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**REQUIEM FOR A REMEDY: THE LAW AND ECONOMICS  
OF *MUTUAL PHARMACEUTICAL v. BARTLETT'S*  
OVER-PREEMPTION**

ROBERT C. BAKER III\*

In *Mutual Pharmaceutical Co. v. Bartlett*,<sup>1</sup> the Supreme Court of the United States considered whether generic pharmaceutical manufacturers could be held strictly liable for unreasonably dangerous, defective drug designs<sup>2</sup> when Food and Drug Administration (“FDA”) regulations prohibited the redesign of generic drugs.<sup>3</sup> Extending the Court’s impossibility preemption in *PLIVA, Inc. v. Mensing*,<sup>4</sup> the Court preempted New Hampshire’s “warning-based design-defect cause[s] of action” because generic manufacturers were unable to cure the defective design under federal law; dual compliance was “impossible.”<sup>5</sup> In so holding, the Court rejected the compensatory focus of the First Circuit<sup>6</sup> and Justice Sotomayor’s dissent in favor of negligence-based, deterrence-centric tort policy.<sup>7</sup> As a result, the

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\* J.D. Candidate, 2016, University of Maryland Francis King Carey School of Law. The author thanks Professor Donald Gifford for his wisdom and guidance, and his editors—Monica Basche, Roberto Berrios, and Alyssa Domzal—for their thoughtful feedback and direction. The author also thanks his family—Robert, Margaret, and Bethany Baker—for their patience, understanding, and encouragement.

1. 133 S. Ct. 2466 (2013).

2. Strict products liability is predominantly derived from the *Restatement (Second) of Torts* § 402A with a minority of states adopting the *Restatement (Third) of Torts: Products Liability*. DAVID G. OWEN, *PRODUCTS LIABILITY LAW* 246 (3d ed. 2015); see also *AMERICAN LAW OF PRODUCTS LIABILITY* § 28.1 (John D. Hodson et al. eds., 3d ed. 2007). New Hampshire adopted the *Restatement Second* approach. *Bartlett*, 133 S. Ct. at 2473.

3. *Bartlett*, 133 S. Ct. at 2470; see 21 U.S.C. § 355(j) (2012) (restricting generic manufacturer autonomy).

4. 131 S. Ct. 2567, 2580–81 (2011) (preempting failure to warn claims because dual compliance with federal law mandating the existing labeling and state law requiring stronger labeling was impossible).

5. *Bartlett*, 133 S. Ct. at 2477–78.

6. *Id.* (rejecting the First Circuit’s “stop-selling rationale” in which a manufacturer could avoid liability by exiting the market).

7. See *infra* Part IV.A. Deterrence and compensation are conflicting functions of tort law. GUIDO CALABRESI, *THE COSTS OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS* 27–29, 37 (1970). Deterrence is best achieved by negligence-based liability; compensation is best ensured by strict liability. See DON DEWEES ET AL., *EXPLORING THE DOMAIN OF ACCIDENT LAW* 205–06 (1996) (identifying optimal tort schemes for varied goals). The Supreme Court has not consistently decided which tort function takes precedence. Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 *GEO. WASH. L. REV.* 449, 471 (2008) (“[T]he Supreme Court’s alternating conception of tort-as-regulation versus tort-as-compensation . . . falls short as a normative prescription for cases yet to be decided . . . [and] begs the institutional ques-

manufacturers of eighty percent of the drug prescriptions dispensed in the United States<sup>8</sup> are immune from most products liability while a victim's ability to recover hangs on a pharmacist's whim.<sup>9</sup>

While correctly decided under New Hampshire's negligence-based "strict"<sup>10</sup> products liability, expansive application of *Bartlett* in other jurisdictions has led to over-simplistic preemption of long-established tort schemes.<sup>11</sup> To protect traditional conceptions of fault<sup>12</sup> from the dissent's reformist law and economic policy, the *Bartlett* Court employed deterrence-centric reasoning to cast compensatory tort policy into a straw man of absolute liability.<sup>13</sup> The resulting anti-compensatory holding invited subsequent courts' preemption of distinguishable tort regimes.<sup>14</sup> The Court, instead, should have curtailed its rejection of compensatory tort policy in deference to states that have adopted "stricter"<sup>15</sup> products liability under modern principles of federalism.<sup>16</sup> Though inapplicable to New Hampshire, the compensatory law and economic policy of Justice Sotomayor's dissent lends legitimacy to states' decisions to maintain "stricter" liability regimes.<sup>17</sup>

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tion of who should decide the critical regulatory policy issues at the heart of the . . . preemption inquiry.").

8. IMS INSTITUTE FOR HEALTHCARE INFORMATICS, THE USE OF MEDICINES IN THE UNITED STATES: REVIEW OF 2011 2 (2012), available at [http://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII\\_Medicines\\_in\\_U.S\\_Report\\_2011.pdf](http://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_U.S_Report_2011.pdf) ("generics . . . represent[] 80% of dispensed prescriptions").

9. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985, 67988 (proposed Nov. 13, 2013), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2013-N-0500-0001> ("access to the courts is dependent on whether an individual is dispensed a brand name or generic drug"); see *infra* Parts II.C, III (discussing preemption of all products liability except manufacturing defects).

10. Traditional strict liability was distinguishable from negligence. See *infra* Part II.C and text accompanying note 157.

11. *E.g.*, *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 477–78 (4th Cir. 2014) (preempting Maryland's consumer expectations approach without state-specific analysis). The consumer expectations approach is older and traditionally "stricter" than modern approaches. See *infra* Part IV.C.

12. See *Thibault v. Sears, Roebuck & Co.*, 395 A.2d 843, 845–46 (discussing New Hampshire's fault system). Fault is a vehicle of deterrence, not compensation. See Guido Calabresi, *Neologisms Revisited*, 64 MD. L. REV. 736, 750 (2005).

13. See *infra* Part IV.A. Law and economics not only "seeks to explain the law, or the legal system, as it is," it provides an avenue for normative analysis to describe how the law should be. RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 31 (8th ed. 2011); Keith N. Hylton, *Calabresi and the Intellectual History of Law and Economics*, 64 MD. L. REV. 85, 91 (2005).

14. See *infra* Parts IV.A, IV.C.

15. Perhaps when states first adopted strict products liability it was truly "strict," meaning that courts did not use negligence principles in their analyses, but strict product liability doctrine has drifted towards negligence as state common law diverged. See *infra* Part IV.C, note 157 and accompanying text. Thus negligence, strict liability, and absolute liability are best thought of on a spectrum rather than as distinct doctrines with the term "stricter" reflecting the degree of drift.

16. See *infra* Part IV.A (discussing federalism).

17. See *infra* Part IV.B.

In response to the Court's expansive generic pharmaceutical preemption, the FDA proposed a rule that undermines the impossibility preemption reasoning of *PLIVA* and *Bartlett*.<sup>18</sup> Specifically, the rule would permit generic manufacturers to unilaterally change their labeling like their brand-name counterparts.<sup>19</sup> Though the rulemaking would render *Bartlett* moot, analysis of the law and economic ideologies shaping the Court's decisionmaking is instructive for predicting the Court's future preemption of tort law.<sup>20</sup>

## I. THE CASE

Shortly after beginning a regimen of prescription sulindac,<sup>21</sup> Karen Bartlett experienced a severe cutaneous hypersensitivity reaction that presented as burn-like wounds on sixty-five percent of her body.<sup>22</sup> Ms. Bartlett was hospitalized for seventy days, much of which she spent in a medically induced coma.<sup>23</sup> She suffered permanent esophageal, vaginal, and pulmonary injuries that prevent normal eating, sexual relations, and aerobic activity; she also suffers from near-blindness and severe disfigurement.<sup>24</sup> Ms. Bartlett's condition necessitated several surgeries and cost millions of dollars in medical expenses.<sup>25</sup>

At the time of Ms. Bartlett's injury, sulindac carried a general warning against "severe skin reactions" and was a known cause of her condition,

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18. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products; Public Meeting; Request for Comments; Reopening of the Comment Period, 80 Fed. Reg. 8577 (February 11, 2015), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2013-N-0500-0081>; see also Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985, 67989, 67995 (proposed Nov. 13, 2013), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2013-N-0500-0001>.

19. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67989.

20. See *infra* Parts IV.A, IV.D.

21. *Bartlett v. Mut. Pharm. Co.*, 731 F. Supp. 2d 135, 142 (D.N.H. 2010) *aff'd*, 678 F.3d 30 (1st Cir. 2012) *rev'd*, 133 S. Ct. 2466 (2013). Sulindac is a generic, anti-inflammatory pain reliever manufactured by Mutual Pharmaceuticals. *Id.*

22. *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 34 (1st Cir. 2012) *rev'd*, 133 S. Ct. 2466 (2013). Ms. Bartlett developed Stevens-Johnson Syndrome and later toxic epidermal necrosis (SJS/TEN), which is characterized by a severe burn-like rash causing dermal separation. *Id.*; Robert A. Schwartz et al., *Toxic Epidermal Necrolysis: Part I. Introduction, History, Classification, Clinical Features, Systemic Manifestations, Etiology, and Immunopathogenesis*, 69 J. AM. ACAD. DERMATOL. 173.e1, 173.e2 (2013).

23. *Bartlett*, 678 F.3d at 34, 43.

24. *Id.* at 43.

25. *Id.* (noting that Bartlett has had twelve surgeries on her eyes alone with more anticipated); *Bartlett v. Mut. Pharm. Co.*, 760 F. Supp. 2d 220, 231 (D.N.H. 2011) *aff'd*, 678 F.3d 30 (1st Cir. 2012) *rev'd*, 133 S. Ct. 2466 (2013) (delineating compensatory damages for medical expenses as approximately \$3.5 million).

Stevens-Johnson Syndrome and toxic epidermal necrosis (“SJS/TEN”).<sup>26</sup> In fact, one of the preeminent SJS/TEN epidemiological studies available at the time specifically implicated sulindac as associated with more reported cases of SJS/TEN than any other pharmaceutical in its drug class.<sup>27</sup> Partially because of this study, the FDA later strengthened sulindac’s labeling to explicitly warn against SJS/TEN.<sup>28</sup>

Ms. Bartlett brought suit under New Hampshire law advancing numerous tort theories, though only one survived summary judgment: she alleged that the manufacturer was strictly liable for marketing an “unreasonably dangerous” product.<sup>29</sup> Importantly, Ms. Bartlett’s failure-to-warn claims failed on case-specific grounds because Ms. Bartlett’s prescribing physician never reviewed sulindac’s label.<sup>30</sup> After a three-week trial, the jury found Mutual Pharmaceutical strictly liable for a design defect and awarded Ms. Bartlett twenty-one million dollars in damages.<sup>31</sup> In response, Mutual Pharmaceutical renewed its motion for judgment alleging that Ms. Bartlett’s design defect claims were preempted by federal regulations prohibiting a manufacturer from redesigning generic sulindac.<sup>32</sup>

The district court denied Mutual Pharmaceutical’s motion and concluded, “[f]ederal law did not require Mutual to sell sulindac. Nor, for that matter, did state law require Mutual to stop selling it, or to redesign it.”<sup>33</sup> Instead, state law created liability for selling a product with greater risks than benefits.<sup>34</sup> The Court of Appeals for the First Circuit affirmed, reasoning that Mutual Pharmaceutical could avoid liability by choosing to stop

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26. *Bartlett*, 678 F.3d at 34; *Bartlett*, 731 F. Supp. 2d at 142.

27. *Bartlett*, 731 F. Supp. 2d at 142 (citing Maja Mockenhaupt et al., *The Risk of SJS and TEN Associated with NSAIDs: A Multinational Perspective*, 30 J. RHEUMATOLOGY 2234 (2003)).

28. *Bartlett v. Mut. Pharm. Co.*, 133 S. Ct. 2466, 2472 (2013) (explaining that a class warning of SJS/TEN was added to all prescription NSAID labeling).

29. *Bartlett*, 731 F. Supp. 2d at 143. Bartlett initially brought suit in New Hampshire Superior Court but the case was removed by Mutual Pharmaceutical. *Id.* Bartlett originally brought claims for breach of warranty, negligence, gross negligence, and fraud. *Bartlett v. Mut. Pharm. Co.*, 08-CV-00358-JL, 2010 WL 3659789, at \*1 (D.N.H. Sept. 14, 2010) (granting summary judgment); *Bartlett*, 731 F. Supp. 2d at 143 n.3, 151.

30. *Bartlett*, 731 F. Supp. 2d at 146. At his deposition, Bartlett’s prescribing physician testified that he never reviewed nor was influenced in any way by sulindac’s labeling so specific causation could not be established. *Id.*

31. *Bartlett v. Mut. Pharm. Co.*, 760 F. Supp. 2d 220, 227, 231 (D.N.H. 2011) *aff’d*, 678 F.3d 30 (1st Cir. 2012) *rev’d*, 133 S. Ct. 2466 (2013) (“\$21.06 million in damages, consisting of . . . \$16.5 million for pain, suffering, and loss of enjoyment of life”). The jury concluded that sulindac’s risks outweighed its benefits making it a defective product unreasonably dangerous to consumers. *Id.* at 227.

32. *Id.* at 227, 247–48.

33. *Id.* at 248 (emphasis added).

34. *Id.* The court cites an underlying order stating: “strict products liability requires . . . that manufacturers compensate consumers for the damage caused by unreasonably dangerous products, not necessarily that they remove such products from the market.” *Id.* (quoting *Bartlett v. Mut. Pharm. Co., Inc.*, 08-CV-358-JL, 2010 WL 3092649, at \*8 (D.N.H. Aug. 2, 2010)).

selling the drug.<sup>35</sup> The court noted, however, that a “developing split in [the preemption jurisprudence of] the lower courts” required decisive resolution by the Supreme Court.<sup>36</sup> The Supreme Court granted certiorari to determine whether federal law preempts New Hampshire’s design defect cause of action.<sup>37</sup>

## II. LEGAL BACKGROUND

In *PLIVA v. Mensing*, the Supreme Court preempted strict products liability when generic pharmaceutical manufacturers could not comply with both the common law and the FDA’s restrictive regulatory framework. The *PLIVA* Court, however, did not address the First Circuit’s stop-selling rationale. Part II.A of this Note discusses the regulatory framework governing generic pharmaceuticals. Part II.B outlines the development and current trends in design-defect strict products liability. Part II.C examines the Court’s rejection of impossibility preemption for brand-name pharmaceutical manufacturers in *Wyeth v. Levine*<sup>38</sup> and its apparent reversal for generic pharmaceutical manufacturers in *PLIVA v. Mensing*.

### A. *The Food, Drug, and Cosmetic Act Enacted a Rigid Approval Process for Generic Pharmaceuticals That Requires Complete Duplication of the Branded Drug*

The Food, Drug, and Cosmetic Act (“FDCA”)<sup>39</sup> requires pharmaceutical manufacturers to gain approval from the FDA prior to marketing a drug.<sup>40</sup> Under the FDCA, New Drug Applications (“NDA”) may only be approved after rigorous FDA vetting, including comprehensive clinical testing, labeling, pharmacovigilance, and risk-benefit analyses.<sup>41</sup> To foster competition in the pharmaceutical market, the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the “Hatch-

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35. *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 37–38, 44 (1st Cir. 2012) *rev’d*, 133 S. Ct. 2466 (2013).

36. *Id.* at 38, 44.

37. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470, 2472 (2013) (citing *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 694 (2012)).

38. 555 U.S. 555 (2009).

39. 21 U.S.C. §§ 301–399f (2012).

40. 21 U.S.C. § 355(a) (2012) (requiring approval from the FDA for all drugs introduced in to interstate commerce).

41. *Id.* §§ 355(b)(1)(A), 355(b)(1)(F), 355(d); 21 C.F.R. §§ 314.50(c)(2)(i), 314.50(c)(2)(ix), 314.50(d)(2), 314.50(d)(5)(iv), 314.50(d)(5)(viii)(2014). Mirroring a risk-utility test, the FDA only considers a drug safe when the “probable therapeutic benefits . . . outweigh [the] risk of harm.” *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000). An NDA is a costly, multi-year iterative process culminating in a multi-thousand page application. See U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-07-49, NEW DRUG DEVELOPMENT 6–8 (2006), available at <http://www.gpo.gov/fdsys/pkg/GAOREPORTS-GAO-07-49/content-detail.html>; see also *Bartlett*, 133 S. Ct. at 2471.

Waxman Act,”<sup>42</sup> created an Abbreviated New Drug Application (“ANDA”) to expedite approval of generic versions of approved, brand-name, NDAs.<sup>43</sup> Under the ANDA framework, a generic pharmaceutical may be approved without the same level of testing as long as it is identical to the NDA reference drug.<sup>44</sup>

While the Hatch-Waxman Act sets out in detail the ANDA approval process, it is silent regarding post-approval pharmacovigilance or other maintenance.<sup>45</sup> Instead, the Act includes an enabling clause in which the FDA “shall promulgate . . . such regulations as may be necessary for the administration of [the Act].”<sup>46</sup> Subsequent FDA regulations curbed ANDA manufacturer autonomy and warned that approval may be withdrawn if ANDA labeling deviates from the reference NDA.<sup>47</sup> FDA regulations require pre-approval for all “major” NDA changes with only narrow express exceptions.<sup>48</sup> One such exception, commonly known as the changes-being-effected (“CBE”) provision, allows manufacturers to unilaterally strengthen labeling to reflect newly acquired safety information.<sup>49</sup> The FDA also requires ongoing pharmacovigilance and periodic reporting for both NDA and ANDA applications.<sup>50</sup>

*B. The “Unreasonably Dangerous” Standard of the Restatement (Second) of Torts Has Developed into Two Distinct Tests to Calculate Strict Products Liability*

Modern strict products liability is derived from the *Restatement (Second) of Torts* Section 402A providing that: “[o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer . . . is

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42. Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 (2012)).

43. 21 U.S.C. § 355(j); H.R. REP. 98-857, pt. 1, at 14 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

44. 21 U.S.C. § 355(j) (2012). For purposes of the statute, identical means chemically equivalent, *id.* § 355(j)(2)(A), bioequivalent in rate of absorption, *id.* § 355(j)(2)(A)(iv), and labeling-equivalent, *id.* § 355(j)(2)(A)(v). Any variations, however, trigger additional testing. *Id.* § 355(j)(2)(C). The regulations refer to the reference listed drug (“RLD”) not the NDA drug because competitively marketed pharmaceuticals may have multiple NDAs. 21 C.F.R. § 314.3 (2014) (defining “Reference listed drug”); *see also* FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS x–xi (35th ed. 2014), *available at* <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf> (last visited Mar. 22, 2015) (discussing RLDs).

45. *See generally* 21 U.S.C. § 355(j) (limiting discussion to the initial application process).

46. Drug Price Competition and Patent Term Restoration Act § 105(a).

47. 21 C.F.R. § 314.150(b)(10) (2014). The regulation excepts deviations that are explicitly permitted. *Id.*

48. *Id.* § 314.70(b)–(d) (outlining “major,” “moderate,” and “minor” changes).

49. *Id.* § 314.70(c)(6)(iii); *see also* *Wyeth v. Levine*, 555 U.S. 555, 568–69 (2009) (analyzing the provision).

50. 21 C.F.R. §§ 314.80–314.81.

subject to liability.”<sup>51</sup> To identify “unreasonably dangerous” “defective condition[s],” two distinct tests emerged: the consumer expectations test and the risk-utility test.<sup>52</sup> The consumer expectations test developed from comments *g* and *i* of Section 402A.<sup>53</sup> The test defined an unreasonably dangerous defective condition as “dangerous to an extent beyond that which would be contemplated by the ordinary consumer . . . with the ordinary knowledge common to the community.”<sup>54</sup> The risk-utility balancing test instead adopted a manufacturer-oriented approach; common considerations include: the usefulness and benefit of the product; the likelihood and severity of danger; and the feasibility, availability, and reasonableness of preventative measures or an alternative design.<sup>55</sup>

The *Restatement (Third) of Torts: Products Liability* officially adopts factors of the risk-utility test, including concepts of reasonableness, foreseeability, negligence, and reasonable alternative design.<sup>56</sup> These factors translate into a restrictive negligence framework diametrically opposed to a consumer expectations approach.<sup>57</sup> For example, under the *Restatement Third*, a drug is only defective if a health care provider “would not prescribe the drug . . . for any class of patients.”<sup>58</sup> As of yet, the *Restatement Third* remains only sparsely followed among the states.<sup>59</sup>

C. *Juxtaposing Wyeth v. Levine and PLIVA v. Mensing,  
Pharmaceutical Tort Liability Turns upon Impossibility Preemption*

In *Wyeth*, the Supreme Court chose not to apply impossibility preemption to failure-to-warn tort liability against brand-name pharmaceutical manufacturers.<sup>60</sup> The Court reasoned that the CBE provision of 21 C.F.R.

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51. RESTATEMENT (SECOND) OF TORTS § 402A (1965).

52. *E.g.*, *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2474 (2013) (applying New Hampshire’s risk-utility test); *Phipps v. Gen. Motors Corp.*, 278 Md. 337, 343–53, 363 A.2d 955, 958–63 (1976) (adopting a consumer expectations approach).

53. *See* RESTATEMENT (SECOND) OF TORTS § 402A cmts. *g* & *i* (1965).

54. *Id.* at cmt. *i*.

55. *See, e.g.*, *Bartlett*, 133 S. Ct. at 2474–75 (outlining risk-utility test); *see also* *Vautour v. Body Masters Sports Indus., Inc.*, 784 A.2d 1178, 1183 (N.H. 2001) (“[W]hile proof of an alternative design is relevant in a design defect case, it should be neither a controlling factor nor an essential element that must be proved in every case.”).

56. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2(b) (1998); *see id.* cmt. *a* (“[s]ubsections (b) and (c), which impose liability for products that are defectively designed or sold without adequate warnings or instructions and are thus not reasonably safe, achieve the same general objectives as does liability predicated on negligence”).

57. *Compare id.* § 6(c) (restricting liability), *with* RESTATEMENT (SECOND) OF TORTS § 402A cmt. *i* (1965) (conditioning liability on ordinary consumer expectations).

58. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6(c) (1998).

59. *See infra* Part IV.C.

60. *Wyeth v. Levine*, 555 U.S. 555, 581 (2009). *Wyeth* arose out of defective labeling of an intravenous (IV) antihistamine used to treat nausea. *Id.* at 559–60. At the time of injury, the drug labeling permitted two methods of administration: (1) via a shot directly into a patient’s vein, or

314.70(c)(6)—that allowed pharmaceutical companies to unilaterally change their labels without FDA pre-approval—foreclosed impossibility preemption.<sup>61</sup> The Court further refused to recognize federal objective preemption by the FDA approval process.<sup>62</sup> The Court reasoned that if Congress believed state lawsuits posed an obstacle to its objectives, it would have enacted express preemption as it had for medical devices.<sup>63</sup> The Court noted that, traditionally, state tort claims were considered complementary to FDA regulation: serving to supplement the FDA’s limited resources by incentivizing manufacturers with “superior access” to post-market data to identify new risks.<sup>64</sup> Under this approach, FDA approval serves as a floor for safety, not a ceiling.<sup>65</sup>

Justice Thomas concurred in judgment expressing a strong distaste for what he termed “implied pre-emption doctrines.”<sup>66</sup> Justice Thomas instead favored narrower impossibility preemption.<sup>67</sup> Arguing federal objective preemption, Justice Alito’s dissent, joined by Chief Justice Roberts and Justice Scalia, proposed that “the real issue is whether a state tort jury can countermand the FDA’s considered judgment” that a warning renders a drug safe.<sup>68</sup> Justice Alito found juries “ill equipped to perform the FDA’s cost-benefit-balancing function.”<sup>69</sup>

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(2) by first inserting an IV-drip and then administering through the drip. *Id.* at 559. The drug labeling warned that the medication would cause irreversible damage if it escaped the vein; the IV-drip method ameliorated this risk. *Id.* The plaintiff alleged that the labeling should have foreclosed the direct “shot” method as unreasonably dangerous. *Id.* at 560.

61. *Id.* at 570–73. Wyeth argued the CBE provision was only implicated when *new* information was acquired and furthermore that the CBE provision conflicts with the misbranding regulations. *Id.* at 568–70. The Court did not adopt this “cramped reading of the CBE regulation.” *Id.* at 570–72.

62. *Id.* at 573–75, 581.

63. *Id.* at 574–75. “Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices.” *Id.* (quoting *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327 (2008)) (internal quotation marks omitted).

64. *Id.* at 578–79 (“[T]he FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.”).

65. *See id.* at 573–74, 578–79 (discussing purpose of regulation).

66. *Id.* at 583 (Thomas, J., concurring in judgment) (“In particular, I have become increasingly skeptical of this Court’s ‘purposes and objectives’ pre-emption jurisprudence. . . . [I]mplied pre-emption doctrines that wander far from the statutory text are inconsistent with the Constitution . . .”).

67. *Id.* at 589–90, 593–94. Justice Thomas expressed a novel twist on impossibility preemption that would foreshadow his opinions in *PLIVA* and *Mutual*. *See id.* at 590 (questioning the “physical impossibility” standard and noting that a “logical-contradiction” standard may prove more apt (quoting Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 260–61 (2000)) (internal quotation marks omitted)).

68. *Id.* at 605 (Alito, J., dissenting).

69. *Id.* at 626.

In *PLIVA v. Mensing*,<sup>70</sup> Justice Thomas, writing for the Court, held that state failure-to-warn claims against generic pharmaceutical manufacturers were in impossible conflict with federal law, precluding manufacturers from controlling their labeling.<sup>71</sup> The *PLIVA* Court explained that the state tort law requires manufacturers who are aware, or should be aware, of a “product’s danger to label that product in a way that renders it reasonably safe.”<sup>72</sup> Federal law, however, requires generic pharmaceutical manufacturers to adopt labeling identical to the branded version of the drug.<sup>73</sup> The plaintiffs argued that generic manufacturers could have unilaterally changed their labels via the CBE provision or issued “Dear Doctor” letters to inform prescribing physicians of the danger.<sup>74</sup> The FDA, under *Auer*<sup>75</sup> deference, rejected both contentions, and instead asserted that federal law created a manufacturer duty to propose stronger labels to the FDA if the manufacturers believed they were warranted.<sup>76</sup> The Court, however, held that the proper question for impossibility analysis “is whether the private party could independently do under federal law what state law requires of it,” not whether the party could possibly influence a consistent result.<sup>77</sup> Since the generic manufacturer could not independently change the labeling under federal law, the state claims were preempted, creating an “unfortunate” disparity between brand and generic tort liability.<sup>78</sup>

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70. 131 S. Ct. 2567 (2011). The controversy in *PLIVA*, arose from the discovery that Reglan, a drug to aid digestion, was found to be causally related to tardive dyskinesia, a neurological disorder, in patients engaging in long-term therapy (incidence of twenty-nine percent). *Id.* at 2572. The plaintiffs developed the condition before the FDA strengthened the warning labeling and sued the generic manufacturer for failure to warn in the face of “mounting evidence.” *Id.* at 2572–73 (quoting *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 605 (8th Cir. 2009)).

71. *Id.* at 2580–81.

72. *Id.* at 2573.

73. *Id.* at 2574 (citing 21 C.F.R. §§ 355(j)(2)(A)(v), 355(j)(4)(G), 314.94(a)(8), 314.127(a)(7) (2014)).

74. *Id.* at 2575–76. “Dear Doctor” letters contain direct warnings sent to healthcare professionals. *Id.* at 2576.

75. *Auer v. Robbins*, 519 U.S. 452 (1997). Under *Auer*, the FDA is granted deference in its interpretation of its own regulations unless “plainly erroneous or inconsistent with the regulation.” *Id.* at 461 (quoting *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 359 (1989)).

76. *PLIVA*, 131 S. Ct. at 2575–77. The FDA interpreted the misbranding provision of 21 U.S.C. § 314.150(b)(10) (2012)—withdrawing ANDA approval for deviating from the brand labeling—to foreclose changes via the CBE provision or the proposed “Dear Doctor” letters. *PLIVA*, 131 S. Ct. at 2575–76. The FDA sought to undermine preemption by interpreting the misbranding provision to impose a duty to notify the FDA of potential product dangers. *Id.* at 2576–77. The Court, however, found preemption regardless of this duty. *Id.* at 2577–78 (finding an additional duty did not resolve impossibility).

77. *PLIVA*, 131 S. Ct. at 2579.

78. *Id.* at 2581 (“We recognize that . . . finding pre-emption here but not in *Wyeth* makes little sense. Had [plaintiffs] taken . . . the brand-name . . . their lawsuits would not be pre-empted. But because pharmacists . . . substituted generic metoclopramide instead, federal law pre-empt

## III. THE COURT'S REASONING

In *Mutual Pharmaceutical Co. v. Bartlett*, the Supreme Court reversed the First Circuit<sup>79</sup> and, extending *PLIVA v. Mensing*,<sup>80</sup> preempted “warning-based design-defect causes of action” against generic drug manufacturers.<sup>81</sup> The Court reasoned that New Hampshire’s design-defect cause of action created a manufacturer duty to comply with an impossible state safety standard under federal law.<sup>82</sup> The dissenting opinions asserted no such affirmative duty and instead reasoned that a manufacturer could comply with state law by paying damages even if it took no action to comply with the heightened state safety standard.<sup>83</sup>

The Court adopted a process of elimination approach to find impossibility preemption.<sup>84</sup> Specifically, the Court reasoned that New Hampshire common law created an affirmative duty for manufacturers to ensure that their products were not “unreasonably dangerous,”<sup>85</sup> then determined that every option available to comply with that duty was prohibited by federal law.<sup>86</sup> New Hampshire applies a risk-utility balancing test to identify unreasonably dangerous products.<sup>87</sup> The test does not technically include set factors; the Court, however, applied the three factors that the New Hampshire Supreme Court has repeatedly used: (1) “the usefulness and desirability of the product,” (2) whether the product’s risks can be reduced without affecting its cost or effectiveness, and (3) the “efficacy of a warning to avoid . . . unreasonable . . . harm from hidden dangers or foreseeable uses.”<sup>88</sup> The Court reasoned that sulindac’s usefulness and risk profile could only be improved by changing the drug’s chemical composition.<sup>89</sup> Sulindac’s composition, however, could not be altered under federal law.<sup>90</sup>

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these lawsuits. We acknowledge the unfortunate hand that federal drug regulation has dealt [plaintiffs] . . .” (citations omitted)).

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

80. *PLIVA*, 131 S. Ct. at 2572; *see also supra* notes 70–72, 78 and accompanying text (discussing the *PLIVA* holding).

81. *Bartlett*, 133 S. Ct. at 2477.

82. *Id.* at 2473–77. The Court derives the state safety standard, that manufacturers must not sell unreasonably dangerous products, from the assessment of liability. *Id.* at 2474.

83. *Id.* at 2480–81 (Breyer, J., dissenting); *see id.* at 2488, 2491 (2013) (Sotomayor, J., dissenting) (dichotomizing duties and incentives).

84. *Id.* at 2473–78 (majority opinion).

85. *Id.* at 2473–74 (noting that New Hampshire has adopted the *Restatement (Second) of Torts* § 402A).

86. *See id.* at 2473–78.

87. *Id.* at 2474.

88. *See id.* at 2474–75 (quoting *Vautour v. Body Masters Sports Indus., Inc.*, 784 A.2d 1178, 1182 (N.H. 2001)) (internal quotation marks omitted).

89. *Id.*

90. *Id.* at 2475; *see also supra* Part II.A (summarizing FDCA regulations). The Court also concluded sulindac’s simple, single ingredient, composition was chemically incapable of redesign. *Bartlett*, 133 S. Ct. at 2475.

Since improving the first two factors was legally impossible, the Court concluded that Mutual Pharmaceutical's only remaining option was to strengthen sulindac's labeling.<sup>91</sup> Relying on *PLIVA*, the Court then found strengthening the labeling similarly impossible.<sup>92</sup> Therefore, the Court held that New Hampshire's design-defect cause of action was "without effect" under the Supremacy Clause because every available avenue to comply with the common law duty was prohibited under federal law.<sup>93</sup>

The Court rejected the lower courts' "'stop-selling' rationale" because of its destructive consequences on preemption jurisprudence.<sup>94</sup> The Court noted that if exiting the market undermined a claim of impossibility, impossibility preemption would be rendered meaningless; ceasing to act would be available in every previous case in which the Court found a "direct conflict" between federal and state laws.<sup>95</sup> As an example, the majority cited *PLIVA* as squarely at odds with the "stop-selling rationale."<sup>96</sup>

In dissent, Justice Sotomayor contended that, properly applied, preemption principles posed no barrier to recovery.<sup>97</sup> Justice Sotomayor advanced a literal reading of impossibility preemption, defining impossibility as two "irreconcilable affirmative requirements" imposed by state and federal laws.<sup>98</sup> She contended that New Hampshire's design defect cause of action "does not require that the manufacturer take any specific action."<sup>99</sup> Instead, she reasoned that New Hampshire common law liability only *permits* or *incentivizes* compliance.<sup>100</sup> Justice Sotomayor explained that, unlike a legal mandate, exposure to liability does not leave a party no choice but to comply.<sup>101</sup> Applying this distinction, Justice Sotomayor distinguished *PLIVA* on the grounds that the Minnesota and Louisiana law in *PLIVA* "un-disputed[ly]" mandated stronger labeling<sup>102</sup> whereas New Hampshire's law only exposed Mutual Pharmaceutical to liability.<sup>103</sup>

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91. *Id.*

92. *Id.* at 2476.

93. *Id.* at 2476–77 (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)) (internal quotation marks omitted).

94. *Id.* at 2477–78.

95. *Id.* at 2477.

96. *Id.* at 2478 (citing *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577–78 (2011)).

97. *Id.* at 2483–84 (Sotomayor, J., dissenting).

98. *Id.* at 2485, 2488 (emphasis added).

99. *Id.* at 2488.

100. *Id.* at 2485–86. Justice Sotomayor acknowledges that an incentive may still implicate express preemption, field preemption, or pose an obstacle to a federal objective. *Id.* She further qualified that "common-law duties may qualify as 'requirements,'" but asserted that no such "duty" was created by the text of New Hampshire's law. *Id.* at 2489 n.5.

101. *Id.* at 2488.

102. *Id.* at 2489 (quoting *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2573 (2011)) (internal quotation marks omitted).

103. *Id.* Justice Sotomayor also authored the dissent in *PLIVA* where she contended generic manufacturers could avoid impossibility by petitioning the FDA. *PLIVA*, 131 S. Ct. at 2587–88.

Justice Sotomayor contended that the majority wrongly assumed that manufacturers must have an option to avoid liability other than exiting the market or paying compensation as a cost of doing business.<sup>104</sup> States, she argued, have the right to ensure compensation for their citizens, and federal law does not grant a manufacturer an absolute right to continue marketing pharmaceuticals free from liability.<sup>105</sup> Justice Sotomayor added that tort liability serves important functions, including assisting the FDA with drug safety<sup>106</sup> and “perform[ing] an important remedial role in compensating” victims.<sup>107</sup> After rejecting literal impossibility preemption, Justice Sotomayor considered and dismissed federal objective preemption.<sup>108</sup>

In reaction, the majority distinguished between strict and absolute liability, reasoning that strict liability “signals a breach of duty” whereas absolute liability “merely serves to spread risk.”<sup>109</sup> The majority, relying on *Riegel v. Medtronic, Inc.*,<sup>110</sup> noted that “most common-law causes of action for . . . strict liability do not exist merely to spread risk, but rather to impose affirmative duties.”<sup>111</sup> Consonant with *Riegel*, the majority asserted that New Hampshire’s products liability jurisprudence had consistently held that a manufacturer bears a “duty to design [its] product reasonably safely for the uses which [it] can foresee.”<sup>112</sup> Furthermore, the Court noted that the New Hampshire Supreme Court had cautioned “that the term ‘unreasonably dangerous’ should not be interpreted so broadly as to impose absolute liability on manufacturers.”<sup>113</sup> The Court emphasized that in New Hampshire “liability without negligence is not liability without fault.”<sup>114</sup>

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104. *Bartlett*, 133 S. Ct. at 2489, 2491, 2494 (Sotomayor, J., dissenting).

105. *Id.* at 2491 (noting an exception if the law poses an obstacle to a federal objective).

106. *Id.* at 2485. The FDA alone is incapable of detecting adverse events with low incidence and long latency; state tort law provides an incentive. *Id.* at 2284–85. Furthermore, tort suits “serv[e] as a catalyst” to identify previously unknown drug dangers.” *Id.* at 2485 (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 451 (2005)).

107. *Id.* (quoting *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002)).

108. *Id.* at 2493–94. Consistent with Justice Sotomayor, Justice Breyer’s dissent also adopts a literal reading of impossibility preemption. *Id.* at 2480–81 (Breyer, J., dissenting). Justice Breyer lends greater weight to federal objective preemption, but, like Justice Sotomayor, rejects it as inapplicable in *Bartlett*. *Id.* at 2481–82.

109. *Id.* at 2473 (majority opinion) (asserting that the respondent conflates strict liability and absolute liability).

110. 552 U.S. 312 (2008).

111. *Bartlett*, 133 S. Ct. at 2474 n.1 (reasoning that medical device causes of action in *Riegel* imposed requirements preempted by federal law).

112. *Id.* at 2473 (quoting *Thibault v. Sears, Roebuck & Co.*, 395 A.2d 843, 847 (N.H. 1978)). *Thibault* explicitly rejected the notion of strict liability as “a tool of social engineering” and concluded that “[u]nlike workmen’s compensation . . . strict liability is not a no-fault system of compensation.” *Thibault*, 395 A.2d at 845–46.

113. *Bartlett*, 133 S. Ct. at 2474 (quoting *Price v. BIC Corp.*, 702 A.2d 330, 333 (N.H. 1997)) (internal quotation marks omitted).

114. *Id.* (quoting *Simoneau v. S. Bend Lathe, Inc.*, 543 A.2d 407, 409 (N.H. 1988)) (internal quotation marks omitted).

## IV. ANALYSIS

*Mutual Pharmaceutical v. Bartlett* was correctly decided given New Hampshire's negligence-based strict products liability, but invited over-expansive preemption of distinguishable state tort-law schemes with its emphatic rejection of Justice Sotomayor's Calabresian law and economic policy.<sup>115</sup> Rather than tailor its holding to New Hampshire, the Court safeguarded deterrence-centric policy goals by rejecting compensatory considerations as a form of absolute liability.<sup>116</sup> The Court erred in both its mischaracterization of compensation and its implicit failure to recognize states' right to experiment with fault under modern principles of federalism.<sup>117</sup>

While the extension of *PLIVA* adds little doctrinally to the Court's jurisprudence, the discussion of law and economic tort policy unveils a deep divide over the supremacy of fault.<sup>118</sup> Four dissenting justices would have imposed liability regardless of Mutual Pharmaceutical's inability to take preventive action.<sup>119</sup> Justice Sotomayor, joined by Justice Ginsburg, would reject fault entirely and rebuild tort liability from a Calabresian *tabula rasa*.<sup>120</sup> Though not adopted, and certainly inconsistent with fault, Justice Sotomayor's Calabresian policies legitimize states' decisions to preserve traditional, "stricter" products liability.<sup>121</sup>

The *Bartlett* Court's conclusion that manufacturers must have an avenue to escape strict liability has led to expansive preemption of distinguishable strict liability schemes.<sup>122</sup> Rather than evaluate specific conflicts with state common-law duties, the lower courts have interpreted *Bartlett* to require preemption whenever a pharmaceutical manufacturer cannot increase product safety under federal law.<sup>123</sup> This approach effectively rejects the

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115. See *infra* Part IV.A. Justice Sotomayor was a student of Professor Calabresi and a fellow judge on the Second Circuit for ten years. Jo Becker & Adam Liptak, *Sotomayor's Blunt Style Raises Issue of Temperament*, N.Y. TIMES (May 28, 2009), <http://www.nytimes.com/2009/05/29/us/politics/29judge.html?pagewanted=all>; Sheryl Gay Stolberg, *Sotomayor, a Trailblazer and a Dreamer*, N.Y. TIMES (May 28, 2009), <http://www.nytimes.com/2009/05/27/us/politics/27websotomayor.html?pagewanted=all>.

116. See *infra* Part IV.A.

117. See *infra* Part IV.A.

118. Cf. Calabresi, *supra* note 12, at 749 ("[T]here is prima facie inefficiency in the fault system. That is, if the fault system worked, one would never find fault liability.").

119. *Bartlett*, 133 S. Ct. at 2480, 2482 (Breyer, J., dissenting with Kagan, J., joining); *id.* at 2482, 2486 (Sotomayor, J., dissenting with Ginsburg, J., joining).

120. See *infra* Part IV.B. Law and economics, as a field, originated in the seminal work of Judge Guido Calabresi—*The Cost of Accidents*—in which Calabresi used economics to theorize a system of tort liability to reduce the cost of accidents more efficiently than fault. CALABRESI, *supra* note 7, at 26; Calabresi, *supra* note 12, at 748; Hylton, *supra* note 13, at 85.

121. See *infra* Part IV.B.

122. See *infra* Part IV.C.

123. See *infra* Part IV.C.

“stricter” liability still assessed by a minority of states and mandates a negligence-based approach to strict products liability.<sup>124</sup>

In the wake of *Bartlett* and *PLIVA*, the FDA proposed a rule to bring generic pharmaceutical liability into parity with branded manufacturers.<sup>125</sup> The rule would extend the CBE exception to allow generic manufacturers to unilaterally change warning labeling.<sup>126</sup> The rule represents an express reversal of the FDA’s amicus position in *PLIVA*.<sup>127</sup> Nevertheless, the FDA position, if finalized, will likely be granted deference and have a lasting effect on the generic pharmaceutical industry.<sup>128</sup> If precedent is any indication, once the impossible conflict with state law is removed, a majority of the Court will be unable to coalesce behind an alternate theory of preemption.<sup>129</sup>

Part IV.A discusses the Court’s rejection of Calabresian absolute liability. Part IV.B assesses the viability of Justice Sotomayor’s compensatory tort policy, legitimizing competing tort schemes preempted post-*Bartlett*. Part IV.C examines the negative impact of *Bartlett*’s over-expansive pro-fault reasoning originating with the preemption of Maryland’s consumer expectations approach and extending to similarly situated jurisdictions. Part IV.D outlines the FDA’s attempt to reverse *PLIVA* and *Bartlett* and predicts the likely impact if its rule is finalized.

A. *The Bartlett Court’s Negligence-Based Tort Policy Proves Dispositive in New Hampshire but Should Not Extend to States That Maintain “Stricter” Products Liability*

The Court should have limited its inquiry to the inconsistency between the First Circuit’s “stop-selling rationale” and New Hampshire law.<sup>130</sup> Instead, in response to Justice Sotomayor’s argument for compensation, the Court rejected compensatory policy as absolute liability and narrowly construed strict products liability through a negligence-based conception of fault.<sup>131</sup> The resulting mischaracterization of strict and absolute liability en-

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124. See *infra* Part IV.C.

125. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985, 67985 (proposed Nov. 13, 2013).

126. *Id.*

127. See *supra* notes 76–77 and accompanying text.

128. See *infra* Part IV.D.

129. See *infra* Part IV.D.

130. See *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2473–74, 2477–78 (2013) (discussing the inconsistencies).

131. See, e.g., *id.* at 2470, 2477 (reasoning that the stop-selling rationale would render impossibility preemption a “dead letter”); see also OWEN, *supra* note 2, at 245 (discussing the overlap between modern strict liability and negligence).

couraged over-simplistic, categorical preemption of “stricter”<sup>132</sup> liability state regimes.<sup>133</sup>

1. *The Bartlett Court Should Have Limited Its Reasoning to New Hampshire’s Negligence-Based, Majority Approach to Strict Products Liability*

The New Hampshire Supreme Court expressly rejected interpretations of its design-defect cause of action that impose absolute liability or liability without fault.<sup>134</sup> Instead, New Hampshire adopted a negligence-based risk-utility balancing test that assesses design defects in the context of reasonable manufacturer conduct.<sup>135</sup> As the *Bartlett* Court correctly held, in New Hampshire, if no reasonable conduct is available to a manufacturer, the product is not defective and the manufacturer is not liable.<sup>136</sup> The Court should have stopped here.

2. *The Court Instead Advanced Deterrence-Centric Tort Policy That Over-Expansively Rejected Competing Compensatory Considerations*

In order to rebut the policy arguments of Justice Sotomayor’s dissent, the Court diverged from the concerns of New Hampshire and adopted pro-deterrence law-and-economic policy incompatible with compensatory considerations.<sup>137</sup> The Court dismissed Justice Sotomayor’s attempt to balance compensation and deterrence, and instead rejected any compensatory purpose behind strict products liability.<sup>138</sup> Compensatory considerations, per

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132. See *supra* note 15 and accompanying text (analyzing liability on a spectrum with “stricter” as the metric of comparison).

133. See, e.g., *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 477–78 (4th Cir. 2014) (preempting Maryland’s consumer expectations approach to strict products liability); *Fullington v. PLIVA, Inc.*, No. 4:10CV00236 JLH, 2014 WL 806149, at \*3 (E.D. Ark. Feb. 28, 2014) (preempting Arkansas’s consumer expectations approach following *Drager*).

134. *Bartlett*, 133 S. Ct. at 2474 (citing *Price v. BIC Corp.*, 702 A.2d 330, 333 (N.H. 1997)) (“cautioning “that the term “unreasonably dangerous” should not be interpreted so broadly as to impose absolute liability on manufacturers or make them insurers of their products”); *id.* (citing *Simoneau v. S. Bend Lathe, Inc.*, 543 A.2d 407, 409 (N.H. 1988)) (“We limit the application of strict tort liability in this jurisdiction by continuing to emphasize that liability without negligence is not liability without fault.” (internal quotation marks omitted)).

135. *Id.* at 2475. The test also weighs the product’s usefulness and desirability to society; however usefulness was not in dispute in *Bartlett*. See *id.* (outlining test).

136. See *id.* at 2475–77.

137. See *id.* at 2473–80 (rejecting compensation as absolute liability, mandating an independent manufacturer capability to escape liability, deriding the stop-selling rationale, and interpreting liability as preemptible affirmative requirements); see also *supra* notes 7, 13 and accompanying text (discussing the conflicting functions of tort liability).

138. Compare *Bartlett*, 133 S. Ct. at 2473 (distinguishing breach of strict liability duties from absolute liability compensatory risk-spreading), with *id.* at 2488 (Sotomayor, J., dissenting) (“New

the Court, are either the result of absolute liability, which is universally rejected,<sup>139</sup> or serve only to promote private deterrence.<sup>140</sup> Any risk-spreading that results from strict liability the Court rejected as inefficient.<sup>141</sup>

The Court further limited strict products liability by foreclosing the possibility of a duty to compensate.<sup>142</sup> Under the Court's deterrence-centric tort policy, a duty to compensate is untenable; manufacturers must have an avenue to "escape liability."<sup>143</sup> Otherwise, a manufacturer is found at fault for doing no wrong and is counter-productively deterred to an inefficient end.<sup>144</sup> For this reason, the same majority Court in both *PLIVA* and *Bartlett* engrafted an *independent* action requirement onto the preemption inquiry: to hold a tortfeasor liable, it must be capable of unilateral preventative action.<sup>145</sup> Given the Court's alternating treatment of "tort-as-compensation" and "tort-as-regulation," its explicit rejection of tort law's compensatory function is incorrectly expansive.<sup>146</sup>

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Hampshire's law, which mandates compensation only for 'defective' products, serves both compensatory and regulatory purposes.").

139. *Id.* at 2473–74 (majority opinion); *see also* AMERICAN LAW OF PRODUCTS LIABILITY, *supra* note 2, § 16.5 (collecting cases rejecting absolute liability).

140. *See, e.g., Bartlett*, 133 S. Ct. at 2473 (concluding that *Bartlett*'s private action serves a regulatory, not compensatory, purpose); *see also* POSNER, *supra* note 13, at 244 (reasoning that if the sole function of compensation is deterrence, compensation serves no purpose when there is nothing to deter). The Court's deterrence-centric policy dictates that the only reason plaintiffs receive the deterrence-payment is to incentivize private enforcement. *See* POSNER, *supra* note 13, at 244.

141. *See Bartlett*, 133 S. Ct. at 2474 n.1 (rejecting risk-spreading as a purpose of strict liability). Risk spreading is more efficiently achieved in the private insurance market with lower administrative costs. *See* POSNER, *supra* note 13, at 254 (discussing administrative costs).

142. *Cf. Bartlett*, 133 S. Ct. at 2477–78 (rejecting the stop-selling rationale as rendering impossibility preemption meaningless because every conflict could be resolved in if the tortfeasor ceased acting). Similarly, a duty to compensate would resolve every conflict. But *see* Part IV.C detailing the warranty-based origins of strict products liability that provided quasi-contractual remuneration.

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

144. *Cf. POSNER*, *supra* note 13, at 244 (discussing the inefficiencies of overcompensation and thereby over-deterrence). Deterrence for conduct outside of a company's control can create contradictory incentives that induce the company to engage in more socially costly alternatives. *Cf. id.* (discussing overcompensation).

145. *See Bartlett*, 133 S. Ct. at 2476 (discussing the manufacturer's inability to take preventative action); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2579 (2011) (citing to *Wyeth* for a unilateral action requirement). The *Wyeth* Court, however, established that available unilateral action was *one* means to defeat impossibility preemption, not the *only* means. *Wyeth v. Levine*, 555 U.S. 555, 568–73 (2009).

146. *See Sharkey*, *supra* note 7, at 460–71 (discussing the Supreme Court's alternating treatment of tort-as-regulation and tort-as-compensation); *compare PLIVA*, 131 S. Ct. at 2577–78, 2580–81 (preempting state failure to warn claims as conflicting regulatory requirements), *with Wyeth*, 555 U.S. at 571–72 (finding no conflict between state and federal regulatory requirements).

3. *The Court's Erroneous Distinction Between Strict and Absolute Liability Reduces State Autonomy and Invites Over-Simplistic Preemption*

While harmless in negligence-based New Hampshire, the Court's dichotomous construction of negligence-based "strict" liability and jurisdictionally verboten absolute liability overlooked the traditionally "stricter" liability middle ground, and thereby instigated preemption of valid, albeit minority, state tort schemes.<sup>147</sup> Strict liability, unlike absolute liability, does not transform manufacturers into insurers for their products.<sup>148</sup> Under an absolute liability regime, manufacturers can be liable even if nothing is wrong with their product.<sup>149</sup> Strict products liability, however, is limited to *unreasonably dangerous, defective* products.<sup>150</sup> If a court finds a product unreasonably dangerous, then by definition the product has something *wrong* with it and the court is not imposing absolute liability.<sup>151</sup>

The Court employs an absolute liability straw man to erroneously reject compensatory arguments and preserve a fault-based tort liability system. The Court's reasoning is syllogistic: (1) all jurisdictions reject absolute liability;<sup>152</sup> (2) Justice Sotomayor's compensatory concerns would impose absolute liability;<sup>153</sup> (3) therefore, all jurisdictions reject compensatory concerns. The error lies in the second premise; the Court mischaracterizes all liability without conventional fault as absolute liability.<sup>154</sup>

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147. See *infra* note 160 (discussing federalism); see also *infra* Part IV.C (listing states that define unreasonably dangerous design defects in terms other than manufacturer conduct).

148. OWEN, *supra* note 2, at 256–57, 288; see also AMERICAN LAW OF PRODUCTS LIABILITY, *supra* note 2, § 16.5 (collecting cases to support that "[t]he doctrine of strict liability has never meant absolute liability").

149. See OWEN, *supra* note 2, at 257, 257 n.108 (distinguishing strict and absolute liability by explaining "something must be *wrong* with a product before a court will hold a seller responsible" under strict liability). Whereas strict liability creates a heightened duty, absolute liability effectively eliminates the duty and breach elements altogether.

150. OWEN, *supra* note 2, at 256–57; see also AMERICAN LAW OF PRODUCTS LIABILITY, *supra* note 2, § 16.5 (collecting cases to identify limitations on strict liability).

151. See OWEN, *supra* note 2, at 256–57 (distinguishing strict and absolute liability). "Defective" was added to § 402A to prevent an overbroad interpretation of "unreasonably dangerous" that assessed absolute liability when an inherently dangerous product performed as designed. 38 A.L.I. PROC. 87–89 (1961).

152. See *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2474 (2013) (rejecting absolute liability); AMERICAN LAW OF PRODUCTS LIABILITY, *supra* note 2, § 16.5 (collecting cases).

153. Compare *Bartlett*, 133 S. Ct. at 2473–74, 2474 n.1 (finding absolute liability to not impose affirmative duties), with *id.* at 2479 (concluding that dissent would ignore common-law duties).

154. See *id.* at 2473–74, 2474 n.1 (distinguishing strict and absolute liability based on the absence of fault). But see *supra* text accompanying note 151 (inferring fault when something is wrong with the product). The Court does not explicitly use the term "fault" in its definition of absolute liability. *Bartlett*, 133 S. Ct. at 2473. The subsequent reasoning, however, makes clear that the imposition of legal duties is synonymous with fault. Compare *id.* ("an 'absolute-liability regime' . . . does not reflect the breach of any duties"), with *id.* at 2474 ("We limit the application

The Court acknowledges states' freedom to adopt the liability regime of their choosing: be it absolute liability, strict liability, or any "stricter" liability there between.<sup>155</sup> In practice, however, the Court fails to account for the historically "stricter" variations.<sup>156</sup> Strict products liability originated from the law of warranty in which liability was "strict" because it [was] based not on a supplier's fault . . . but on the frustration of consumer expectations of product safety."<sup>157</sup> While possibly closer to absolute liability than its modern fault-based counterparts, this consumer expectations approach remains distinct.<sup>158</sup>

The Court's sharp, aspirational dichotomy, however, implicitly suggests that any regime short of imposing "true absolute liability" creates a preemptible duty sounding in negligence-based strict liability.<sup>159</sup> By generalizing, as opposed to limiting its ruling to New Hampshire's majority, risk-utility, approach, the Court in effect legislated the only tenable law for design-defect claims: one that is preempted by FDA regulations. The Court's expansive approach sounds the death knell for traditional strict products liability in contravention of principles of federalism.<sup>160</sup>

*B. Justice Sotomayor's Law and Economic Tort Policy Supports the Traditional Compensatory Role of State Tort Liability in the Generic Pharmaceutical Industry*

Channeling the law and economic works of Judge Guido Calabresi, Justice Sotomayor raises legitimate compensatory policy concerns in opposition to the *Bartlett* Court's over-expansive construction of fault.<sup>161</sup> Justice

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of strict tort liability . . . [by] emphasiz[ing] that liability without negligence is not liability without fault." (quoting *Simoneau v. S. Bend Lathe, Inc.*, 543 A.2d 407, 409 (N.H. 1988)) (internal quotation marks omitted)).

155. See *Bartlett*, 133 S. Ct. at 2474 n.1 (acknowledging the possibility of a "true absolute liability state-law system"); see also *supra* note 15 and accompanying text (characterizing liability on a spectrum with the term "stricter" as the metric).

156. See *id.* ("most common-law causes of action for negligence and strict liability do not exist merely to spread risk" (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323–24 (2008))).

157. OWEN, *supra* note 2, at 245, 247. Over the decades, however, fault crept back into "strict" liability as courts increasingly applied principles of foreseeability and risk-utility balancing, transforming "strict" products liability into a sobriquet for negligence. *Id.* at 245.

158. See *supra* notes 149–151 and accompanying text (distinguishing liability for product defects from absolute liability that applies regardless of something wrong with the product).

159. See *Bartlett*, 133 S. Ct. at 2474 n.1 (rejecting risk spreading as absolute liability).

160. See *supra* text accompanying note 157 (discussing the origins of strict liability). States' ability to experiment is fundamental to the American system of justice. POSNER, *supra* note 13, at 893.

161. *E.g.*, *Bartlett*, 133 S. Ct. at 2485 (Sotomayor, J., dissenting) (cautioning against "remov[ing] all means of judicial recourse" (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)) (internal quotation marks omitted)); see also Sharkey, *supra* note 7, at 466–71 (chronicling the Court's pro-tort-as-compensation precedent and recognizing the "strong state interest in compensating victims").

Sotomayor states that the function of pharmaceutical tort liability is to protect and compensate.<sup>162</sup> This distinctly Calabresian approach is antithetical to a fault-based regime bound solely to the deterrence of wrongful conduct.<sup>163</sup> Justice Sotomayor would instead loosen the requirements of fault, consistent with a “stricter,” more traditional, treatment of liability, to ensure compensation.<sup>164</sup>

Justice Sotomayor does not advocate abandoning the primary deterrent role of tort liability.<sup>165</sup> She necessarily, however, subordinates the Court’s concerns with counter-productive deterrence<sup>166</sup> to secure compensation for plaintiffs.<sup>167</sup> In addition to the considerations of justice,<sup>168</sup> compensation serves two economic purposes: it internalizes product dangers into prices;<sup>169</sup> and diminishes the societal costs<sup>170</sup> associated with “social and economic dislocations”<sup>171</sup> arising from concentrated losses.<sup>172</sup> Both economic “pur-

162. *See Bartlett*, 133 S. Ct. at 2488 (Sotomayor, J., dissenting) (“strict-liability regimes . . . serve[] both compensatory and regulatory purposes”); *see also id.* at 2484–85 (explaining that legislative history indicates Congress meant to supplement the protection and compensation offered by state regulation and common-law liability). Congress has preserved common-law liability for generic prescription drugs even while expressly preempting liability for medical devices. *Id.* at 2484, 2484 n.2 (citing 21 U.S.C. § 360k(a) (2012)).

163. CALABRESI, *supra* note 7, at 240–42 (characterizing fault as an oversimplified bilateral view of tort liability focused on the efficient division of costs to reduce the number of torts).

164. *See Bartlett*, 133 S. Ct. at 2489 (Sotomayor, J., dissenting) (seeking to impose liability absent available preventative action); *see also supra* text accompanying note 157 (discussing traditionally “stricter” liability); *infra* Part IV.C (examining tort regimes clinging to “stricter” liability standards). Liability serves no deterrent purpose if the manufacturer has no available action to deter.

165. *Bartlett*, 133 S. Ct. at 2488 (Sotomayor, J., dissenting) (“As is typically true of strict-liability regimes, New Hampshire’s law, which mandates compensation only for ‘defective’ products, serves both compensatory and regulatory purposes.”).

166. *See supra* notes 140, 144 and accompanying text (discussing inefficient over-deterrence).

167. *See Bartlett*, 133 S. Ct. at 2491–92, 2496 (Sotomayor, J., dissenting) (seeking to impose liability as a cost of doing business to secure a remedy for a seriously injured consumer).

168. *See id.* at 2485 (describing tort liability’s “important remedial role”).

169. POSNER, *supra* note 13, at 232 (“Strict liability in effect impounds information about product hazards into the price of the product, causing a substitution away from hazardous products by consumers who may be completely unaware of the hazards.”). Efficient internalization, however, is limited to unknown dangers. *Id.* When consumers are cognizant of risks, they will privately insure. *Id.* As evidenced by Ms. Bartlett’s case, the consumer market for pharmaceuticals is characterized by unknown dangers and under-insurance; therefore economic policy dictates compensation. *See, e.g., Bartlett v. Mut. Pharm. Co.*, 760 F. Supp. 2d 220, 230–31 (D.N.H. 2011) *aff’d*, 678 F.3d 30 (1st Cir. 2012) *rev’d*, 133 S. Ct. 2466 (2013) (suggesting Ms. Bartlett had no knowledge of the risks of sulindac).

170. The societal costs are the economic waste that results from an ill-prepared individual being unable to bear the damages and becoming a drain on society. *Cf. CALABRESI, supra* note 7, at 42, 44–45 (detailing disruptive costs and economic dislocations arising from concentrated losses from accidents).

171. *Id.* at 43–45 (referencing “the problem of poverty”).

172. *Cf. id.* at 39–45 (framing an *individual’s* losses from an accident in terms of pain or utility). *But see* Richard A. Posner, *Guido Calabresi’s the Costs of Accidents: A Reassessment*, 64

poses” are derived from the assumption that consumers will act rationally and efficiently if given sufficient information and resources.<sup>173</sup>

Justice Sotomayor advocates transforming tort liability into a cost of doing business.<sup>174</sup> This Calabresian Enterprise Liability approach allocates liability to the party best able to spread the otherwise concentrated losses (“lowest cost avoider”)<sup>175</sup> and reduce administrative transfer costs.<sup>176</sup> Sensitive to the injustice of deterring “faultless” parties, Justice Sotomayor implicitly adopts the proposition that “it is only fair that an industry should pay for the injuries it causes.”<sup>177</sup> Justice Sotomayor does not recommend a system in which no relation exists between the payer and the victim.<sup>178</sup> Instead, she implicitly assigns lowest cost avoider status to the party “most likely to cause the burden”—generic pharmaceutical manufacturers—to diminish inadvertent deterrence.<sup>179</sup> Enterprise liability is not naturally so constrained, and, in fact, the brand manufacturer may prove a more efficient candidate given its greater control over the product.<sup>180</sup> Mutual Pharmaceutical, however, could also serve as an efficient loss spreader by internalizing the cost of liability into prices.<sup>181</sup>

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MD. L. REV. 12, 16 (2005) (criticizing the *Costs of Accidents* because loss of utility is not an economic cost).

173. See DEWEES ET AL., *supra* note 7, at 189–90 (using the availability of information to explain the impact of liability regimes). With perfect information, producers will take cost-justified accident avoidance (precautions); similarly consumers will take care). *Id.*

174. *Bartlett*, 133 S. Ct. at 2491 (Sotomayor, J., dissenting).

175. CALABRESI, *supra* note 7, at 50–51, 143–44. Concentrated losses refer to large economic costs accrued against one person over a short amount of time. *Id.* at 39. Economic waste and inefficiency are reduced when losses are borne by parties able to pay, such as insurance companies. *Cf.* at 39, 50–51 (outlining the benefits to the *individual*).

176. *Id.* at 50–51, 150. Enterprise Liability is a common-sense approach that assigns liability to the enterprise that caused the harm. Guido Calabresi, *Some Thoughts on Risk Distribution and Law of Torts*, 70 YALE L.J. 499, 500–01 (1961) [hereinafter “Calabresi, *Some Thoughts*”].

177. See *Bartlett*, 133 S. Ct. at 2491 (Sotomayor, J., dissenting) (reasoning the manufacturer of an unreasonably dangerous drug should pay compensation); Calabresi, *Some Thoughts*, *supra* note 176, at 500 (“[I]t is only fair that an industry should pay for the injuries it causes. . . . [L]osses should be borne by the doer, the enterprise, rather than distributed on the basis of fault.” (internal quotation marks omitted)). In *Bartlett*, fault is contested, but causation is undisputed. *Bartlett*, 133 S. Ct. at 2472.

178. See CALABRESI, *supra* note 7, at 22–23 (correcting the myth that there is a “necessary financial link between injurers and victims”); Calabresi, *Some Thoughts*, *supra* note 176, at 514 (“Proper resource allocation militates strongly against allocating to an enterprise costs not closely associated with it . . .”).

179. See *Bartlett*, 133 S. Ct. at 2491 (Sotomayor, J., dissenting) (seeking to impose manufacturer liability as a cost doing business); see also Calabresi, *Some Thoughts*, *supra* note 176, at 505 (“the loss should be placed on the party which is most likely to cause the burden”).

180. See, e.g., *Wyeth v. Levine*, 555 U.S. 555, 570–73 (2009) (discussing brand manufacturers ability to independently change labeling); see also CALABRESI, *supra* note 7, at 50–54 (describing Enterprise Liability).

181. See *supra* note 169 and accompanying text.

Justice Sotomayor justifies allocating tort liability as a cost of doing business by differentiating statutory mandates from common-law liability.<sup>182</sup> She argues that, though the punishment may be identical, a manufacturer that violates a statutory mandate breaks the law; whereas a manufacturer that accrues liability has not broken any law.<sup>183</sup> She reasons that this moral distinction translates into a material difference in social and legal expectations: statutory mandates are expected to evoke specific, compliant performance, whereas common law liability evokes only an amoral, economic choice.<sup>184</sup> This economic incentive model removes state tort liability from considerations of fault and immunizes common-law claims from federal preemption.<sup>185</sup>

Justice Sotomayor's departure from fault-based liability is particularly significant in light of the codification of negligence within "strict" products liability by the *Restatement (Third) of Torts*.<sup>186</sup> While many jurisdictions have only selectively adopted the *Restatement Third*, a weakened version of strict products liability has largely pervaded the legal system.<sup>187</sup> For those states concerned by the weakened compensatory function of tort law, Justice Sotomayor outlines a policy roadmap to justify reverting state "design-defect" liability to its traditionally "stricter" origins.<sup>188</sup>

*C. Post-Bartlett the Court's Impossibility Preemption Reasoning Has Been Expansively Applied to Preempt "Stricter" Liability Tort Schemes*

In the wake of *Bartlett*, courts have engaged in large-scale preemption of state common-law claims against generic manufacturers.<sup>189</sup> While many

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182. See *Bartlett*, 133 S. Ct. at 2491 n.8 (Sotomayor, J., dissenting) (distinguishing paying a fine from breaking the law).

183. *Id.*

184. *Id.* Justice Sotomayor compares this distinction to *National Federation of Independent Business v. Sebelius*, 132 S. Ct. 2566 (2012), where a condition that triggers a tax does not equate to a "legal command" to take specific action. *Bartlett*, 133 S. Ct. at 2491 n.8.

185. *But see supra* Part IV.A (characterizing the *Bartlett* Court's reasoning as subjecting all common-law claims to potential preemption).

186. See *supra* note 57 and accompanying text. The *Restatement (Third) of Torts* "largely dismantles" the traditional framework of *Restatement Second* § 402A and, as a result, many states have declined to adopt it. OWEN, *supra* note 2, at 246.

187. See *supra* note 2 (describing adoption of *Restatement Third*); see also *infra* note 202 (chronicling the transition towards negligence-based liability).

188. See *supra* notes 148–151, 154, 179 and accompanying text (contradicting the Court's assertion that fault is the distinguishing factor between strict and absolute liability); see also *infra* notes 203, 204 (detailing the stricter origins of state common law).

189. *E.g.*, *Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605, 613 (5th Cir. 2014) (preempting Louisiana law); *Eckhardt v. Qualitest Pharm., Inc.*, 751 F.3d 674, 679 (5th Cir. 2014) (preempting Texas law); *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 477–78 (4th Cir. 2014) (preempting Maryland law); *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 406–07 (6th Cir. 2013) (preempting Tennessee law); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1290 (10th Cir. 2013) (preempting Okla-

of the preempted state claims were directly analogous to New Hampshire, some proved materially distinguishable.<sup>190</sup> In one such case, *Drager v. PLIVA USA, Inc.*,<sup>191</sup> the Fourth Circuit preempted Maryland's consumer expectations test, interpreting *Bartlett* to preempt all state strict-liability claims.<sup>192</sup> The court reasoned that regardless of the method used to calculate an "unreasonably dangerous" design defect, *Bartlett* mandates that companies must have an avenue to escape liability and finds federal law eliminates all means for them to do so.<sup>193</sup>

Both the Eighth Circuit and Pennsylvania initially protested the categorical application of preemption, absent state-specific analysis, but *Drager* has since become the dominant approach.<sup>194</sup> The Fourth Circuit's reasoning in *Drager* is problematic because the *Bartlett* Court mandate—that manufacturers must have an avenue to escape liability—is derived from New Hampshire's risk-utility test, not the *Restatement Second* Section 402A in

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homa law and noting "[i]t is for the state courts . . . to engage in the delicate policy considerations predicate to the expansion of the scope of state tort law"); *Wagner v. Pfizer, Inc.*, No. 13-cv-497-jdp, 2014 WL 3447476, at \*3 (W.D. Wis. July 11, 2014) (preempting Wisconsin law); *Fullington v. PLIVA, Inc.*, No. 4:10CV00236 JLH, 2014 WL 806149, at \*3 (E.D. Ark. Feb. 28, 2014) (preempting Arkansas law); *Wilson v. Amneal Pharm., L.L.C.*, No. 1:13-CV-00333-CWD, 2013 WL 6909930, at \*14 (D. Idaho Dec. 31, 2013) (preempting Idaho law); *Ko v. Mut. Pharm. Co., Inc.*, No. C-13-00890-RMW, 2013 WL 5692375, at \*2 (N.D. Cal. Oct. 18, 2013) (preempting California law); *Gardley-Starks v. Pfizer, Inc.*, No. 4:10-CV-099-SA-JMV, 2013 WL 5423951, at \*3 (N.D. Miss. Sept. 26, 2013) (preempting Mississippi law); *In re Fosamax Prods. Liab. Litig.*, 965 F. Supp. 2d 413, 420 (S.D.N.Y. 2013) (preempting New York law).

190. See, e.g., *Fullington v. Pfizer, Inc.*, 720 F.3d 739, 746–47 (8th Cir. 2013) ("In contrast to New Hampshire's risk-utility approach, Arkansas state courts focus on consumer expectations in determining whether a product is unreasonably dangerous. Consequently, 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. Therefore, we reverse the dismissal . . . and remand." (citations omitted)); *Neeley v. Wolters Kluwer Health, Inc.*, No. 4:11-CV-325 JAR, 2013 WL 3929059, at \*10 (E.D. Mo. July 29, 2013) ("Likewise, the Kentucky Supreme Court's analysis of defective design cases focuses on consumer expectations. Accordingly, the Court denies the motion to dismiss." (citation omitted)). On remand from *Fullington*, the court followed *Drager*. *Fullington*, 2014 WL 806149, at \*3.

191. 741 F.3d 470 (4th Cir. 2014).

192. *Drager*, 741 F.3d at 477–78.

193. *Id.*; cf. *Bartlett*, 133 S. Ct. at 2493 (Sotomayor, J., dissenting) (citing majority opinion at 2475 for the proposition that a company must have an avenue to escape liability). Another way of stating the *Drager* reasoning is that common-law claims create a manufacturer duty to take steps to lessen unreasonable danger, and that this duty is impossible to perform under *Bartlett*. *Drager*, 741 F.3d at 477–78. The court in *Drager* also argued that a risk-utility approach would apply because the drug at issue malfunctioned and Maryland engages in a risk-utility inquiry for malfunctioning products. *Id.* at 478 n.2.

194. *Fullington*, 720 F.3d at 746–47; *Hassett v. Dafoe*, 74 A.3d 202, 211–12, 217 (Pa. Super. Ct. 2013), appeal denied 99 A.3d 926 (Pa. 2014) (table). But see *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, 2014 WL 1632149, at \*9 (S.D. Ill. Apr. 24, 2014) (following *Drager*); *Fullington*, 2014 WL 806149, at \*3 ("The Fourth Circuit is correct: whether a state follows the risk-utility approach or the consumer-expectations approach does not affect the application of *Bartlett*.")

general.<sup>195</sup> Nothing in the *Restatement Second* forecloses a duty to compensate.

Necessary and insurmountable to the *Bartlett* holding is the bevy of New Hampshire common law that rejects any form of liability without fault.<sup>196</sup> Consistent with this ideology, New Hampshire adopted a risk-utility test that only imposes liability if reasonable preventative measures were available (duty) that were not taken (breach).<sup>197</sup> Under this approach a product manufacturer “must have a way to ‘escape liability’”—preventative action must be available—or it cannot be found at fault.<sup>198</sup> Fault, however, is a state construct subject to state discretion.<sup>199</sup> If a state chooses to infer fault, or otherwise lessen the preconditions to find fault, the need for an “escape liability” requirement evaporates.<sup>200</sup> Via the consumer expectations test, several states, Maryland included, have done just that.<sup>201</sup>

The consumer expectations test pre-dates the risk-utility approach and is derived from the law of implied warranty rather than negligence-balancing.<sup>202</sup> The test harkens back to the original adoption of strict products liability when a manufacturer was “subject to liability to the . . . consumer even though [it] . . . exercised all possible care in the preparation and sale of the product.”<sup>203</sup> Whereas a risk-utility test eliminates liability when a manufacturer exercises all possible care, a consumer expectations test

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195. See *Bartlett*, 133 S. Ct. at 2474–75 (deriving the escape liability requirement from a negligence-based, risk-utility duty to improve product safety with reasonable and available manufacturer conduct). By the same token, the prohibition of the stop-selling rationale relied upon in *Drager* is dependent on a risk-utility, negligence-based approach.

196. *Id.* at 2473–74.

197. See *id.* at 2475–76 (reasoning that the risk-utility test is premised on manufacturers having a duty to take reasonable preventative action).

198. See *id.* at 2493–95 (Sotomayor, J., dissenting) (citing *id.* at 2475 (majority opinion)) (discussing the “automatic conflict” because of a manufacturer’s inability to act).

199. See *supra* notes 155–160 (discussing federalism and fault).

200. See, e.g., *Bartlett*, 133 S. Ct. at 2473 (distinguishing strict and absolute liability noting that strict liability “still signals a breach of duty”). If this breach of duty is inferred, the manufacturer’s ability to escape liability is immaterial.

201. See Dawn M. Goulet & Mark R. Miller, *Show v. Ford and the Continued Role of the Consumer-Expectation Test in Illinois Product Liability Litigation*, 15 TRIAL J. 47 n.6 (Winter 2013) (collecting cases). *Drager* is the primary authority for preemption of the consumer expectations test; other jurisdictions have merely followed suit. E.g., *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1140–41 (8th Cir. 2014) (relying on *Drager*); *Fullington v. PLIVA, Inc.*, No. 4:10CV00236 JLH, 2014 WL 806149, at \*3 (E.D. Ark. Feb. 28, 2014) (following *Drager*).

202. OWEN, *supra* note 2, at 291–93. The consumer expectations test was the dominant approach in the 1960’s and 1970’s, but the majority of courts transitioned to a risk-utility balancing approach because the consumer expectations test proved poorly adapted to cases involving obvious dangers, atypical victims, or complex product designs. OWEN, *supra* note 2, at 293–99. Under the risk-utility test, a product is considered defective if the costs of prevention are less than the safety benefit. OWEN, *supra* note 2, at 301. This test is indistinguishable from negligence. OWEN, *supra* note 2, at 300–01.

203. RESTATEMENT (SECOND) OF TORTS § 402(a) cmt. a. (1965); see also OWEN, *supra* note 2, at 256 (discussing § 402A).

does not assess a manufacturer's exercise, non-exercise, or inability to exercise any degree of care; manufacturer conduct, available or not, is not part of the inquiry.<sup>204</sup>

Similarly, the Maryland consumer expectations test is concerned with protecting justified consumer expectations, not with ensuring that companies have an avenue to escape liability.<sup>205</sup> "The relevant inquiry . . . focuses not on the conduct of the manufacturer but rather on the product itself."<sup>206</sup> Under Maryland's test, a defect, or breach of duty, is inferred whenever a product is deemed more dangerous than an ordinary consumer would contemplate.<sup>207</sup> This inference distorts manufacturer duties and comparatively relaxes fault.<sup>208</sup> This "stricter" liability, however, remains distinguishable from absolute liability.<sup>209</sup> While Maryland's test offers little guidance regarding the scope of manufacturer duties, the Maryland Court of Appeals discussed compensatory policy when adopting its strict liability approach.<sup>210</sup>

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204. Compare OWEN, *supra* note 2, at 292 (discussing consumer expectations) with OWEN, *supra* note 2, at 303 (outlining liability under the risk-utility test). The difference in scope between the risk-utility and consumer expectations tests is compensatory. Rational actors only take precautions that are cheaper than the sanction. John C.P. Goldberg, *Twentieth-Century Tort Theory*, 91 GEO. L.J. 513, 535. Therefore, under either liability regime, manufacturers will stop taking precautions at the same, non-cost-effective point. *Id.* The only difference is liability beyond the cost-effective threshold.

205. See, e.g., *Phipps v. Gen. Motors Corp.*, 278 Md. 337, 350–53 363 A.2d 955, 962–63 (1976) (adopting strict liability in Maryland to establish warranty-like liability without standard warranty defenses or proof requirements).

206. *Phipps*, 278 Md. at 344, 363 A.2d at 958; see also *Binakonsky v. Ford Motor Co.*, 133 F.3d 281, 285 (4th Cir. 1998) ("*Phipps* clearly explains the fundamental difference between negligence and strict liability in [the above quoted] terms.>").

207. *Halliday v. Sturm, Ruger & Co.*, 368 Md. 186, 193–95, 792 A.2d 1145, 1150 (2002); *Phipps*, 278 Md. at 352, 363 A.2d at 963 ("Proof of a defect in the product at the time it leaves the control of the seller implies fault on the part of the seller sufficient to justify imposing liability for injuries caused by the product. Where the seller supplies a defective and unreasonably dangerous product, the seller or someone employed by him has been at fault in designing or constructing the product.>").

208. Compare *Halliday*, 368 Md. at 195–96, 200–03, 792 A.2d at 1151, 1154–55 (explicating Maryland's modern consumer expectations test at length without mentioning duties), with *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2473–74 (2013) (explaining New Hampshire's risk-utility test in terms of duties).

209. See *Phipps*, 278 Md. at 351–52, 363 A.2d at 963 ("[T]he theory of strict liability is not a radical departure from traditional tort concepts. Despite the use of the term 'strict liability' the seller is not an insurer, as absolute liability is not imposed on the seller for any injury resulting from the use of his product." (emphasis added) (citing *Dippel v. Sciano*, 155 N.W.2d 55, 63 (Wis. 1967))). Liability is only imposed when a product malfunctions.

210. *Phipps*, 278 Md. at 343, 363 A.2d at 958 ("Various justifications for imposing strict liability in tort on manufacturers have been advanced by the courts. It has been said that the cost of injuries caused by defective products should in equity be borne by the manufacturers that put such products on the market . . . . It has also been suggested that imposing strict liability on manufacturers for defective products is equitable because it shifts the risk of loss to those better able financially to bear the loss. Another reason advanced is that a consumer relies upon the seller in expecting that a product is safe for the uses for which it has been marketed, and that this expectation is better fulfilled by the theory of strict liability than traditional negligence or warranty theories.

The court in *Drager* did not conduct any specific analysis of the Maryland consumer expectations test.<sup>211</sup> The court instead relied on the *Bartlett* Court's over-simplified reasoning that state law based on *Restatement Second* Section 402A creates a manufacturer duty to reduce the unreasonably dangerous nature of its products; a duty frustrated by federal law regardless of the state's definition of "unreasonably dangerous."<sup>212</sup> While the simplest approach is to treat all common law based upon the *Restatement Second* alike—and if the *Restatement* was a recent adoption, this approach would be reasonable—five decades of common law evolution in states with divergent liability schemes suggests that a categorical approach is overly simplistic.<sup>213</sup> Whereas federal law invalidates New Hampshire's finding of fault under its risk-utility approach, no conflict arises if Maryland infers fault under its consumer expectations test. Therefore, the Fourth Circuit's preemption of the Maryland consumer expectations test in *Drager*, while an accurate reflection of the *Bartlett* Court's over-expansive reasoning, failed to account for states' ability to alter the "duties" created by strict liability. The subsequent adoption of the *Drager* reasoning by other jurisdictions is similarly suspect.<sup>214</sup>

The consumer expectations test has many distinct jurisdictional variants.<sup>215</sup> Some jurisdictions have adopted a hybrid approach by inserting the

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And still another reason advanced is that the requirement of proof of a defect rendering a product unreasonably dangerous is a sufficient showing of fault on the part of the seller to impose liability without placing an often impossible burden on the plaintiff of proving specific acts of negligence." (citations and internal quotation marks omitted)); *see also id.* at 958 n.3 (referencing Guido Calabresi, *Some Thoughts supra* note 176, at 499).

211. *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 477–78 (4th Cir. 2014).

212. *Id.* ("The Court in *Bartlett* did not determine that the New Hampshire law was preempted because it applied the risk-utility approach. Instead, it concluded that there was no action that the defendant could take . . . to avoid strict liability."). The court's interpretation of *Bartlett* is accurate; its application, however, is unfortunate because it presumes that the Maryland consumer expectations approach only assesses liability if a company fails to take action. No such conflict exists.

213. *E.g., Phipps*, 278 Md. at 343–53, 363 A.2d at 958–63 (adopting *Restatement Second* strict liability nearly four decades ago). Unlike other Supremacy Clause jurisprudence, impossibility preemption does not lend itself to expansive application. *See Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2485 (2013) (Sotomayor, J., dissenting) ("Impossibility pre-emption 'is a demanding defense' that requires the defendant to show an 'irreconcilable conflict' between federal and state legal obligations." (citation omitted)); *see also Wyeth v. Levine*, 555 U.S. 555, 589–90, 593–94 (2009) (Thomas, J., concurring in judgment) (distinguishing impossibility preemption from broader doctrines such as Congressional purposes and objectives preemption).

214. *See, e.g., Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1140–41 (8th Cir. 2014) (relying on *Drager* to preempt Missouri's undefined, "collective intelligence" approach); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, 2014 WL 1632149, at \*9 (S.D. Ill. Apr. 24, 2014) (relying on *Drager* to preempt Illinois' Consumer Expectation test); *Fullington v. PLIVA, Inc.*, No. 4:10CV00236 JLH, 2014 WL 806149, at \*3 (E.D. Ark. Feb. 28, 2014) (adopting the reasoning of *Drager* to preempt Arkansas' consumer expectations approach).

215. OWEN, *supra* note 2, at 298, 485–86, 485 n.56, 489.

consumer expectations test into the risk-utility balancing test.<sup>216</sup> Other states, however, have clung to a pure consumer expectations test either exclusively or as an alternate to risk-utility.<sup>217</sup> For those states with warranty-based consumer expectations strict liability, courts should not presume *Bartlett* impossibility preemption.<sup>218</sup> Instead, courts should engage in a state-specific analysis of the scope of fault, the nature of manufacturer common-law duties, and the legal necessity of an avenue to escape liability.

*D. Responding to Expansive Bartlett Preemption, the FDA Proposed a Rule to Render Bartlett Moot and Reinstate Generic Pharmaceutical Products Liability*

On November 13, 2013, the FDA published a notice of proposed rulemaking that would amend its CBE regulation to bring ANDA (generic) manufacturers into parity with NDA (brand) manufacturers.<sup>219</sup> If issued, the amendment would reinstate generic manufacturer strict products liability by “eliminat[ing] the preemption of certain failure-to-warn claims” by *PLIVA* and *Bartlett*.<sup>220</sup> The FDA specifically addressed the arbitrary disparity resulting from *Wyeth* and *PLIVA*, noting that liability turns upon a pharmacist’s whim.<sup>221</sup> The cited purpose of the rule, however, is not expressly compensatory; rather, the rule is intended to rectify the disincentives created by preemption by “ensur[ing] that generic drug companies actively participate with FDA in ensuring the timeliness, accuracy, and completeness of drug safety labeling.”<sup>222</sup>

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216. OWEN, *supra* note 2, at 297–98, 489, 489 nn.82–83; *see also* Goulet & Miller, *supra* note 201, at 46 n.5 (collecting cases).

217. *See* OWEN, *supra* note 2, at 293, 293 n.356, 485, 485 nn.56–57.

218. *Hassett v. Dafoe*, 74 A.3d 202, 211–12 (Pa. Super. Ct. 2013), *appeal denied* 99 A.3d 926 (Pa. 2014) (table) (“Absent from the vast majority of [*Bartlett* preemption] cases is the identification of 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. Furthermore, as the *Bartlett* Court’s analysis of New Hampshire law illustrates, pre-emption issues are state-law specific.”). *Hassett* held: “without a careful analysis of the applicable state law, pre-emption of all design defect claims is premature. . . . Thus, we agree with the trial court that blanket dismissal of all claims on pre-emption grounds . . . is unwarranted.” *Id.* at 217.

219. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985, 67989 (proposed Nov. 13, 2013). In addition to changing the CBE provision of 21 C.F.R. 314.70(c)(6), the FDA proposed creating a corresponding exception under the misbranding provision of 21 C.F.R. 314.150(b)(10)(iii) to allow for temporary differences in labeling. *Id.* at 67994.

220. *Id.* at 67988–89.

221. *Id.* at 67988 (“As a result of the decisions in *Wyeth* . . . and *P[LIVA]* . . . access to the courts is dependent on whether an individual is dispensed a brand name or generic drug.”).

222. *Id.* at 67989. Communication breakdowns are not a theoretical problem. *See, e.g., Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 359 (Iowa 2014) (“Although required by federal regulations to mirror the brand defendant’s label, *PLIVA* did not update its metoclopramide packaging to include the new warning . . . . The record is silent as to why *PLIVA* failed to add that warning.”). The FDA also intends the proposed rule to address the problem of orphaned ANDAs.

The FDA reopened the comment period in early 2015 after “an explanatory statement accompanying the Consolidated and Further Continuing Appropriations Act . . . supported . . . consider[ing] alternative solutions to the proposed rule.”<sup>223</sup> As of this writing, the FDA estimates a final rule will issue in September 2015.<sup>224</sup> In the previous comment period, just over one hundred comments were submitted, largely from the generic pharmaceutical industry.<sup>225</sup> The main industry concerns include consumer confusion arising from contradictory NDA and ANDA labeling and that generic manufacturers ill-equipped to unilaterally alter labeling.<sup>226</sup>

If the rule goes into effect as proposed, generic pharmaceutical manufacturers will fall under the auspices of *Wyeth* unless *Wyeth* is overturned.<sup>227</sup> Given the voting shift from *Wyeth* to *PLIVA* and *Bartlett*—the *Wyeth* dissent functionally became the *PLIVA* and *Bartlett* majority—predicting *Wyeth* would be overturned is not without merit.<sup>228</sup> The conflict

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Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67986, 67988. The FDA notes: “[a]mong drugs for which a generic version is available, approximately 94 percent are dispensed as a generic.” *Id.* at 67988. As such, brand manufacturers may discontinue marketing after generic entry, effectively orphaning related ANDAs. *Id.* Given this trend, the FDA notes that “it is time to provide ANDA holders with the means to update product labeling.” *Id.*

223. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products; Public Meeting; Request for Comments; Reopening of the Comment Period, 80 Fed. Reg. 8577, 8577–78 (February 11, 2015), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2013-N-0500-0081> (citing 160 CONG. REC. H9314 (daily ed. Dec. 11, 2014) (statement of Rep. Rogers)).

224. FDA, *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products*, REGULATIONS.GOV (last visited Mar. 24, 2015), <http://www.regulations.gov/#!documentDetail;D=FDA-2013-N-0500> (outlining docket and timetable).

225. *See id.* (summarizing rulemaking docket).

226. *See* FDA, *Memorandum of Meeting with GPhA (September 8, 2014)*, REGULATIONS.GOV (Dec. 17, 2014), <http://www.regulations.gov/#!documentDetail;D=FDA-2013-N-0500-0080> (detailing concerns). Disparate labeling for the same pharmaceutical, however, has existed for decades among drugs with multiple NDA versions. *See* for example acetaminophen or ibuprofen. Furthermore, any confusion created by the rule would be temporary; CBE changes still require FDA approval, and, upon approval, all other application holders would be required to follow suit. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67992 (explaining the process via flow chart). The FDA also proposed publishing all CBE-supplements on its labeling website. *Id.*

227. *See Wyeth v. Levine*, 555 U.S. 555, 570–73 (2009) (finding impossibility preemption inapplicable because under the CBE provision *Wyeth* could unilaterally change labeling); *see also supra* notes 60–65 and accompanying text (discussing *Wyeth*).

228. *Compare Wyeth*, 555 U.S. at 604 (Alito J., dissenting with Roberts, C.J., and Scalia, J. joining), with *PLIVA v. Mensing*, 131 S. Ct. 2567, 2571 (2011) (Thomas, J., delivering opinion with Roberts, C.J., Scalia, J., and Alito, J., joining and Kennedy, J. joining in part) and *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2469–70 (2013) (Alito, J., delivering opinion with Roberts, C.J., Scalia, J., Kennedy, J., and Thomas, J., joining). The operative question is: if *Wyeth* was decided today, would it be decided differently? The structural differences are not probative: Justices Sotomayor and Kagan replaced Justices Stevens and Souter, respectively, in the dissents of *PLIVA* and *Bartlett*. *Compare Wyeth*, 555 U.S. at 556, 558 (Stevens J. delivering opinion with

preemption divide, however, as evidenced by the doctrinal shift between *Wyeth* and *PLIVA*, and then confirmed by *Bartlett*, suggests that a reversal of *Wyeth* is unlikely.<sup>229</sup> Justice Alito's *Wyeth* dissent advocated broad federal objective preemption based on the common-sense conflict between laymen juries declaring a drug unreasonably dangerous and FDA experts declaring it safe.<sup>230</sup> In contrast, the majority in *Bartlett* does not mention federal objective preemption once.<sup>231</sup> If Justice Alito, writing for the Court, had support for broader federal objective preemption, given his *Wyeth* dissent, he would have at least *addressed* broader preemption in *Bartlett*, if not relied upon it entirely. Justice Thomas, however, as expressed by his *Wyeth* concurrence, will not support federal objective preemption.<sup>232</sup> Without the support of Justice Thomas, if the FDA's proposed rule goes into effect, *Wyeth* will then govern the generic pharmaceutical industry, ensuring compensation for individual litigants.

If the FDA rulemaking fails, however, states should look to Justice Sotomayor and Judge Calabresi for economic and equitable policy justifications to maintain states' role in pharmaceutical oversight and to ensure compensation for their injured citizens.<sup>233</sup> States should also consider the novel development of innovator (brand) liability advanced by judges in the aftermath of *PLIVA* and *Bartlett* to find NDA holders liable for injuries caused by their ANDA counterparts.<sup>234</sup> Furthermore, legislatures should

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Kennedy J., Souter J., Ginsberg J., and Breyer J. joining), with *PLIVA*, 131 S. Ct. at 2582 (Sotomayor, J., dissenting with Ginsburg, J., Breyer, J., and Kagan, J. joining) and *Bartlett*, 133 S. Ct. at 2480 (Breyer, J., dissenting with Kagan, J., joining) and *id.* at 2482 (Sotomayor, J., dissenting with Ginsburg, J., joining). The potential ideological change by Justices Thomas and Kennedy may, however, prove dispositive.

229. Compare *Wyeth*, 555 U.S. at 605, 609–12, 626 (Alito J., dissenting) (arguing based on federal objective preemption), with *PLIVA*, 131 S. Ct. at 2580–81 (deciding with impossibility preemption) and *Bartlett* 133 S. Ct. at 2476–77 (same); see also Sharkey, *supra* note 7, at 459, 471–72 (reporting that the common thread running through the Supreme Court's alternating treatment of tort-as-regulation and tort-as-compensation has been agency deference). For example *PLIVA*, 131 S. Ct. at 2575–77 followed the FDA's interpretation.

230. *Wyeth*, 555 U.S. at 609, 626 (Alito J., dissenting); see also *supra* notes 68–69 and accompanying text (discussing *Wyeth* dissent).

231. See generally *Bartlett*, 133 S. Ct. 2466. The only mention of federal objective preemption is by the dissents rebutting it as inapplicable. See *supra* note 108 (outlining the dissents' rejection of federal objective preemption).

232. See *Wyeth*, 555 U.S. at 583 (Thomas, J., concurring in judgment) (characterizing implied preemption doctrines such as federal objective preemption as unconstitutional); see also *supra* note 66 and accompanying text (discussing the *Wyeth* concurrence).

233. See *infra* Part IV.B

234. See, e.g., *Wyeth, Inc. v. Weeks*, No. 1101397, 2014 WL 4055813, at \*23 (Ala. Aug. 15, 2014) (adopting "innovator liability" to hold brand name pharmaceutical manufacturers liable for injuries caused by bioequivalent generic pharmaceutical drugs); *Dolin v. SmithKline Beecham Corp.*, No. 12 C 6403, 2014 WL 804458, at \*12–13 (N.D. Ill. Feb. 28, 2014) (recognizing brand-name liability for negligence even when a generic version caused the harm, but not for strict products liability); see also *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 414 (6th Cir. 2013) (Stranch, J., dissenting) (echoing the *Fullington* dissent in advocating brand manufacturer liability

consider compensatory economic policies in future lawmaking to diminish concentrated losses and efficiently reduce the societal cost of accidents.

## V. CONCLUSION

In *Mutual Pharmaceutical v. Bartlett*, the Supreme Court concluded that design-defect common law liability creates a preemptible duty in impossible conflict with federal generic pharmaceutical regulations.<sup>235</sup> While correctly decided in New Hampshire, the Court's reasoning discouraged "stricter" constructions of the duty<sup>236</sup> and thus invited erroneous preemption of Maryland's distinguishable calculation of design defect liability.<sup>237</sup> The erroneous preemption in Maryland was then adopted in several similarly situated jurisdictions without significant state-specific analysis.<sup>238</sup> As a result, for purposes of federal preemption, all state design-defect "strict" liability is treated as negligence.<sup>239</sup> This treatment runs contrary to modern principles of federalism and disregards legitimate compensatory policy concerns supporting traditional strict liability.<sup>240</sup>

The Court's expansive reasoning is best explained through the lens of law and economic tort policy. Justice Sotomayor, in dissent, advanced compensatory policy that would transform design defect liability into a cost of doing business.<sup>241</sup> The Court responded with classic pro-deterrence policy that analogized a compensatory duty to absolute liability and supported an expansive interpretation of FDA regulations.<sup>242</sup>

The Court's sweeping impossibility preemption triggered backlash from the FDA who proposed an amendment to its regulations to undermine the impossibility in *PLIVA* and *Bartlett* and reinstate generic pharmaceutical liability.<sup>243</sup> Though the rulemaking could render *Bartlett* moot, analysis of the ideologies driving the Court's decisionmaking remains instructive for predicting the Court's ongoing tort-as-regulation treatment of products liability.<sup>244</sup>

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for generic drugs.); Fullington v. Pfizer, Inc., 720 F.3d 739, 748 (8th Cir. 2013) (Murphy, J., dissenting) (positing brand manufacturer liability for generic drugs); Huck v. Wyeth, Inc., 850 N.W.2d 353, 403 (Iowa 2014) (Hecht, J., dissenting) ("[T]he universe of imaginable scenarios in which an actor who has not manufactured or sold a product may nevertheless both cause and be liable for damages caused is enormous.").

235. *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466, 2470 (2013).

236. *See supra* Part IV.A; *see also supra* Part IV.C (discussing the duties created by "stricter" strict liability).

237. *See supra* Part IV.C.

238. *See supra* Part IV.C.

239. *See supra* Part IV.C.

240. *See supra* Part IV.A–C.

241. *See supra* Part IV.B.

242. *See supra* Part IV.A.

243. *See supra* Part IV.D.

244. *See supra* Parts IV.A–B.