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# The Demise of Drug Design Litigation Death by Federal Preemption

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ESSAY

THE DEMISE OF  
DRUG DESIGN LITIGATION:  
DEATH BY FEDERAL PREEMPTION

AARON D. TWERSKI\*

*For over half a century, courts and commentators have disagreed as to the standards governing liability for drug design cases. In the last several years, the United States Supreme Court decided two cases that will have a profound effect on whether drug design defect cases, in general, are federally preempted. In PLIVA v. Mensing and Mutual Pharmaceutical Co. v. Bartlett, the Court preempted product liability actions for failure to warn and design defect against the manufacturers of generic drugs that met the FDA standard for the brand name drug. In these cases, the Court made wide-ranging statements that are applicable to brand name drugs as well. This Essay finds the Bartlett Court erred in having read New Hampshire law too narrowly. At the same time, the Court's reasoning has opened a debate as to the scope of federal preemption for brand name drugs. This Essay argues that the sweeping language in these two cases leads to the conclusion that common law drug design cases involving brand name drugs will fall prey to federal preemption.*

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## INTRODUCTION

More than half a century has passed since the American Law Institute adopted section 402A of the Restatement (Second) of Torts, imposing strict liability for the sale of defective products.<sup>1</sup> From the outset, the rules governing liability for design defects for prescription drugs have been shrouded in mystery.<sup>2</sup> In particular, the history of the

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1. RESTATEMENT (SECOND) OF TORTS, § 402A (AM. LAW INST. 1965).

2. See, e.g., DAVID G. OWEN, PRODUCTS LIABILITY LAW 36–37 (3d ed. 2015) [hereinafter OWEN, PRODUCTS LIABILITY LAW] (highlighting how secondary design issues create special problems because companies may not be required to offer optional safety devices); George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 YALE L.J. 1087, 1087–89 (2000) (pointing out that exemptions in the updates of the Restatement of Torts do not resolve issues around defects in prescription drugs and medical devices); Richard L. Cupp, Jr., *The Continuing Search for Proper Perspective: Whose Reasonableness Should Be at Issue in a Prescription Product Design Defect Analysis?*, 30 SETON HALL L. REV. 233, 233–34 (1999) (exploring the two approaches to design defects in prescription products: “reasonable physician” versus “reasonable manufacturer”); Richard L. Cupp, Jr., *Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach*, 63 GEO. WASH. L. REV. 76, 79–80 (1994) (“Scholars appear nearly unanimous in their criticism of the original language of comment k as a model of confusion.”); Margaret Gilhooley, *When Drugs Are Safe for Some but Not Others: The FDA Experience and Alternatives for Products Liability*, 36 Hous. L. REV. 927, 929 (1999) (“The Restatement’s ‘defect test’ has been the subject of critical commentary that has been primarily focused on whether a reasonable alternative design should be considered in determining whether a drug poses unreasonable risks and is thus defective, and whether the defect test should be based on the assessment of a reasonable manufacturer rather than a reasonable provider.”); Michael D. Green, *Prescription Drugs, Alternative Designs, and the Restatement (Third): Preliminary Reflections*, 30 SETON HALL L. REV. 207, 209 (1999) (exploring the reasons for the differential treatment for

now famous “comment k” dealing with unavoidably unsafe products has been recounted many times,<sup>3</sup> and courts have given at least eight different interpretations as to its meaning.<sup>4</sup> But all this debate as to the correct common law rule for drug design liability may be overshadowed, and perhaps rendered moot, by the expanded preemption doctrine set forth in recent United States Supreme Court cases.

The United States Supreme Court’s holding in *Mutual Pharmaceutical Co. v. Bartlett*<sup>5</sup> that manufacturers of generic drugs are immune from defective drug design claims has opened a debate about whether design claims against manufacturers of brand name drugs are

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defects in pharmaceuticals); James A. Henderson, Jr., *Prescription Drug Design Liability Under the Proposed Restatement (Third) of Torts: A Reporter’s Perspective*, 48 RUTGERS L. REV. 471, 494 (1996) (explaining how courts’ varied approaches to prescription drug defect has led to confusion); James A. Henderson, Jr. & Aaron D. Twerski, *Drug Designs Are Different*, 111 YALE L.J. 151, 151–52 (2001) [hereinafter Henderson & Twerski, *Drug Designs Are Different*] (responding to Conk’s criticism of the RESTATEMENT’s reinterpretation of pharmaceutical liability); David G. Owen, *Dangers in Prescription Drugs: Filling a Private Law Gap in the Healthcare Debate*, 42 CONN. L. REV. 733, 743–45 (2010) (recognizing courts’ confusion when applying the exemptions of comment k); Joseph A. Page, *Generic Product Risks: The Case Against Comment k and for Strict Tort Liability*, 58 N.Y.U. L. REV. 853, 854–56 (1983) (commenting on the debate over whether pharmaceutical companies should be held strictly liable for their products); Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment K*, 42 WASH. & LEE L. REV. 1139, 1139–40 (1985) (highlighting that scholars have found the RESTATEMENT’s definition of product liability “obscure” or “meaningless”); Victor E. Schwartz & Phil Goldberg, *A Prescription for Drug Liability and Regulation*, 58 OKLA. L. REV. 135, 136–37 (2005) (highlighting the divide in courtrooms in that some judges will seek “justice” for the claimants while others will adhere to fundamental principles of tort law); Sidney H. Willig, *The Comment k Character: A Conceptual Barrier to Strict Liability*, 29 MERCER L. REV. 545, 546–50 (1978) (raising many questions for how comment k should apply the product liability cases).

3. See *supra* note 2. Most recently, the Author joined with Professor James A. Henderson, Jr. to set forth their views as to the meaning of comment k in James A. Henderson, Jr. and Aaron D. Twerski, *Drug Design Liability: Farewell to Comment k*, 67 BAYLOR L. REV. 521 (2015) [hereinafter Henderson & Twerski, *Farewell to Comment k*].

4. See Henderson & Twerski, *Farewell to Comment k*, *supra* note 3, at 542–44 (demonstrating that courts’ interpretations of comment k range from holding that manufacturers of prescription drugs are entitled to escape liability for drug designs completely; that it is the plaintiff’s burden to prove that the risks of a drug outweigh its benefits; and that it is a defendant’s burden to prove that a drug’s benefits outweigh its risks). Per the Restatement, unavoidably unsafe products are products that “are quite incapable of being made safe for their intended and ordinary use,” as with drugs that pose a high degree of risk in addition to some valuable therapeutic benefit. See RESTATEMENT (SECOND) OF TORTS, § 402A cmt. k (Am. Law Inst. 1965).

5. 570 U.S. 472 (2013).

preempted as well.<sup>6</sup> This Essay argues that *Bartlett* was wrongly decided because the Court did not understand New Hampshire law.<sup>7</sup> Had the Court properly understood New Hampshire law, it is possible that it would not have preempted the design claim. This Essay will examine the various claims that fly under the banner of drug “design defect” and conclude that some are, or should be, federally preempted. However, this Essay also acknowledges that some claims may not be preempted, though to recognize such claims would constitute very bad common law. To cut through the maze of issues, Part I will undertake an analysis of *Bartlett* and demonstrate why the Court’s failure to understand New Hampshire product liability law may have led to an erroneous decision. Part II will examine the three types of drug design defect claims that are subject to risk-utility balancing. The first type seeks recovery on the grounds that the drug manufacturer should have adopted a reasonable alternative design (RAD). The second type attacks the design of the drug on the grounds that taking into account the usage of the drug by all patients the drug’s risks outweigh its utility, although the drug may be useful to at least one class of patients. The third type challenges the drug on the grounds that no reasonable health provider would prescribe the drug for any class of patients. For each type of claim, Part II of this Essay will assess whether it constitutes a valid common law claim, and whether it is or will be federally preempted. Part II will also suggest the claims of drug design that may

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6. See *id.* at 490 (explaining that the state-law-based design defect claims were preempted because New Hampshire law, which required a manufacturer to make a drug safer by altering its composition or labeling, conflicted with federal law, which prohibited a manufacturer from making such unilateral changes); see also cases cited *infra* notes 84–86; Bexis, “Pre-Approval” Design Defects—No Such Thing, DRUG & DEVICE LAW (May 8, 2017), <http://www.druganddevicelawblog.com/2017/05/pre-approval-design-defects-%E2%88%92no-such-thing.html>; Frederick G. Helmsing, Jr., *Preemption of Design Defect Claims Involving Brand-Name Drugs*, IN-HOUSE DEF. Q., 36 (Spring 2016), <https://www.mcdowellknight.com/wp-content/uploads/Helmsing-InHouse-Defense-Quarterly.pdf>; Eric Lindenfeld, *Brand Name Preemption: The New Frontier in Pharmaceutical Product Liability Litigation*, 72 FOOD & DRUG L.J. 636, 636–38 (2017); Derek M. Stikeleather & Brian M. Lands, *Courts Increasingly Recognize Federal Preemption of Claims Involving All FDA-Approved Medications*, FOR THE DEF., Sept. 2016, at 53, [https://www.gdldlaw.com/site/rte\\_uploads/files/FTD-1609-Stikeleather-Lands.pdf](https://www.gdldlaw.com/site/rte_uploads/files/FTD-1609-Stikeleather-Lands.pdf); Symposium, *Liability for Defective Drug and Medical Device Design*, BROOKLYN LAW SCHOOL (2018), <https://www.brooklaw.edu/newsandevents/events/2018/02-09-2018> (Paul D. Rheingold, Professors Anita Bernstein, Mark Geistfeld, Catherine M. Sharkey, and Aaron Twerski presented at this event).

7. See *infra* text accompanying notes 47–67.

not be subject to preemption. This Essay will conclude that the Court's drug preemption decisions have created a sea change in the law and that defective drug litigation will in the future focus almost entirely on failure to warn claims.

I. *MUTUAL PHARMACEUTICAL CO. v. BARTLETT*: WHERE THE COURT WENT WRONG

In December 2004, Karen Bartlett consulted Dr. Tahsin Ergin regarding pain in her right shoulder.<sup>8</sup> Dr. Ergin prescribed a non-steroidal anti-inflammatory drug (NSAID), Clinoril, to alleviate the pain.<sup>9</sup> Bartlett took the prescription to a local New Hampshire pharmacy, which filled the prescription with Sulindac, a generic substitute of Clinoril, manufactured by Mutual Pharmaceutical Co. (Mutual).<sup>10</sup> Within weeks of taking Sulindac, Bartlett contracted Steven-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN).<sup>11</sup> According to the court, "[Bartlett] spent about three months in the hospital recovering, two of them in a medically induced coma, and emerged with permanent injuries, including blindness."<sup>12</sup>

Bartlett initially brought suit in the New Hampshire Superior Court alleging state law claims in strict liability, negligence, and fraud.<sup>13</sup> The strict liability and negligence claims were predicated on failure to warn about the safety risks and defective design of Sulindac.<sup>14</sup> The defendant, Mutual, removed the case to the New Hampshire federal district court.<sup>15</sup>

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8. *Bartlett v. Mut. Pharm. Co.*, 731 F. Supp. 2d 135, 142 (D.N.H. 2010).

9. *Id.*

10. *Id.*

11. *Id.*; see also LISTER HILL NAT'L CTR. FOR BIOMEDICAL COMM'NS., NIH, GENETICS HOME REFERENCE: STEVENS-JOHNSON SYNDROME/TOXIC EPIDERMAL NECROLYSIS 1 (2018), <https://ghr.nlm.nih.gov/condition/stevens-johnson-syndrome-toxic-epidermal-necrolysis> (describing SJS and TEN as "severe skin reaction[s] most often triggered by particular medications," which begin with flu-like symptoms and progress to painful blistering of the skin and mucous membranes).

12. *Bartlett*, 731 F. Supp. 2d at 142; see also *Bartlett v. Mut. Pharm. Co.*, 760 F. Supp. 2d 220, 262 (D.N.H. 2011) (describing that Bartlett "suffered burns and lost skin over nearly two-thirds of her body; . . . lost her sight . . . ; lost the ability to have sexual intercourse due to vaginal injuries; . . . lost the ability to eat normally due to esophageal stricture . . . ; lost the ability to engage in aerobic activities . . . due to lung injuries; . . . suffered scarring to her face, back, anus, and vagina; and . . . suffers from post-traumatic stress disorder").

13. *Bartlett*, 731 F. Supp. 2d at 143.

14. *Id.*

15. *Id.*

After discovery, Mutual moved for summary judgment on all claims, including the failure to warn and defective design claims.<sup>16</sup> The district court held that enough evidence existed to warrant denying summary judgment on whether the drug's label contained adequate warnings,<sup>17</sup> but the court then found that Bartlett had not made out a prima facie case on causation.<sup>18</sup> In order to establish causation, Bartlett needed to prove that Dr. Ergin would not have used Sulindac, or would have used it differently, had the defendant provided an adequate warning. Bartlett could not prove this, however, because Dr. Ergin admitted that he never reviewed Sulindac's label. The court concluded that, even if Mutual had a duty to provide a stronger warning, it would not have affected Dr. Ergin's prescribing decision since he would not have read it.<sup>19</sup> As to the defective

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16. *Id.* at 144.

17. *See id.* at 144–46 (observing also that Mutual was “much closer to meeting the summary judgment standard than Bartlett” on the failure to warn issue, but concluding on the record before it that this issue was for the jury).

18. *Id.* at 145–46.

19. *See id.* at 143, 145–46 (pointing out that Dr. Ergin testified that “nothing about [Sulindac's label] influenced [his] prescribing of the drug” and that Dr. Ergin admitted he also did not consult the brand name drug's identical label “in detail” before prescribing Sulindac, relying instead on his background knowledge of other drugs similar to Sulindac). The inability to establish cause-in-fact in pharmaceutical failure to warn cases has been an important factor in motivating plaintiffs to allege defective drug design. *See* Henderson & Twerski, *Farewell to Comment k*, *supra* note 3, at 539–40. Claims based on defective drug design remove the issue of whether an inadequate warning was actually read and acted upon because a drug that is indeed defective should not have been marketed and prescribed in the first place. *Id.* For example, there is little question that Sulindac caused the severe injuries suffered by Bartlett. *See* Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 478 (2013) (“In a very small number of patients, . . . both Sulindac and popular NSAIDs . . . have the serious side effect of causing two hypersensitivity skin reactions . . . : toxic epidermal necrolysis, and . . . Stevens-Johnson Syndrome.”). Courts have granted summary judgment for defendants on the failure to warn issue where the treating physician testifies that he or she would not have read or heeded a stronger warning. *See, e.g., In re Fosamax Prods. Liab. Litig.*, No. 1:0b-MD-1789-JFK, 2010 WL 1257299, at \*5, \*7 (S.D.N.Y. Mar. 26, 2010) (granting the pharmaceutical company's motion for judgment as a matter of law regarding the plaintiff's failure to warn claim, finding that her physician's testimony regarding warnings of a drug's efficacy was not sufficient evidence for a reasonable jury to conclude that the defendant failed to warn of a specific risk); *Miller v. Alza Corp.*, 759 F. Supp. 2d 929, 936 (S.D. Ohio 2010) (“[W]here the treating physician unequivocally testifies that s/he would have prescribed the subject drug despite adequate warnings, judgment as a matter of law is appropriate.”); *see also* *Wright v. Am. Home Prods. Corp.*, No. 06-CV-4183-NKL, 2008 WL 1820902, at \*3 (W.D. Mo. Apr. 18, 2008) (explaining that “the failure of a drug manufacturer to provide . . . an adequate warning of risks associated with a prescription product is ‘not the proximate

design claim, the court, after a review of the evidence, found that a reasonable jury could find that Sulindac was unreasonably dangerous.<sup>20</sup>

The case then went to trial solely on the issue of design defect to decide whether Sulindac's risks outweighed its utility.<sup>21</sup> Mutual argued throughout that, under New Hampshire product liability law, a plaintiff must establish that a RAD existed.<sup>22</sup> The court, relying on several recent New Hampshire cases, held that a plaintiff need only prove that a drug's risks outweighed its utility.<sup>23</sup> In another lengthy opinion, the court reviewed the expert testimony and found it sufficiently credible for jury determination.<sup>24</sup> The jury found for Bartlett in the amount of \$21.06 million.<sup>25</sup>

Mutual appealed to the United States Court of Appeals for the First Circuit.<sup>26</sup> In the interim between the district court's decision and the First Circuit's affirmance, the Supreme Court decided *PLIVA, Inc. v. Mensing*,<sup>27</sup> holding that any failure to warn claim against a generic drug manufacturer was preempted on the ground that the Hatch-Waxman

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cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated" (quoting *Lachance v. Am. Home Prods. Corp.*, No. 01-0890-CV-W-ODS, 2006 WL 89850, at \*2 (W.D. Mo. Jan. 13, 2006)); *Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174, 1196–97 (D.N.M. 2008) (citing extensive authority that if the physician knew of the risk or would have prescribed the drug in any event, the drug manufacturer's failure to warn of the risk is not the proximate cause of the patient's injury). For a comprehensive state-by-state compilation of the law regarding failed proof of causation when health-care providers testify that they never read warnings provided by the drug manufacturer, see Bexis, *Don't Forget About a Prescribing Physician's Failure to Read Warnings*, DRUG & DEVICE LAW (Oct. 17, 2013), <http://www.druganddevicelawblog.com/2013/10/dont-forget-about-prescribing.html>.

20. *Bartlett*, 731 F. Supp. 2d at 149, 151 (rejecting Mutual's argument that Bartlett's strict liability and negligence claims were "really failure[ ]to[ ]warn claims because the only 'defect' that Bartlett allege[d] [wa]s an inadequate safety warning" and responding that Bartlett alleged that "Sulindac [wa]s defective because its safety risks outweigh its medical benefits, making it an unreasonably dangerous product").

21. See *Bartlett v. Mut. Pharm. Co.*, 760 F. Supp. 2d 220, 227, 229 (D.N.H. 2011).

22. *Id.* at 229–30, 241–42.

23. *Id.* at 241–42.

24. *Id.* at 232–41 (discussing as evidence that Sulindac's risks outweighed its benefits as a pain reliever for adult shoulder pain, inter alia, 133 reports to the FDA of SJS and TEN attributed to Sulindac over the past twenty-five years, including twenty-nine reported fatalities, and FDA's estimates that ninety percent of cases go unreported, which together allowed Bartlett to argue that it was possible to infer that Sulindac had caused hundreds of deaths over twenty-five years).

25. *Id.* at 227.

26. *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 34 (1st Cir. 2012).

27. 564 U.S. 604 (2011).



Act<sup>28</sup> prohibited generic manufacturers from independently changing the content of warning labels.<sup>29</sup> Thus, even if the manufacturer had asked the FDA for help in strengthening the corresponding brand name warning label, it still would not have satisfied the state-law requirement for adequate labeling so as to avoid a failure to warn claim.<sup>30</sup> Because only a unilateral change to its labeling would have put Mutual in compliance with state law, it was impossible for Mutual to comply simultaneously with the state law requiring change and the federal law requiring adherence to the brand name drug's label.<sup>31</sup> Mutual seized on *PLIVA* to argue that it could not effectuate a change to the design of Sulindac, and thus the design claim should be preempted as well.<sup>32</sup> The First Circuit rejected the argument on the grounds that New Hampshire law did not require a change in the design or a RAD in order to declare a drug unreasonably dangerous.<sup>33</sup> The court could simply perform risk-utility balancing to find that a drug's risks outweighed its benefits and assess damages accordingly.<sup>34</sup>

The stage was now set for review by the Supreme Court.<sup>35</sup> Justice Alito, after setting out the facts and the relevant federal statutes, set out to prove that Mutual was faced with an "impossibility" problem because it could not comply with its state-law tort duty to strengthen its warning on Sulindac's label and its federal law duty to not alter Sulindac's label.<sup>36</sup> To justify his position, Justice Alito found that New Hampshire's version of strict liability is regulatory and imposes a duty on a manufacturer to either improve its warning or change its design.<sup>37</sup>

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28. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984 § 101, 21 U.S.C. § 355(j) (2012) (setting forth the "abbreviated new drug applications" requirements that a manufacturer must meet in order to market a generic drug, including requirements that the new drug have the same active ingredient(s); the same route of administration, dosage, and strength, or the same biochemical effect; and the same labeling as that of the brand name drug).

29. *PLIVA, Inc.*, 564 U.S. at 618–19.

30. *See id.* at 619 ("State law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label.").

31. *Id.* at 618–19.

32. *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 37 (1st Cir. 2012).

33. *Id.* at 35–36.

34. *See id.* at 35–38 (holding, as to Mutual's argument that the design claim was preempted, that it would need to await final word from the Supreme Court as to whether the Supreme Court would broaden the *PLIVA* warning exception to drug design cases).

35. *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013).

36. *See id.* at 475–76.

37. *Id.* at 480–82.

His opinion correctly states that New Hampshire is committed to a risk-utility balancing approach and then goes on to say:

While the set of factors to be considered is ultimately an open one, the New Hampshire Supreme Court has repeatedly identified three factors as germane to the risk-utility inquiry: “the usefulness and desirability of the product to the public as a whole, whether the risk of danger could have been reduced without significantly affecting either the product’s effectiveness or manufacturing cost, and the presence and efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers or from foreseeable uses.”<sup>38</sup>

Justice Alito then decided that since Mutual could not redesign Sulindac because the Hatch-Waxman Act prohibits a generic manufacturer from altering the chemical composition of the brand name drug, the only way that the manufacturer could make the drug safer would be to alter the warning.<sup>39</sup> However, since under *PLIVA*, a generic manufacturer is not permitted to change the warnings from that given by the name brand manufacturer, Mutual was placed in an impossible position; it could not comply with both New Hampshire products liability law and the federal mandate of the Hatch-Waxman Act.<sup>40</sup> The key to this conclusion was that under New Hampshire law, the drug manufacturer has a tort duty that it can fulfill only by either improving the warning or altering the chemical composition of Sulindac.<sup>41</sup> Since by federal law, the manufacturer may do neither, the plaintiffs were preempted from bringing their action.<sup>42</sup>

Finally, Justice Alito confronted an argument set forth in the First Circuit’s opinion that would have supported the imposition of damages even though the plaintiff was preempted from asserting its common-law action.<sup>43</sup> The court of appeals had held that the defendant, realizing that its warning on Sulindac was inadequate, had the option to “stop selling” Sulindac, thus removing the drug from the market, in order to avoid tort liability.<sup>44</sup> In a sharp retort, Justice Alito’s majority opinion held that “[a]dopting the First Circuit’s stop-selling rationale would mean . . . the vast majority—if not all—of the cases in

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38. *Id.* at 483 (quoting *Vautour v. Body Masters Sports Indus., Inc.*, 784 A.2d 1178, 1182 (N.H. 2001)).

39. *Id.* at 483–84.

40. *Id.* at 486–87.

41. *Id.* at 480–82.

42. *Id.* at 483–87.

43. *Id.* at 488 (citing *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 37–38 (1st Cir. 2012)).

44. *Id.*; see also *Bartlett*, 678 F.3d at 37.

which the Court has found impossibility pre-emption, were wrongly decided.”<sup>45</sup> Just as in *PLIVA*, the simple expedient of leaving the market was argued but given no consideration by the Court.<sup>46</sup>

Justice Alito erred in his reading of New Hampshire law and misconstrued the leading case on the issue of unreasonable danger, *Vautour v. Body Master Sport Industries, Inc.*<sup>47</sup> In *Vautour*, the plaintiff was injured while operating a leg press exercise machine manufactured by the defendant.<sup>48</sup> The leg press machine bore a warning regarding proper use, which the plaintiff failed to heed; as a result, the plaintiff suffered serious injury.<sup>49</sup> The plaintiff argued that the machine was defectively designed but did not propose an alternative design that would have avoided the injury.<sup>50</sup> Section 2(b) of the Restatement (Third) of Torts: Products Liability requires that, in order to prevail in a design defect case, a plaintiff must present evidence of a RAD that could have prevented the plaintiff’s harm.<sup>51</sup> The New Hampshire court rejected the RAD requirement.<sup>52</sup> Instead, it would suffice for the jury to find that the leg press machine was unreasonably dangerous utilizing risk-utility balancing.<sup>53</sup>

In a casebook that this Author co-wrote, we express confusion regarding the *Vautour* holding.<sup>54</sup> In performing risk-utility balancing, there are only two options: either the product can be made safer by better warnings or a RAD, or else the product is so dangerous that it should not have been marketed at all.<sup>55</sup> Thus, if the warning on the leg press machine was adequate and no RAD was available, the risk-

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45. *Mut. Pharm. Co.*, 570 U.S. at 489.

46. *Id.* at 489–90.

47. 784 A.2d 1178 (N.H. 2001).

48. *Id.* at 1180.

49. *Id.*

50. *See id.* (describing the machine as designed with two fixed safety stops that the user was warned to engage when doing calf exercises and recounting the plaintiff’s expert’s admission that his recommendation of adjustable rather than fixed stops similarly would not have prevented injury if the user failed to manually engage the stops).

51. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(b) (AM. LAW INST. 1998); *see also Vautour*, 784 A.2d at 1182–84 (discussing at length the court’s reasons for rejecting the Restatement test and opting instead for a risk-utility test that would allow a jury to decide whether a product was unreasonably dangerous).

52. *Vautour*, 784 A.2d at 1182–84.

53. *See id.* at 1182, 1184.

54. AARON D. TWERSKI ET AL., TORTS: CASES AND MATERIALS 653–54 (4th ed. 2017).

55. *See infra* text accompanying notes 58–62 (explaining that imposing liability when a product cannot be made safer either by a better warning or a RAD requires the manufacturer to pay damages to all those injured by the product, meaning a manufacturer may instead simply stop manufacturing the product).

utility formula simply says if you cannot make it better, then do not market the product. Products liability cognoscenti refer to this form of absolute liability as “category liability.”<sup>56</sup> The most famous case supporting category liability is *O’Brien v. Muskin Corp.*<sup>57</sup> In that case, the plaintiff was seriously injured when he dove from a considerable height into an above-ground swimming pool.<sup>58</sup> The plaintiff argued that his injury was brought about by the vinyl lining on the bottom of the pool, which made the pool slippery.<sup>59</sup> The case proceeded on the premise that there was no reasonable alternative design to the vinyl liner.<sup>60</sup> The New Jersey Supreme Court was clear that, even absent a RAD, liability could attach under risk-utility balancing.<sup>61</sup> The court held:

The evaluation of the utility of a product also involves the relative need for that product; some products are essentials, while others are luxuries. A product that fills a critical need and can be designed in only one way should be viewed differently from a luxury item. Still other products, including some for which no alternative exists, are so dangerous and of such little use that under the risk-utility analysis, a manufacturer would bear the cost of liability of harm to others.

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56. See OWEN, PRODUCTS LIABILITY LAW, *supra* note 2, at 618 (“Whether courts properly may assign such ‘product category liability’ has been characterized as the ‘last frontier’ of products liability law: a borderland at the edge of law where fights erupt over whether manufacturers should be held responsible, without the usual proofs of defect, for selling products adjudged by a court or jury to be more bad than good.”); Mark A. Geistfeld, *A Roadmap for Autonomous Vehicles: State Tort Liability, Automobile Insurance, and Federal Safety Regulation*, 105 CALIF. L. REV. 1611, 1628 (2017) (proclaiming that “courts have roundly rejected” categorical liability claims in order “[t]o preserve the role of informed consumer choice across product categories”); James A. Henderson, Jr. & Aaron D. Twerski, *Closing the American Products Liability Frontier: The Rejection of Liability Without Defect*, 66 N.Y.U. L. REV. 1263, 1298–1300, 1305–07, 1316–18 (1991) (asserting that courts are not competent to assess product-category liability and explaining that product-category liability, unlike design-defect liability, does not involve “merely a marginal design variation,” but instead an allegedly unsafe distinguishing feature of a product that, if altered, would place the product in a completely different product category); David G. Owen, *Defectiveness Restated: Exploding the “Strict” Products Liability Myth*, 1996 U. ILL. L. REV. 743, 774–75 n.139 (1996) (stating disapprovingly that some courts have framed risk-utility analysis “in terms of the overall costs and benefits of the product design taken as a *whole*,” rather than the “marginal[] risks and benefits of adopting the particular design safety feature proposed by the plaintiff”).

57. 463 A.2d 298 (N.J. 1983), *superseded by statute*, N.J. STAT. ANN. § 2A:58C-3(a) (1)–(2) (West 2018).

58. *O’Brien*, 463 A.2d at 302.

59. *Id.*

60. *Id.* at 302–03.

61. *Id.* at 306.

That cost might dissuade a manufacturer from placing the product on the market, even if the product has been made as safely as possible. Indeed, plaintiff contends that above-ground pools with vinyl liners are such products and that manufacturers who market those pools should bear the cost of injuries they cause to foreseeable users.<sup>62</sup>

*O'Brien* is not the only case advocating category liability—several other courts have done so.<sup>63</sup> A cadre of academics also support liability on this basis.<sup>64</sup> Professor Henderson and this Author have written extensively about the issue in law journals and in our casebook.<sup>65</sup> This is not the forum to rehash our strong objection to the idea. The point is that New Hampshire has embraced it. Thus, liability was not regulatory in the sense that Justice Alito set forth in *Bartlett*. New Hampshire did not impose a duty on Mutual to develop a better warning nor did it require Mutual to redesign Sulindac.<sup>66</sup> It simply allowed a jury to find that the Sulindac, as designed with the warnings

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62. *Id.* The court went on to say:

A critical issue at trial was whether the design of the pool, calling for a vinyl bottom in a pool four feet deep, was defective. The trial court should have permitted the jury to consider whether, because of the dimensions of the pool and slipperiness of the bottom, the risks of injury so outweighed the utility of the product as to constitute a defect. In removing that issue from consideration by the jury, the trial court erred. To establish sufficient proof to compel submission of the issue to the jury for appropriate fact-finding under risk-utility analysis, it was not necessary for plaintiff to prove the existence of alternative, safer designs. Viewing the evidence in the light most favorable to plaintiff, even if there are no alternative methods of making bottoms for above-ground pools, the jury might have found that the risk posed by the pool outweighed its utility.

*Id.*

63. See, e.g., *Bowersfield v. Suzuki Motor Corp.*, 111 F. Supp. 2d 612, 618–19 (E.D. Pa. 2000); *Bifolck v. Philip Morris, Inc.*, 152 A.3d 1183, 1203 (Conn. 2016) (“A plaintiff may . . . allege that a product . . . was too dangerous to market to the consumer irrespective of whether it could have been designed to be safer . . .”); *Halphen v. Johns-Manville Sales Corp.*, 484 So. 2d 110, 113–14 (La. 1986), *superseded by statute*, LA. STAT. ANN. § 9:2800.56 (2018).

64. See, e.g., Carl T. Bogus, *War on the Common Law: The Struggle at the Center of Products Liability*, 60 MO. L. REV. 1, 8–9 (1995); Ellen Wertheimer, *The Smoke Gets in Their Eyes: Product Category Liability and Alternative Feasible Designs in the Third Restatement*, 61 TENN. L. REV. 1429, 1454 (1994).

65. See *supra* notes 54, 56.

66. See *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 503 (2013) (Sotomayor, J., dissenting).

as given, was unreasonably dangerous.<sup>67</sup> Justice Sotomayor, in her dissent, was quite correct when she said:

The court first told the jury to determine whether [S]ulindac was unreasonably dangerous by weighing its danger against its utility. The court further instructed the jury that if it determined that [S]ulindac was unreasonably dangerous without reference to the warning label, it could then consider the presence and efficacy of the label to evaluate whether the product was unreasonably dangerous “even with its warning.” In other words, to hold Mutual liable, the jury was required to find that [S]ulindac “was unreasonably dangerous *despite* its warning, not because of it.” The District Court also explained to the jury that because Bartlett’s claim addressed only whether [S]ulindac’s design was defective, Mutual’s conduct, “which included any failure to change its warning, was ‘not relevant to this case.’”<sup>68</sup>

Deciding that New Hampshire products liability law allows a court to impose liability whenever the risk of a product outweighs its utility, does not end the inquiry as to whether plaintiffs should have been preempted from bringing their design defect claim. Justice Alito specifies that his decision preempting Bartlett’s design claim is predicated on the “regulatory” nature of New Hampshire’s product liability law that imposes duties that Mutual could not fulfill without running afoul of federal law.<sup>69</sup> He leaves open the question as to whether Bartlett’s design claim would have been preempted if New Hampshire imposed “absolute liability.”<sup>70</sup> In a telling footnote, he says, “We can thus save for another day the question whether a true absolute-liability state-law system could give rise to impossibility preemption. As we have noted, most common law causes of action for negligence and strict liability do not exist merely to spread risk, but rather impose affirmative duties.”<sup>71</sup>

Justice Alito does not define the term “absolute liability,” but by contrasting it with the affirmative duty either to impose better warnings or an alternative design, he must mean risk-utility balancing that holds a manufacturer absolutely liable even though the product has adequate warnings and no RAD is available. One takes the product as it is and decides whether its risks outweigh its utility. That is the very

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67. *See id.*

68. *Id.* at 509–10 (citations omitted).

69. *Id.* at 480–82 (majority opinion).

70. *Id.* at 482 n.1.

71. *Id.* (citations omitted).

situation the Court would have faced if it had correctly interpreted New Hampshire law. Thus, rather than saving the question for another day, the Court should have directly confronted preemption for “absolute liability.” Since the Court did not face that question, this Essay will explore whether preemption of design liability is appropriate under a regime of absolute liability for drug design.

## II. THE IMPLICATIONS OF THE THREE TYPES OF DRUG DESIGN CLAIMS FOR PREEMPTION ANALYSIS

Before examining the scope of preemption brought about by *PLIVA* and *Bartlett*, it is necessary to examine the three types of drug design claims. The degree of their validity as common law claims is inexorably tied to the likelihood that they will be federally preempted.

### A. Reasonable Alternative Design Test for Defective Drug Design

#### 1. Post-FDA Approval of the Drug

It is irrational to believe that a court should entertain a claim that a prescription drug should be declared defective in design because its manufacturer should have developed a reasonable alternative drug that would reduce the risk to the patient while still preserving the drug’s benefit.<sup>72</sup> In an earlier publication, my co-author and I argue that it is beyond the competence of courts to decide whether a RAD for a drug should have been developed.<sup>73</sup> For any drug to be marketed in the United States, it must obtain Food and Drug Administration (FDA) approval.<sup>74</sup> Any major change in the chemical composition of a drug requires that the applicant submit a New Drug Application (NDA).<sup>75</sup> That essay details the long and arduous process for obtaining FDA approval. First, the applicant must submit an investigational drug application (IND) to allow the applicant to conduct clinical trials.<sup>76</sup> After approval is obtained, the drug goes through three critical phases that test the safety and the efficiency of the drug to first a limited group

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72. One commentator advocates applying the RAD test set forth in Restatement (Third) of Torts: Products Liability § 2(b) that governs products in general to drug designs. See, e.g., Conk, *supra* note 2, at 1088–90.

73. Henderson & Twerski, *Drug Designs Are Different*, *supra* note 2, at 163–67.

74. *Bartlett*, 570 U.S. at 484.

75. *Id.* at 476–77.

76. Henderson & Twerski, *Drug Designs Are Different*, *supra* note 2, at 164.

of patients, and then to a large cadre of patients.<sup>77</sup> During any stage of the process, the FDA may reject the drug or require modifications.<sup>78</sup> The vetting can take over a decade<sup>79</sup> and can cost several billion dollars.<sup>80</sup> The FDA has found that a new compound entering initial clinical testing is estimated to have only an eight percent chance of reaching market.<sup>81</sup> No court could confidently predict that a RAD proposed by a litigant would ever be approved. A strong majority of commentators agree that a RAD test is simply unworkable.<sup>82</sup>

However, post-*Bartlett*, it would seem quite clear that, for a drug that has received FDA approval, any argument that it can be modified by a RAD is federally preempted. Justice Alito's reasoning leaves little doubt when he said that "once a drug—whether generic or brand name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug.'"<sup>83</sup> If a court were to find a post-FDA approval drug to be a RAD, it would almost certainly be struck down on the same impossibility grounds set forth in *Bartlett*.<sup>84</sup>

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77. *Id.* at 165.

78. *Id.*

79. See JAMES T. O'REILLY & KATHERINE A. VAN TASSEL, FOOD AND DRUG ADMINISTRATION § 13.1 (4th ed. 2017).

80. *Id.*

81. *Id.*

82. See, e.g., OWEN, PRODUCTS LIABILITY LAW, *supra* note 2, § 18.2 (arguing designing a drug that would pass the RAD test is impossible); Michael D. Green, *supra* note 2, at 219–20 (arguing there are no possible changes that can be made to several types of drugs); David S. Torborg, Comment, *Design Defect Liability and Prescription Drugs: Who's in Charge?*, 59 OHIO ST. L.J. 633, 649 (1998) (arguing a new test needs to be developed by FDA experts, not juries and judges).

83. *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 477 (2013) (citation omitted).

84. See *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 298 (6th Cir. 2015); *Fortner v. Bristol-Myers Squibb Co.*, No. 17cv1562 (DLC), 2017 WL 3193928, at \*5 (S.D.N.Y. July 26, 2017); *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 185–86 (S.D.N.Y. 2016); *Rheinfrank v. Abbott Labs., Inc.*, 137 F. Supp. 3d 1035, 1040–41 (S.D. Ohio 2015); *Small v. Amgen, Inc.*, No. 2:12-cv-476-FtM-29MRM, 2016 WL 7228863, at \*4 (M.D. Fla. Sept. 28, 2016); *Barcal v. EMD Serono, Inc.*, No. 5:14-cv-01709-MHH, 2016 WL 1086028, at \*4 (N.D. Ala. Mar. 21, 2016); *Batoh v. McNeil-PPC, Inc.*, 167 F. Supp. 3d 296, 322 (D. Conn. 2016); *Fleming v. Janssen Pharms., Inc.*, 186 F. Supp. 3d 826, 832–34 (W.D. Tenn. 2016). But see *Warren v. Boehringer Ingelheim Pharms., Inc.*, No. 1:16-cv-01326-SEB-DML, 2017 WL 3970666, at \*9–15 (S.D. Ind. Sept. 8, 2017) (explaining that the impossibility pre-emption did not apply because *Bartlett* did not stand for the proposition that "every successful state law design defect claim will impose a change on the design of drug requiring FDA approval before it is made").



## 2. *Pre-FDA Approval of Drug*

Seeking to avoid the almost certain preemption of design claims attacking a drug that has already been approved by the FDA, plaintiffs have sought to preserve the design claim by moving it forward. The new claim is that the drug manufacturer should have submitted a RAD to the FDA at the outset, instead of the drug that ultimately was approved.<sup>85</sup> Although several courts have bought into this theory,<sup>86</sup> many have not.<sup>87</sup> First, the selfsame arguments presented for negating the presentation of a RAD post-FDA approval apply with equal force to pre-FDA approval claims. Requesting courts to compress a process that takes the FDA a decade or more is ludicrous. A trial of several weeks cannot compare to the FDA's layers of animal and human testing, which assure a drug's safety and efficacy. As noted earlier, only a small percentage of drugs proposed to the FDA ever pass the initial IND level and even fewer meet final approval.<sup>88</sup> How a court could censure a manufacturer for not developing a different drug without any assurance of its safety by the FDA is beyond comprehension.<sup>89</sup>

As to preemption, the court in *PLIVA* made short order of the argument that a plaintiff could challenge an FDA approved drug based

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85. For a list of cases in which the plaintiff has made this claim, see *infra* note 86.

86. See, e.g., *In re Xarelto (Rivaroxaban) Products Liab. Litig.*, MDL No. 2592, 2017 WL 1395312, at \*3 (E.D. La. Apr. 13, 2017); *Young v. Bristol-Myers Squibb Co.*, No. 4:16-CV-00108-DMB-JMV, 2017 WL 706320, at \*8 (N.D. Miss. Feb. 22, 2017); *Guidry v. Janssen Pharms., Inc.*, 206 F. Supp. 3d 1187, 1206–09 (E.D. La. 2016); *Sullivan v. Aventis, Inc.*, No. 14-cv-2939-NSR, 2015 WL 4879112, at \*6 (S.D.N.Y. Aug. 13, 2015); *Estate of Cassel v. Alza Corp.*, No. 12-cv-771-WMC, 2014 WL 856023, at \*5 (W.D. Wis. Mar. 5, 2014).

87. See, e.g., *Yates*, 808 F.3d at 299–300; *Gustavesen v. Alcon Labs. Inc.*, 272 F. Supp. 3d 241, 254–55 (D. Mass. 2017); *Fortner*, 2017 WL 3193928, at \*2; *Utts*, 226 F. Supp. 3d at 185–86; *Small*, 2016 WL 7228863, at \*4; *Fleming*, 186 F. Supp. 3d at 832–33.

88. Henderson & Twerski, *Drug Designs Are Different*, *supra* note 2, at 164, 166.

89. It is difficult to conjure a common law pre-sale duty for failure to develop a drug. In one sense, all RAD's should have been developed before put on the market. Yet, prior to sale, nothing has occurred to impose liability. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. g (AM. LAW INST. 1965) (“The rule stated in this Section applies only where the product is, at the time it leaves the seller's hands, in a condition . . . which will be unreasonably dangerous” to [the ultimate consumer].”); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (AM. LAW INST. 1998) (“A product is defective when, at the time of sale or distribution, . . . is defective in design . . .”). The notion that a duty exists prior to the time of sale is simply foreign to products liability law. Prior to the time of sale, a manufacturer always has the option to withdraw its product from the market. In the case of drugs, a pre-sale theory is nonsensical because the FDA regularly rejects proposed drugs and there can be no assurance that a drug will be allowed on the market until final approval is given. See Beck, *supra* note 6.

on the supposition of what the FDA might do if asked to respond to a change.<sup>90</sup> *PLIVA* involved a generic drug that had to be the exact equivalent of the brand name drug both with regard to its chemical composition and its labeling. The generic drug manufacturer did not have the same option available to the brand name drug of strengthening the warnings by submitting a “change being effected” warning to the FDA.<sup>91</sup> Plaintiffs argued that “if the Manufacturers had asked the FDA for help in changing the corresponding brand name label, they might eventually have been able to accomplish under federal law what state law requires.”<sup>92</sup> The Court rejected the argument saying that, “[t]he question for ‘impossibility’ is whether the private party could independently do under federal law what state law requires of it.”<sup>93</sup> To do as plaintiffs asked “would render conflict preemption largely meaningless because it would make most conflicts between state and federal law illusory.”<sup>94</sup> None of the cases opting for the “pre-approval theory” have adequately responded to either the common law or preemption arguments that negate this novel theory.

### 3. *Aggregative Risk-Utility Balancing: What Does It Mean and Should It Be Preempted in Drug Design Cases?*

For products liability design defect cases predicated on risk-utility balancing, the majority of courts require a plaintiff to prove the availability of a RAD.<sup>95</sup> It is important to understand that requiring a RAD may condemn a defendant’s design even if the design under attack may be preferred by one or more classes of users or consumers. For example, in *Uloth v. City Tank Corp.*,<sup>96</sup> a garbage truck was designed

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90. See *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620–21 (2011).

91. Unlike major changes to the chemical properties of a drug, a pharmaceutical manufacturer may in some circumstances independently strengthen a warning without first receiving FDA approval. The leading case setting for the constitutional doctrine of preemption with regard to failure to warn drug claims is *Wyeth v. Levine*. See 555 U.S. 555 (2009). A drug manufacturer that argues that the FDA would not have approved a stronger warning must provide “clear evidence” that the FDA would not have approved a change to the proposed label. *Id.* at 571.

92. *PLIVA, Inc.*, 564 U.S. at 619.

93. *Id.* at 620.

94. *Id.*

95. OWEN, PRODUCTS LIABILITY LAW, *supra* note 2, § 8.5; Aaron D. Twerski & James A. Henderson, Jr., *Manufacturers’ Liability for Defective Designs: The Triumph of Risk-Utility*, 74 BROOK. L. REV. 1061, 1079 (2009).

96. 384 N.E.2d 1188 (Mass. 1978).

such that sanitation workers could suffer the loss of extremities.<sup>97</sup> Running the full width of the truck was a rear step on which the workers rode between stops.<sup>98</sup> The step was about two feet above the ground, with a four-inch-wide loading sill located another foot above the step.<sup>99</sup> The garbage was loaded into the “trash hopper” area, just past the sill, where a packer blade moved the garbage into storage area during the compaction process.<sup>100</sup> The packer blade acts like scissors, forming a sharp point where it touches the loading sill.<sup>101</sup> The problem with this design is that a sanitation worker may inadvertently step onto the “trash hopper” or use his hand to push garbage in before the blade reaches the garbage.<sup>102</sup> However, RADs are available to avert such tragedies. The truck may be designed with an interrupted cycle so that it stops midway and requires a sanitation worker to manually engage the blade to complete the cycle, or it may be designed with a dead man’s control which requires the sanitation worker to have his hands on the buttons as the blade descends.<sup>103</sup> Under either scenario, the likelihood of a worker losing an arm or a leg is substantially reduced.<sup>104</sup> However, some sanitation workers may not like these safety features. When they complete the garbage collection for their route they may be done for the day and can go home. If one of the workers must stand behind the truck and engage the safety device, that worker cannot be moving to the next home to collect the garbage. Some sanitation workers who are confident that they can avoid injury by exercising care may prefer the more dangerous, but more efficient, blade device. Nonetheless, when a tragedy occurs, and the plaintiff argues that the safety device should have been installed, the RAD disregards the preference of some sanitation workers in favor of the overall safety of all sanitation workers.<sup>105</sup> The risk outweighs the utility of the more efficient, yet more dangerous, compaction chamber blade. The welfare of

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97. *Id.* at 1190.

98. *Id.*

99. *Id.*

100. *Id.*

101. *Id.*

102. *See id.* at 1190–91 (describing how the plaintiff’s foot was cut off by the packer blade of the garbage truck).

103. *Id.*

104. *Id.* at 1191.

105. For a similar analogy utilizing a consumer product as an example of RAD recognizing aggregative risk, see Henderson & Twerski, *Drug Designs Are Different*, *supra* note 2, at 169–71 (explaining one family’s misuse of a water vaporizer causes the product to be deemed defective therefore inhibiting another family’s correct use of the product).

one class of workers is sacrificed to the greater number of workers who will be exposed to serious injury.

In the case of prescription drugs, it may well be that the aggregative risks of a drug may exceed its benefits, although the drug benefits one or more classes of patients. Consider the following hypothetical:

ABC Pharmaceuticals, Inc. (ABC) manufactures a drug, NOAC. The drug is effective to treat the most severe cases of acne. NOAC is viewed as a miracle drug for those suffering from acne who have become recluses because they are ashamed to go out in public because of their skin condition. One of the side effects of NOAC is that in rare cases it can cause glaucoma. After ten years of testing, the FDA approved the drug and mandated a black box warning on the drug insert<sup>106</sup> about the dangers of glaucoma and insisted that ABC send “dear doctor” letters<sup>107</sup> to all physicians apprising them of the risk. The warnings also told the physicians that NOAC is not to be prescribed for mild forms of acne and is only to be prescribed if the acne is severe and the patient has not responded to other less dangerous anti-acne drugs. ABC did not advertise the drug in the media.

Jim, an eighteen-year-old suffering from mild acne is prescribed NOAC by Dr. X who had not read the warnings. Jim contracted glaucoma and sued Dr. X and ABC. Jim has no failure to warn claim against ABC because ABC warned adequately about the risk of glaucoma and because Dr. X did not read the warnings that ABC provided. Dr. X has one million dollars of malpractice coverage. Jim’s damages for his reduced vision are five million dollars.

Jim alleges that NOAC is defectively designed because the drug is unreasonably dangerous. The jury predicates its findings on the testimony of experts that the rare cases of glaucoma causing loss of vision is greater than the benefits of NOAC to those suffering from

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106. A black box warning is the strictest warning put in the labelling of prescription drugs by the FDA when there is reasonable evidence of an association of a serious hazard with the drug. See 21 C.F.R. § 201.57(c)(1) (2011); 21 C.F.R. § 201.80(e) (2011) (for products approved before June 2001).

107. “Dear Doctor letters are an important and required document to alert health care professionals to previously unknown adverse reactions linked to a drug, changes in dosage that could improve a drug’s effectiveness and other important information. It is not just a letter mailed to the doctors but a process that assures that important information regarding a prescription product is appropriately distributed.” FDAMAP, *FDA’s Requirements for a Dear Doctor Letter* (Aug. 30, 2018), <http://www.fdamap.com/fda-requirements-for-a-dear-doctor-letter.html>.

severe acne due to the likelihood of misprescription by doctors to those suffering from mild acnes.<sup>108</sup>

Should ABC be held liable based on the jury's assessment that the drug's design risk outweighs its utility? Should those who need the drug be deprived of it because in, the macro sense, it will cause too much harm in relation to its benefit? In previous work,<sup>109</sup> and in the Products Liability Restatement, we took the position that it would be unfair to condemn the drug as defectively designed and effectively remove it from the market to the detriment of the patients who truly need the drug.<sup>110</sup>

Given *Bartlett*, this issue has now taken on constitutional significance. In the hypothetical posed above, NOAC's warnings were adequate and there existed no alternative drug to treat severe acne. Can the state allow a common law remedy based on a finding of unreasonable danger, thus negating the FDA's determination that the drug is reasonably safe so that it is approved for marketing? As in *Bartlett*, ABC had fulfilled its duty to warn, and there was no alternative drug available to treat severe acne.<sup>111</sup> The only avenue available to avoid liability would be not to market NOAC. The defendant in *Bartlett* could not warn because he was prevented by the Hatch-Waxman Act, and it could not alter the design of the drug for the same reason.<sup>112</sup> After running out of state common law duties to make the drug safer, the defendant was left with the sole option of not marketing a FDA

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108. This is a hypothetical case and is not intended as an analogy to the litigation around the adequacy of warning of the anti-acne drug Accutane that took place over a period of years. See, e.g., *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 841–42 (Neb. 2000).

109. Henderson & Twerski, *Drug Designs Are Different*, *supra* note 2, at 171–72.

110. The author was co-reporter with Professor James A. Henderson of the Restatement (Third) of Torts: Products Liability (1998). In Section 6 (c) Comment b, one of the reasons that we believe it unnecessary to impose macro risk-utility on pharmaceutical manufacturers when there exists a class of patients for whom the drug in question was proper was that a misprescription by a physician could be dealt with by malpractice. Henderson & Twerski, *Drug Designs Are Different*, *supra* note 2, at 171. Malpractice may, in cases of very serious injury, be an inadequate remedy. Damages may exceed insurance coverage. In some states, malpractice damages are severely limited by statute. See, e.g., CAL. CIV. CODE § 3333.2 (West 2018) (\$250,000 cap on noneconomic loss); KAN. STAT. ANN. § 60-19a02 (\$250,000–\$350,000 cap on non-economic loss depending on years that cause of action accrued). There may be other modes of controlling misprescriptions of dangerous drugs short of banning distribution of the drug. See Catherine M. Sharkey, *States versus FDA*, 83 GEO. WASH. L. REV. 1609 (2015).

111. If a FDA approved drug would be a reasonable alternative drug that was safer and equally effective the author would find no problem with imposing liability. See Henderson & Twerski, *Drug Designs Are Different*, *supra* note 2 at 155–59.

112. *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 477 (2013).

approved drug to avoid tort liability. This remaining option, however, is an option that *Bartlett* teaches flies in the teeth of preemption jurisprudence. Now that the “stop selling” rationale has been declared invalid, the manufacturer is faced with the identical “impossibility” conflict between state and federal law.

#### 4. *Is the Restatement Test for Defective Drug Design Preempted?*

The Third Restatement test for drug design defects has received support from some state courts, but it has not been addressed by the Supreme Court. Section 6(c) provides:

A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable healthcare providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.<sup>113</sup>

This section of the Restatement has received a lukewarm reception by the courts.<sup>114</sup> More recently, the Pennsylvania Supreme Court in *Lance v. Wyeth*,<sup>115</sup> adopted section 6(c) as the governing rule of the case.<sup>116</sup> The plaintiff’s decedent, a thirty-five-year-old woman, died after taking a weight reducing pill, Redux, for four months.<sup>117</sup> Plaintiff alleged that defendant, Wyeth, knew or should have known that Redux caused pulmonary hypertension (PPH).<sup>118</sup> Ultimately, as a result of ingesting the drug, she contracted PPH and died.<sup>119</sup> The court noted that plaintiff did not present a failure to warn claim because no warning

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

114. *Mills v. Bristol-Myers Squibb Co.*, No. CV11-00986-PHX-FJM, 2011 WL 4708850, at \*2–3 (D. Ariz. Oct. 7, 2011) (acknowledging that Arizona courts have not officially adopted the Restatement (Third) of Torts); *see also* *Madsen v. Am. Home Products Corp.*, 477 F. Supp. 2d 1025, 1037 (E.D. Mo. 2007) (acknowledging that Iowa has adopted § 6(c)); *Gebhardt v. Mentor Corp.*, 191 F.R.D. 180, 185 (D. Ariz. 1999) (predicting that Arizona would adopt § 6 (c)), *aff’d mem.*, 15 F. Appx. 540 (9th Cir. 2001). Several courts have rejected § 6(c). *See* *Fraser v. Wyeth, Inc.*, 992 F. Supp. 2d 68, 83–84 (D. Conn. 2014); *In re Fosamax Prods. Liab. Litig.*, 742 F. Supp. 2d 460, 471–72 (S.D.N.Y. 2010) (applying Florida law); *Bryant v. Hoffman-La Roche, Inc.*, 585 S.E.2d 723, 728 (Ga. Ct. App. 2003); *Mele v. Howmedica, Inc.*, 808 N.E.2d 1026, 1038–39 (Ill. App. Ct. 2004); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 840 (Neb. 2000).

115. 85 A.3d 434 (Pa. 2014).

116. *Id.* at 451.

117. *Id.* at 437.

118. *Id.*

119. *Id.*

concerning Redux would have been sufficient.<sup>120</sup> Her claim was that Redux was so dangerously designed that no physician knowing the risk and benefits of the drug would have prescribed the drug for any class of patients.<sup>121</sup> The Pennsylvania court agreed that if a jury found that the defendant had violated the Restatement test, liability could be established.<sup>122</sup>

The Restatement test ultimately allows a common law design defect claim to prevail over the FDA's approval of a drug. The only thing that a defendant can do to escape liability is to stop selling the drug—a position that is in direct contravention of *Bartlett*.<sup>123</sup> Perhaps for a drug that is so egregiously dangerous, the Supreme Court might craft an exception to *Bartlett*. But, otherwise, the *Bartlett* dissent is quite correct in predicting that the majority has rendered drug design defect immune from common law actions.<sup>124</sup>

It is difficult to predict how broad the Supreme Court would have read its preemption doctrine had it correctly interpreted New Hampshire product liability law in *Bartlett*. It is not clear whether the decision that Sulindac was unreasonably dangerous was based on a finding that, although it was a proper drug for some patients, it was in the aggregate unreasonably dangerous because its overall risks outweighed its utility or whether the facts would support a finding that no reasonable doctor knowing of the risks of horrendous injuries would not prescribe Sulindac for any class of patients.<sup>125</sup> Would the

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120. *See id.*

121. *Id.* at 448.

122. *Id.* at 447.

123. *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 488 (2013).

124. *Id.* at 497–98 (Sotomayor, J., dissenting) (indicating that “federal drug law and state common law liability have long been understood to operate in tandem to promote consumer safety”).

125. It is likely that the jury found for plaintiff based on the theory that Sulindac was so dangerous that it should not be prescribed for any class of patients. The trial court's jury instructions point in that direction:

*Defective condition.* In deciding whether [S]ulindac's design presented unreasonable danger, you should consider the usefulness and desirability of the product to the public as a whole. A product is defective as designed if the magnitude of the danger outweighs the utility (or usefulness) of the product. You should also consider whether [S]ulindac's risk of danger, if any, could have been reduced without significant impact on the product's effectiveness or its manufacturing cost. Liability may exist if the manufacturer did not take available and reasonable steps to lessen or eliminate the danger of even a useful and desirable product.

Jury Instructions at 15, *Bartlett v. Mut. Pharm. Co.*, 760 F. Supp. 2d 220 (D.N.H. 2010) (No. 08-cv-358-JD), 2010 WL 3500124. A careful reading of the trial court's decision

Supreme Court find preemption on either of the two contingencies? The Court took the easy way out and did not confront the problem leaving it and left it for a future court to decide the issue. This much is certain. If the Court were to preempt all risk-utility claims set forth in this Essay, the cause of action for design defect for drugs that has been the subject of such contention over the years is effectively dead.

It is likely, however, that a small subset of design claims may not be preempted. For example, in *Gustavesen v. Alcon Laboratories*,<sup>126</sup> consumers brought a class action alleging that pharmaceutical companies intentionally designed eye droppers to dispense more liquid than the human eye is capable of absorbing.<sup>127</sup> The FDA approves the size of the eye dropper containers.<sup>128</sup> Any change in the container constitutes a “major change”<sup>129</sup> that requires supplemental FDA approval.<sup>130</sup> The Court, relying on the arguments set forth earlier in this article, held that the plaintiff’s claims were preempted.<sup>131</sup> It is certainly possible that the Supreme Court might take issue with the FDA characterization of a change in volume of the drops created by the bottle’s stopper as a “major change” requiring FDA approval, and could find it a “minor change” that the pharmaceutical manufacturer could undertake independently.<sup>132</sup>

### CONCLUSION

The substantial likelihood that federal preemption will bar most common law drug design suits has been created by three pronouncements by the United States Supreme Court. Taken together they have created the perfect storm. First, the statement by Justice Alito in the majority opinion in *Bartlett* that “[o]nce a drug—whether generic or brand name—is approved, the manufacturer is prohibited from making any major changes to the ‘qualitative or quantitative formulation of the drug.’”<sup>133</sup> Second, the majority opinion

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does not reveal that Sulindac was the drug of choice for other diseases. See *Bartlett*, 760 F. Supp. 2d at 233–40.

126. 272 F. Supp. 3d 241 (D. Mass. 2017).

127. *Id.* at 243, 249–50.

128. *Id.* at 251.

129. *Id.*

130. *Id.*

131. *Id.* at 252.

132. *Id.* at 250–52.

133. *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 477 (2013) (quoting 21 C.F.R. § 314.70(b)(2)(i) (2012)).



holding in *PLIVA* that the ability of a pharmaceutical manufacturer to request changes to a drug is irrelevant to the issue of whether the drug is preempted against common law suits. The pharmaceutical manufacturer must be able independently to effect the change.<sup>134</sup> Third is the holding by Justice Alito in the majority opinion in *Bartlett* that one cannot avoid preemption of common law tort liability if there is a conflict between state and federal law duties by choosing not to sell the drug that has been approved by the FDA. The “stop selling” solution violates basic principles of federal preemption.<sup>135</sup> Unless the Court will backtrack on any of these propositions, it would appear that most common law drug design suits, whatever the common law theory supporting such actions, will be barred.

If design defect claims are to be federally preempted, how significant will the impact be on drug litigation? The overwhelming majority of cases against pharmaceuticals have always been based on failure to warn.<sup>136</sup> If the failure to warn claim is well-founded, the plaintiffs lose their cases primarily because the physician testifies that she never read any warning or would have prescribed the drug even had she read a stronger warning. Drug design, despite the fascination of scholars with this issue, has played only a minor role in drug litigation.<sup>137</sup> The pillars of the republic will not fall if this questionable theory is laid to rest.

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134. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 619 (2011).

135. *Bartlett*, 570 U.S. at 488.

136. For a list of cases where plaintiffs have brought claims for failure to warn, see *supra* note 86.

137. The focus of this Essay was not to take a normative position on the wisdom of preemption in drug design cases. The major point is that the justices in both *PLIVA* and *Bartlett* have spoken with such clarity that this author does not see how these decisions will not preempt design claims against manufacturers of brand name drugs. The statements by the justices were not just dicta. They were vital to the holdings in both cases. Others have taken a strong position on this issue of preemption of drug design cases. See, e.g., Catherine M. Sharkey, *Tort-Agency Partnerships in an Age of Preemption*, 15 THEORETICAL INQUIRIES IN L. 359, 362–68 (2014) (arguing that state law design defect and failure to warn claims are preempted by parallel federal requirements); Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, 1 J. TORT L. 1, 3 (2006) (noting that federal preemption of state tort actions for pharmaceutical companies).