanying text.

365. See *supra* notes 184–97 and accompanying text.

366. See *supra* notes 76–97 and accompanying text.

367. See *supra* notes 92–93, 155–56 and accompanying text.

368. See *supra* notes 195–208 and accompanying text.

369. See *infra* Part III.B.1–4.

content of the test, will therefore be preempted by federal generic drug regulations.<sup>370</sup>

This section more carefully analyzes these distinctions between jurisdictions and applies preemption principles to these differences. Part III.B.1 discusses preemption of design defect suits against generic drug manufacturers in consumer expectations jurisdictions. Part III.B.2 discusses preemption of design defect suits against generic drug manufacturers in risk-utility test jurisdictions with an alternative design requirement. Part III.B.3 discusses preemption of design defect suits against generic drug manufacturers in prudent manufacturer test jurisdictions. Part III.B.4 discusses preemption of design defect suits against generic drug manufacturers under the Restatement (Third)'s test. Finally, Part III.B.5 discusses preemption of design defect suits against generic drug manufacturers under a true absolute liability regime.

### 1. Consumer Expectations

Post-*Bartlett*, federal law preempts design defect claims against generic drug manufacturers in jurisdictions that determine defectiveness via the consumer expectations test. As established above, a jurisdiction that determines defectiveness under a consumer expectations test will ask a jury to determine what a reasonable consumer would expect regarding the safety of the product.<sup>371</sup> This ultimately imposes a duty on generic drug manufacturers in such jurisdictions to design the generic drug to be as safe as a reasonable consumer would expect it to be.<sup>372</sup>

In order to avoid preemption in these jurisdictions, a plaintiff must show that there is some behavior that the generic drug manufacturer can engage in which would not expose the generic drug manufacturer to liability, other than refraining from selling the drug.<sup>373</sup> Thus, this invites the critical question: How may a generic drug manufacturer alter a consumer's expectations regarding the safety of a generic drug without changing the drug's warnings, changing the drug's actual composition, or stopping the sale of the drug completely?

Because they properly follow the word of *Bartlett*, courts like the *Fullington II* court are correct when they hold that there is in fact no other route that a generic drug manufacturer can take with regard to the design of its product to avoid liability, without refraining from selling the drug.<sup>374</sup> As correctly noted in *In re Yasmin*, while the risk-utility test and consumer expectations tests allow a reasonable person to consider different factors to determine whether the design is "defective," ultimately, the only way that the generic drug manufacturer would be able to change the reasonable consumer's expectations would be to change the drug's composition,

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370. See *infra* Part III.B.1–4.

371. See *supra* note 100 and accompanying text.

372. See *supra* notes 93, 100, 192–93 and accompanying text.

373. See *supra* notes 195–208 and accompanying text.

374. See *supra* notes 281–84 and accompanying text.



change its labeling, or stop selling the product.<sup>375</sup> No court has yet to accept any theory as to any further option that the generic drug manufacturer could undertake to avoid liability.<sup>376</sup>

## 2. Risk-Utility Test Requiring a Safe or Safer Alternative Design

Jurisdictions that require the finding that there exists a safe or safer alternative design under a risk-utility test before a breach of duty can be found are preempted following *Bartlett*. Jurisdictions that impose such a requirement may only have valid claims when a generic drug manufacturer feasibly could have distributed its drug to the public by some alternative method that would have allowed the product to be deemed “safe,” or “safer” than its present state.<sup>377</sup>

As stated in *Booker*, *Davis*, and *Johnson*, the alternative design requirement, where implemented, is a part of the risk-utility test.<sup>378</sup> Despite the fact that in some jurisdictions, as in *Booker*, alternative design will be a factor (albeit a large one in the risk-utility test) and in some jurisdictions, like in *Johnson* and *Davis*, it consists of one prong, both should be preempted similarly.<sup>379</sup> Ultimately, by determining defectiveness under any risk-utility test, these jurisdictions all impose a duty upon the manufacturer, much like the New Hampshire law in *Bartlett*, to design products that are reasonably safe.<sup>380</sup> Regardless of the factors used to evaluate what is “reasonably safe” in the risk-utility test, the only way the generic drug manufacturer could change a reasonable person’s evaluation of these factors would be to change a drug’s composition, change the drug’s labeling, or refrain from selling the drug.<sup>381</sup>

## 3. Prudent Manufacturer Test

Federal law preempts design defect suits in jurisdictions applying the prudent manufacturer test after *Bartlett*. These jurisdictions apply a risk-utility test, but assume that defendants knew of the product’s condition.<sup>382</sup>

The attribution of knowledge to the manufacturer plays no additional role in the analysis of state law duties after *Bartlett*. The knowledge requirement serves to impute an understanding of the risks of the drug upon the manufacturer,<sup>383</sup> but like the traditional risk-utility test, while different factors or considerations may ultimately identify whether the generic drug is safe, the ways in which the generic drug manufacturer can alter the perception of these factors can solely be accomplished by changing the

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375. See *supra* notes 274–75 and accompanying text.

376. See, e.g., *supra* note 296 and accompanying text.

377. See *supra* notes 113–15, 313–14 and accompanying text.

378. See *supra* notes 301, 307, 312 and accompanying text.

379. See *supra* notes 301, 307, 312 and accompanying text.

380. See *supra* note 193 and accompanying text.

381. See *supra* notes 201–08 and accompanying text.

382. See *supra* notes 119–22, 125–29 and accompanying text.

383. See *supra* notes 119–22 and accompanying text.

composition, changing the labeling, or ceasing sale of the product.<sup>384</sup> The hindsight test might ultimately change the standard that a judge instructs to a jury,<sup>385</sup> but it offers no additional option as to how a drug manufacturer can avoid liability besides the option rejected in *Bartlett*.<sup>386</sup>

#### 4. Section 6(c) of the Restatement (Third)

Federal law preempts design defect claims where the test for defect is designated by Section 6(c) of the Restatement (Third). Ultimately, a generic drug manufacturer can only avoid state liability under this test when the benefits are greater than the risks for some class of person.<sup>387</sup> The benefits and risks, as seen in *Bartlett*, can only be altered by changing the drug label, changing the drug composition, or stopping the sale of the drug.<sup>388</sup>

#### 5. True Absolute Liability Regimes

As *Hassett* stated, *Bartlett* suggests that design defect claims in true absolute liability regimes remain viable.<sup>389</sup> The application of this theory is in fact viable, because true absolute liability regimes, unlike strict liability regimes, do not impose duties upon manufacturers.<sup>390</sup> Rather, because they find liability regardless of whether the manufacturer produced a defective product, they do not impose any duty on the manufacturer at all, because the law does not require the manufacturer to provide a reasonably safe product.<sup>391</sup>

In *Bartlett*, the majority found that the “requirement” imposed by state tort law equated to the *duty* imposed by state tort law.<sup>392</sup> Without such a duty, however, there cannot be a “requirement” imposed by state law.<sup>393</sup> Thus, the state duty necessary to find physical impossibility conflict preemption would not exist, leaving the absolute liability design defect claim not preempted under *Bartlett*.<sup>394</sup> When there is no state requirement, logically there cannot be conflicting federal and state standards.<sup>395</sup>

#### CONCLUSION

Unfortunately for consumers of FDA-approved drugs, state strict liability design defect claims against generic drug manufacturers are preempted no matter which test for defect is used. Ultimately, the legal formulation for

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384. *See supra* notes 201–08 and accompanying text.

385. *See supra* note 122 and accompanying text.

386. *See supra* notes 296, 376 and accompanying text.

387. *See supra* note 131 and accompanying text.

388. *See supra* notes 201–08 and accompanying text.

389. *See supra* note 243 and accompanying text.

390. *See supra* notes 152–61 and accompanying text.

391. *See supra* notes 152–61 and accompanying text.

392. *See supra* note 188 and accompanying text.

393. *See supra* notes 152–61 and accompanying text.

394. *See supra* notes 76–77.

395. *See supra* notes 76–77.

defect, no matter how defect is defined, will only be able to be altered by changing the drug's label, changing the drug's composition, or having the drug company refrain from selling the drug at all. This is exactly why the Court in *Bartlett* found federal law preempted a design defect claim under New Hampshire law, and this logic applies equally to all other state design defect laws applying strict liability principles. However, there is an opening for design defect claims under true absolute liability regimes. These regimes, because they do not require the finding of "defect," do not impose a state duty, rendering physical impossibility preemption an impossibility.