

**NOT EXACTLY THE SAME: AN EXAMINATION OF  
HOW GENERIC SUBSTITUTION LAWS  
INADEQUATELY PROTECT CONSUMERS' NEEDS IF  
TAKING GENERIC DRUGS RESULTS IN INJURIES**

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ABSTRACT

*Every day, millions of Americans take generic prescription drugs, not thinking once about what their legal options would be should taking those drugs result in injuries. Unbeknownst to them, due to very recent developments in the law, in all but a few jurisdictions consumers are totally powerless to recover if they are hurt after taking generic drugs.*

*Common knowledge dictates that there is no difference between generic and brand-name drugs, and state laws even require pharmacists to fill consumers' prescriptions with the generic versions of brand-name drugs, absent explicit directions from the physicians to the contrary. While it is true that generic and brand-name drugs are identical in terms of bioequivalence and therapeutic effect, they are not identical in one crucial, but underappreciated, regard: the possibility of recourse if taking generic drugs results in injuries and the consumers want to recover under failure to warn or design defect claims. Starting with a Supreme Court decision in 2011, case law has made it clear that in these situations, neither the generic nor the brand-name manufacturers of the drugs are liable, thus leaving consumers entirely without recourse.*

*This Note examines the history of the FDA and drug regulation, the federal laws and cases that make up the current regulatory landscape, and state generic substitution laws. This Note then identifies a problem that goes largely undiscussed: because recent Supreme Court decisions have made it so consumers are powerless to recover for injuries sustained after taking generic drugs, which generic substitution laws effectively forced upon them, those laws should change to reflect the needs of consumers. This Note then suggests solutions to this problem, including a call for consumers to petition their legislatures to change generic substitution laws to be*

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*more favorable to consumers, and a challenge to the constitutionality of the laws.*

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## INTRODUCTION

In 2014, 3.8 billion prescriptions were filled nationwide, 88% of which were filled with generic versions of brand-name drugs.<sup>1</sup> The dominance of generic drugs is not without good reason: the cost of a generic drug is on average 80–85% lower than its brand-name counterpart.<sup>2</sup> In 2014 alone, generic drugs saved \$254 billion.<sup>3</sup> Despite

1. GENERIC PHARM. ASS'N, *GENERIC DRUG SAVINGS IN THE U.S.* 2 (2015), available at [http://www.gphaonline.org/media/wysiwyg/PDF/GPhA\\_Savings\\_Report\\_2015.pdf](http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf).

2. *Facts About Generic Drugs*, FDA 2 <http://www.fda.gov/downloads/Drugs/ResourcesForYou/>

this immediate economic benefit, some consumers of generic drugs have learned the hard way that because of how the law regulating generic and brand-name drugs has developed since 2011, the immediate gratification of lower prices at the pharmacy does not pay off when the patient is injured due to an inadequate warning label on the packaging of the drug. Consider, for example, the plaintiff in *Mutual Pharmaceutical Co. v. Bartlett*, who developed toxic epidermal necrolysis and had 65% of her body “deteriorated, . . . burned off, or turned into an open wound” after taking a generic drug.<sup>4</sup> Another example is the plaintiffs in *PLIVA, Inc. v. Mensing*, who developed tardive dyskinesia, a serious movement disorder that results in involuntary, repetitive, and purposeless bodily movements, after taking a generic drug.<sup>5</sup> The plaintiffs in these cases were powerless to receive compensation for their injuries.<sup>6</sup> Throughout this Note, I will refer to a lawsuit where the plaintiff was injured after taking a generic drug as a “generic suit,” and a lawsuit where the plaintiff was injured after taking a brand-name drug as a “brand-name suit.”

The unfortunate state of affairs that has developed in the majority of states is one in which consumers who have been injured due to inadequate warning labels on generic drugs cannot recover for their injuries from *anyone*. In short, this is because generic drug manufacturers are required to use the same exact warning labels as their brand-name counterparts;<sup>7</sup> the Supreme Court has held that state law failure to warn and design defect claims against generic manufacturers are preempted by federal law;<sup>8</sup> the overwhelming number of courts that have ruled on the issue have held there is no “innovator liability” that extends to the brand-name manufacturer of a drug when the victim takes a generic version of the drug;<sup>9</sup> and all states

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Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/UCM305908.pdf (last visited Dec. 22, 2015). In 2011, the average price of a brand-name prescription was \$268, and the average price of a generic prescription was \$33. Gregory Stanton, Carolina Herrera & Julianne Nelson, *Spending on Prescriptions in 2011*, HEALTH CARE COST INST. 1 (Sept. 2012), available at [http://www.healthcostinstitute.org/files/HCCI\\_IB4\\_Prescriptions.pdf](http://www.healthcostinstitute.org/files/HCCI_IB4_Prescriptions.pdf).

3. GENERIC PHARM. ASS'N, *supra* note 1.

4. 133 S. Ct. 2466, 2472 (2013).

5. 131 S. Ct. 2567, 2569 (2011).

6. *See id.*

7. 21 U.S.C. § 355(j)(2)(A)(v) (2015).

8. *Bartlett*, 133 S. Ct. at 2470; *PLIVA*, 131 S. Ct. at 2569.

9. *See* Wesley E. Weeks, Comment, *Picking Up the Tab for Your Competitors: Innovator Liability After PLIVA, Inc. v. Mensing*, 19 GEO. MASON L. REV. 1257, 1258 n.9 (2012) (“Innovator liability is a term that has been used to refer to failure to warn liability imposed on a brand-name drug manufacturer when the plaintiff took a generic version of the drug.”).

have enacted generic substitution laws that recommend or require pharmacists to fill prescriptions with generic versions of brand-name drugs.<sup>10</sup> The result is problematic for consumers: in jurisdictions that do not recognize innovator liability,<sup>11</sup> injured consumers cannot receive compensation from *anyone* in generic suits—federal law preempts lawsuits against the generic manufacturers,<sup>12</sup> and the courts' rejections of innovator liability shield brand-name manufacturers.<sup>13</sup>

While the result is troubling for consumers, far too much attention is paid to the concept of innovator liability, while another problem goes largely undiscussed. In most states, generic substitution laws effectively force patients into receiving generic versions of brand-name drugs.<sup>14</sup> Generic substitution laws are particularly troubling because the average American is not aware of the complex legal landscape that has developed in this space and does not think she will be without recourse should taking a generic drug that does not adequately apprise her of the dangers of the drug result in injury. Although generic substitution laws provide a putative benefit to consumers to the extent that the laws save consumers money at the pharmacy, they also effectively eliminate the possibility of consumers receiving compensation should they be injured in ways not warned of on the drugs' labels.

Because recent Supreme Court decisions have made it so consumers are powerless to recover for injuries sustained after taking generic drugs, which generic substitution laws effectively forced on them, those laws ought to change to reflect consumers' needs. To be clear, this Note does not advocate for the abolishment of generic substitution laws; surely, they provide a benefit to consumers. This Note advocates for generic substitution laws to be more consumer-friendly by warning the consumers that they cannot win in a generic suit. This Note begins by explaining the background and history of the laws that regulate this space and then discusses the differences

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10. See OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, ASPE ISSUE BRIEF: EXPANDING THE USE OF GENERIC DRUGS 4–5 (2010) [hereinafter ASPE ISSUE BRIEF], available at <http://aspe.hhs.gov/sites/default/files/pdf/76151/ib.pdf>.

11. The vast majority of jurisdictions do not recognize innovator liability—only Alabama, California, and Vermont do. See *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 708–09 (D. Vt. 2010); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 664–77 (Ala. 2014); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 304–05 (Cal. Ct. App. 2008).

12. *PLIVA*, 131 S. Ct. at 2572.

13. See *Weeks*, *supra* note 9, at 1258.

14. See *infra* Part II.B.

among the various generic substitution laws.<sup>15</sup> Next, this Note discusses the Supreme Court decisions that eliminated the possibility of recovery, followed by a discussion of state and federal cases dealing with innovator liability.<sup>16</sup> Finally, this Note suggests changes to generic substitution laws, and then discusses possible constitutional challenges to the laws.<sup>17</sup>

## I. BACKGROUND

### A. History of Federal Regulation of the Pharmaceutical Industry

#### 1. Early regulation

The modern era of the Food and Drug Administration (FDA) began when Congress passed the Federal Food and Drugs Act of 1906,<sup>18</sup> in part as a response to Upton Sinclair's *The Jungle*.<sup>19</sup> At this time, the FDA was known as the Bureau of Chemistry, and the Federal Food and Drugs Act added regulatory functions to the scientific mission of the agency.<sup>20</sup> The Federal Food and Drugs Act prohibited the interstate transport of illegal food and drugs<sup>21</sup> but did not require any type of approval or notification before drugs entered the market.<sup>22</sup>

It was not until the passage of the Federal Food, Drug, and Cosmetic Act (FDCA) that a notification system was implemented through which the FDA was authorized to require evidence of the

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15. See *infra* Part II.A-C.

16. See *infra* Part II.D-E.

17. See *infra* Part III.

18. Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768 (1906) (repealed 1938); see John P. Swann, *FDA's Origin*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm> (last updated June 23, 2014) [hereinafter *FDA's Origin*].

19. John P. Swann, *FDA History - Part 1*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054819.htm> (last updated June 18, 2009) [hereinafter *FDA History*]. *The Jungle* is an exposé on the deleterious conditions in the meatpacking industry. *Id.*

20. *FDA's Origin*, *supra* note 18.

21. *FDA History*, *supra* note 19. The Federal Food and Drugs Act actually focused on the regulation of food, as opposed to drugs, because the Bureau of Chemistry at that time viewed food as posing a greater public health problem than adulterated or misbranded drugs. *Id.*

22. See Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 419 (2011).

safety of new drugs before they entered the market.<sup>23</sup> Congress enacted the FDCA as a response to the deaths of 107 people who took a liquid form of Elixir Sulfanilamide, a drug used to treat streptococcal infections.<sup>24</sup> Through the FDCA, Congress authorized the FDA to require drug manufacturers to provide safety data through new drug applications (NDAs).<sup>25</sup>

In 1962, Congress dramatically expanded the FDA's regulatory authority regarding new drugs with the passage of the Kefauver-Harris Amendments to the FDCA, passed as a response to the thalidomide tragedy.<sup>26</sup> The Kefauver-Harris Amendments changed the NDA system from a notification process, through which manufacturer could sell drugs sixty days after filing the NDAs, to an approval system, through which the FDA had to affirm drugs safety and effectiveness before manufacturers could sell them.<sup>27</sup>

The FDA then changed the procedure for the approval of generic drugs.<sup>28</sup> Generic drug manufacturers had to submit only abbreviated new drug applications (ANDAs) if the manufacturers were seeking approval to make generic versions of brand-name drugs that were found to be safe and effective prior to 1962. With ANDAs, ge-

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23. Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301-399f (2015)); *Legislation*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Legislation/default.htm> (last updated July 2, 2015).

24. Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, FDA CONSUMER MAG., June 1981, available at <http://www.fda.gov/downloads/aboutfda/whatwedo/history/origin/ucm125604.doc>. The drug was used for some time in powder and tablet forms and was remarkably effective, but a salesperson reported demand for a liquid form of the drug. A chemist found that sulfanilamide dissolves well in diethylene glycol, so S.E. Massengill Co., the company that made the drug, created a liquid version using diethylene glycol and shipped it all over the country. Scientists had not tested the new formulation for toxicity, and the chemist who created the liquid form failed to note that diethylene glycol, commonly used as an antifreeze, is a deadly poison. After taking the liquid form of the drug, 107 people died, including many children. *Id.*; *Legislation*, *supra* note 23.

25. See Kelly, *supra* note 22, at 419.

26. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified in relevant part throughout 21 U.S.C. § 355 (2015)); *Legislation*, *supra* note 23. Thalidomide was a widely used drug in the late 1950s and early 1960s in Europe to treat nausea in pregnant women. James H. Kim & Anthony R. Scialli, *Thalidomide: The Tragedy of Birth Defects and the Effective Treatment of Disease*, 122(1) TOXICOLOGICAL SCI. 1, 1 (2011). Thalidomide was later shown to have caused severe birth defects in over 10,000 children worldwide. *Id.* Less than 100 children in the United States were born with birth defects from their mothers taking the drug because the FDA challenged the safety of the drug and did not allow it to be sold. See generally John Swann, *Dr. Frances Kelsey, Who Protected Americans from Thalidomide, Turns 100*, FDA VOICE (July 24, 2014), <http://blogs.fda.gov/fdavoices/index.php/2014/07/dr-frances-kelsey-who-protected-americans-from-thalidomide-turns-100/>.

27. See Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1762, 1764-68 (1996).

28. See Kelly, *supra* note 22, at 420.

neric manufacturers had to demonstrate bioavailability and bioequivalence, showing that the generic drugs were as safe as the brand-name drugs.<sup>29</sup> For generic versions of brand-name drugs that the FDA approved after 1962, generic manufacturers had to submit a full NDAs, including clinical data demonstrating that the drugs were safe.<sup>30</sup> In 1980, the FDA created and allowed the use of “paper NDAs” for generic versions of brand-name drugs approved before or after 1962, allowing generic manufacturers to point to published scientific literature to demonstrate the drugs’ safety, rather than generic manufacturers having to conduct their own clinical trials.<sup>31</sup>

Lastly, and remaining true today, manufacturers of brand-name drugs that are already on the market may, without FDA approval, add or strengthen warnings, precautions, adverse reactions, instructions about dosage and administration, and other similar cautions.<sup>32</sup> These permissible alterations to the label are known as “changes being effected” (CBE) regulations.<sup>33</sup> Importantly, generic manufacturers may *not* unilaterally alter labels using the CBE process.<sup>34</sup>

## 2. *The Hatch-Waxman Act*

The complex and varying drug approval systems prompted the passage of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, in order to simplify the process of bringing generic drugs to market.<sup>35</sup> The Hatch-Waxman Act amended the FDCA to allow generic drug manufacturers to file ADNAs instead of paper NDAs, regardless of when the FDA approved the brand-name drugs.<sup>36</sup> Under the amended FDCA, generic drug manufacturers need only to show that the generic drugs are bioequivalent to the brand-name drugs; that the active ingredients of the generic drugs are of the pharmacological or therapeutic class as that of the brand-name drugs; that the generic drugs have the same therapeutic effects as the brand-name

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29. *See id.*

30. *See id.*

31. *See id.*

32. 21 C.F.R. § 314.70(c)(6)(iii) (2008).

33. *See id.* § 314.70(c)(3).

34. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2575 (2011).

35. Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in relevant part at 21 U.S.C. § 335(j) (2015)).

36. *See* Samantha Koopman, Comment, *Hidden Risks of Taking Generic Drugs over Brand-name: The Impact of Drug Labeling Regulations on Injured Consumers and the Pharmaceutical Industry*, 34 J. NAT’L ASS’N ADMIN. L. JUDICIARY 112, 120 (2014).

drugs when administered for the same conditions; and that the generic drugs carry with them the exact same warning labels as their brand-name counterparts.<sup>37</sup> By allowing generic drug manufacturers to submit ANDAs instead of paper NDAs, generic manufacturers are able to save a significant amount of money: it costs only one to two million dollars to bring a generic drug to market, whereas it costs upwards of a billion dollars to bring a brand-name drug to market.<sup>38</sup> The Hatch-Waxman Act allows generic manufacturers to save time as well: since they no longer have to conduct their own clinical trials, time is not wasted, as they simply use the brand-name drugs' clinical data and tests.<sup>39</sup> Before the passage of the Hatch-Waxman Act, "only 35[%] of the top-selling drugs with expired patents . . . had generic versions available. Today, nearly all do."<sup>40</sup>

### B. Generic Substitution Laws

States have added their own wrinkle to the pharmaceutical regulatory landscape by way of generic substitution laws. Generic substitution laws recommend or require pharmacists to dispense generic versions of drugs, unless the prescribing physician specified that the pharmacist must fill the prescription with the brand-name drug.<sup>41</sup> All states have generic substitution laws, with several variations among them.<sup>42</sup>

In eleven states, the prescribing physician must expressly give permission for the pharmacist to substitute.<sup>43</sup> In the other thirty-nine states, the pharmacist may substitute unless the prescribing physician expressly forbids it.<sup>44</sup> In some states, if a prescribing physician wishes to forbid substitution, depending on the state statute she must write "Brand Medically Necessary," "Dispense as Written," or something similar.<sup>45</sup> In other states, there is a box that reads "Brand

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37. 21 U.S.C. § 355(j)(2)(A)(iv)-(v) (2015).

38. ASPE ISSUE BRIEF, *supra* note 10, at 4-5.

39. See Matthew Avery, Note, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 176 (2008).

40. Danielle L. Steele, Comment, *The "Duty of Sameness" as a Shield – Generic Drug Manufacturers' Tort Liability and the Need for Label Independence After PLIVA, Inc. v. Mensing*, 43 SETON HALL L. REV. 441, 459 (2013).

41. ASPE ISSUE BRIEF, *supra* note 10, at 7.

42. Koopman, *supra* note 36, at 114.

43. *Id.* at 121 n.51. These eleven states are Alabama, Delaware, Indiana, Maine, Missouri, New York, Oklahoma, Pennsylvania, South Carolina, Utah, and Washington. *Id.*

44. *Id.* at 121 n.52.

45. ASPE ISSUE BRIEF, *supra* note 10, app. A.

Only,” “Do not Substitute,” “Dispense as Written,” or something similar, that the prescribing physician must check or initial if she wishes to forbid substitution.<sup>46</sup>

When the prescribing physician has not expressly forbade substitution, fourteen states *require* substitution.<sup>47</sup> The remaining thirty-six states *allow* substitution.<sup>48</sup> In ten states, the pharmacist does not have to notify the patient that she is substituting.<sup>49</sup> In Arizona, the pharmacist does not have to notify the patient of the substitution if a third party is reimbursing the cost of the drug.<sup>50</sup> In Iowa and Ohio, the pharmacist does not have to notify the patient of the substitution if public funding is reimbursing the cost of the drug.<sup>51</sup> In five states, the pharmacist must inform the patient of the substitution, but the patient does not have the right to refuse it.<sup>52</sup> In twenty-nine states, the pharmacist must notify the patient of the substitution, which the patient may refuse.<sup>53</sup> In Maine, Tennessee, and Vermont, the pharmacist must notify the patient of the substitution, which the patient may refuse, but the patient must pay the additional costs of the brand-name drug out-of-pocket if she refuses it.<sup>54</sup>

### C. Failure to Warn Claims

When a consumer is injured after ingesting a drug, a common cause of action is the failure to warn claim, which stems from the notion that unreasonably dangerous products should not be sold without adequate warnings. The Restatement (Second) of Torts pro-

46. *Id.*

47. *Id.* These states are Florida, Hawaii, Kentucky, Maine, Massachusetts, Minnesota, Nevada, New Jersey, New York, Rhode Island, Tennessee, Vermont, Washington, and West Virginia. *Id.*

48. *Id.*

49. See Koopman, *supra* note 36, at 122 n.55. These states are Alabama, Illinois, Kansas, Maryland, Massachusetts, Michigan, New Mexico, New York, North Carolina, and Wyoming. *Id.*

50. ARIZ. REV. STAT. ANN. § 32-1963.01(B)(2) (2014).

51. IOWA CODE ANN. § 155A.32(2)(b) (West 2013); OHIO REV. CODE ANN. § 4729.38(A)(3)(a) (West 2013).

52. Koopman, *supra* note 36, at 122 n.55. These states are California, Colorado, Delaware, Indiana, and Virginia. *Id.*

53. *Id.* at 122 n.59. These states are Alaska, Arkansas, Connecticut, Florida, Georgia, Hawaii, Idaho, Kentucky, Louisiana, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Texas, Utah, Washington, West Virginia, and Wisconsin. *Id.*

54. ME. REV. STAT. ANN. tit. 32, § 13781 (West 2013); TENN. CODE ANN. § 53-10-205(d) (West 2013); VT. STAT. ANN. tit. 18, § 4605(B) (West 2013).

vides that “[o]ne who sells any product in a defective condition *unreasonably dangerous* to the user or consumer . . . is subject to liability for physical harm thereby caused to the ultimate user or consumer . . . .”<sup>55</sup> Failure to warn is a strict liability claim.<sup>56</sup> The policy behind strict liability is that

the [manufacturer], by marketing [the] product for use and consumption, has undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it; that the public has the right to and does expect, in the case of products which it needs and for which it is forced to rely upon by the [manufacturer], that reputable [manufacturers] will stand behind their goods; that public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, . . . and that the consumer of such products is entitled to the maximum of protection at the hands of someone, and the proper persons to afford it are those who market the products.<sup>57</sup>

In order for a drug or other product not to be unreasonably dangerous, it must carry with it directions and/or a warning label that instructs the user how to use it properly.<sup>58</sup> However, a warning label is not necessary when the product is dangerous or potentially dangerous only when consumed in excessive quantity or over a long period of time, if the danger or potential danger is generally known.<sup>59</sup> The Restatement also explains the warning necessary for products that are unavoidably unsafe, such as some drugs.<sup>60</sup> Unavoidably unsafe products that “are quite incapable of being made safe for their intended and ordinary use” are not *unreasonably dangerous* if they are “properly prepared . . . and accompanied by proper directions and warning.”<sup>61</sup>

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55. RESTATEMENT (SECOND) OF TORTS § 402A(1) (1965) (emphasis added).

56. *Id.* § 402A(1) cmt. a.

57. *Id.* § 402A(1) cmt. c (emphasis added).

58. *Id.* § 402A(1) cmt. j.

59. *Id.* For example, a seller of high-fat junk food need not place a warning on her product that excessive or long-term consumption of the food could have negative health consequences on the heart.

60. *Id.* § 402A(1) cmt. k.

61. *Id.*

*D. The Preemption Cases**1. Introduction*

In generic suits, manufacturers raise the defense that federal law preempts state law failure to warn claims. Although the preemption doctrine is not contained within the text of the Constitution or in any federal statute, it has developed as a judicial interpretation of the Supremacy Clause.<sup>62</sup> If a federal law preempts a state law, the state law is invalid.<sup>63</sup> There are two types of preemption: express preemption and implied preemption.<sup>64</sup> Express preemption exists when a federal law contains in it a preemption clause that invalidates a state law or cause of action.<sup>65</sup> There are two types of implied preemption: field preemption and conflict preemption. Field preemption exists when “Congress, though not expressly so stating, [implies] that it is preempting state law by occup[ying] . . . an entire field of regulation, so that no room is left for supplementary state regulation . . . .”<sup>66</sup> Conflict preemption “occurs when (a) compliance with both state and federal law is impossible, or (b) when state law stands as an impediment to a federal purpose.”<sup>67</sup>

There is a presumption against preemption in areas of law that states traditionally occupy.<sup>68</sup> In these areas, a party can overcome the presumption if it shows that the “clear and manifest purpose of Congress” was to preempt state laws.<sup>69</sup>

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62. U.S. CONST. art. VI, § 2 (“This Constitution, and the laws of the United States which shall be made in pursuance thereof . . . , shall be the supreme law of the land; and the judges in every State shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding.”).

63. See *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981) (“It is basic to [the Supremacy Clause] that all conflicting state provisions be without effect.”); see also *McCulloch v. Maryland*, 17 U.S. (1 Wheat.) 316, 326–27 (1819).

64. See *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 95 (1983).

65. See, e.g., 49 U.S.C. § 30103(b) (2015) (federal motor vehicle safety preemption clause that expressly preempts any state motor vehicle standards).

66. *Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1111 (4th Cir. 1988).

67. *Id.*

68. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (“[T]he States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.” (internal quotation mark omitted)).

69. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). The “clear and manifest purpose” standard does not require that the preemption be express. *Id.*

## 2. Wyeth v. Levine

In *Wyeth v. Levine*, the Supreme Court held that FDA regulation of prescription drugs does not preempt failure to warn brand-name suits.<sup>70</sup> The plaintiff had to have her arm amputated after taking a brand-name drug, the accompanying literature to which did not explain to the administering clinician exactly how to administer the drug in the safest possible way.<sup>71</sup> The plaintiff sued the manufacturer, Wyeth, for failure to warn.

In its defense, Wyeth argued that the FDA's regulatory system preempted brand-name suits, insofar as it would have been impossible to unilaterally alter the label of the package without violating federal law, and that allowing state law tort actions would "create[] an unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress," because the claims would "substitute[] a lay jury's decision about drug labeling for the expert judgment of the FDA."<sup>72</sup> Essentially, Wyeth argued preemption by impossibility and preemption by interference.

The Supreme Court rejected both arguments. Regarding the preemption by impossibility argument, the Court held that because CBE regulations<sup>73</sup> allow manufacturers to modify labels in order to provide better warnings without first getting approval from the FDA, and there was no evidence that Wyeth had attempted to do so,

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70. 555 U.S. 555, 555–56 (2009).

71. The plaintiff, Diana Levine, had to have her arm amputated after doctors treated her with Phenergan. *Id.* at 558. Phenergan is Wyeth's brand name for promethazine hydrochloride, an antihistamine used to treat nausea. *Id.* at 559. The Phenergan that Levine took was injectable and could be administered either intramuscularly or intravenously. *Id.* If administered intravenously, the drug can be administered using either the IV-push or IV-drip method. *Id.* The IV-push method involves a direct injection of the drug into the vein of the patient, whereas the IV-drip method involves slow introduction of the drug, in a saline solution, from a hanging bag that slowly feeds the solution to a catheter inserted into the patient's vein. *Id.* Levine was administered Phenergan via the IV-push method in April of 2000, as treatment for nausea resulting from a migraine. *Id.* When she received the Phenergan, some of the drug entered one of Levine's arteries and contacted arterial blood. *Id.* This could have occurred because either the needle punctured the artery or because the drug seeped into the tissue surrounding the vein into which the needle was an inserted. *Id.* Due to the Phenergan contacting arterial blood, Levine developed gangrene, forcing the doctors to amputate first her right hand, and then her entire right forearm. *Id.* Levine, a professional musician, sued for pain and suffering, medical expenses, and the loss of her livelihood. *Id.* Levine argued that Wyeth was liable for her injuries because, although Phenergan said on its label that there is a danger of gangrene and amputation if the drug inadvertently enters an artery, the drug was defective because it did not instruct clinicians administering the drug to use the safer IV-drip method, as opposed to the riskier IV-push method. *Id.* at 559–60.

72. *Id.* at 563–64 (quotation marks omitted).

73. 21 C.F.R. § 314.70(c)(6)(iii)(A) (2008).

federal law did not preempt the state law claim.<sup>74</sup> Regarding Wyeth's preemption by interference argument, the Court held that the claims did not present an obstacle, because "[i]f Congress thought state-law suits posed an obstacle to its objective, it surely would have enacted an express [preemption] provision at some point during the FDCA's 70-year history."<sup>75</sup>

### 3. *PLIVA, Inc. v. Mensing*

In *PLIVA, Inc. v. Mensing*, the Supreme Court held that FDA regulations preempt failure to warn generic suits against generic manufacturers.<sup>76</sup> The plaintiffs alleged that "despite mounting evidence that long term metoclopramide use carries a risk of tardive dyskinesia far greater than that indicated on the label, [neither the brand-name nor the generic manufacturer] had changed their labels to adequately warn of that danger."<sup>77</sup> The plaintiffs argued that the CBE process allows generic drug manufacturers, in addition to brand-name drug manufacturers, to unilaterally modify warning labels.<sup>78</sup> The manufacturers argued that federal law preempted the state law

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74. *Wyeth*, 555 U.S. at 568-73.

75. *Id.* at 574.

76. 131 S. Ct. 2567, 2569 (2011).

77. The plaintiffs, Gladys Mensing and Julie Demahy, were prescribed in 2001 and 2002, respectively, and took for several years metoclopramide, the generic form of the drug Reglan, and both women developed tardive dyskinesia. *Id.* at 2573. Metoclopramide "increases muscle contractions in the upper digestive tract. This speeds up the rate at which the stomach empties into the intestines. [Metoclopramide] is used short-term to treat heartburn caused by gastroesophageal reflux in people who have used other medications without relief of symptoms." *Reglan*, DRUGS.COM (Feb. 15, 2012, 10:50 AM), [www.drugs.com/reglan.html](http://www.drugs.com/reglan.html). Tardive dyskinesia is a side effect of neuroleptics that occurs after taking the medication for months or years. Joseph V. Campellone, *Tardive Dyskinesia*, MEDLINEPLUS (May 20, 2014), <http://www.nlm.nih.gov/medlineplus/ency/article/000685.htm>. Symptoms include facial grimacing, finger movement, jaw swinging, repetitive chewing, and tongue thrusting. *Id.* Up to 29% of patients who take metoclopramide over a period of several years will develop tardive dyskinesia. *PLIVA*, 131 S. Ct. at 2572. The FDA first approved metoclopramide in 1980, and in 1985, the brand manufacturer of metoclopramide strengthened the warning label to warn, "tardive dyskinesia . . . may develop in patients treated with metoclopramide," and an insert in the packaging warned, "[t]herapy longer than 12 weeks has not been evaluated and cannot be recommended." Steele, *supra* note 40, at 479. In 2005, after the plaintiffs first started using metoclopramide, the brand manufacturer of metoclopramide changed again the warning label to add, "[t]herapy should not exceed 12 weeks in duration." *Id.* In 2009, the FDA ordered a black box warning for metoclopramide stating, "[t]reatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible . . . . Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases." *PLIVA*, 131 S. Ct. at 2573. A black box warning is the strongest that the FDA will order. *Id.* at 2573; see 21 C.F.R. § 201.57(a)(4) (2015).

78. *PLIVA*, 131 S. Ct. at 2575; see 21 C.F.R. § 314.70(c)(3) (2008).

tort claims because federal statutes and FDA regulations require generic manufacturers to use the same warning labels as that of their brand-name counterparts.<sup>79</sup>

The FDA filed an *amicus curiae* brief, denying that the generic manufacturers could have unilaterally strengthened the warning labels using the CBE process.<sup>80</sup> The Court deferred to the FDA's interpretation of the CBE process and held that because the generic manufacturers could not have unilaterally modified or strengthened their labels without violating federal law, the state law tort claim was preempted.<sup>81</sup> The Supreme Court also rejected the plaintiffs' argument that the generic suit was not preempted because the manufacturers did not petition the FDA to change the CBE requirements to allow a generic drug manufacturer to unilaterally engage in the CBE process.<sup>82</sup> In so deciding, Justice Thomas wrote,

[i]f these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force. We do not read the Supremacy Clause to permit an approach to pre-emption that renders conflict pre-emption all but meaningless.<sup>83</sup>

#### 4. Mutual Pharmaceutical Co. v. Bartlett

Two years after its decision in *PLIVA*, the Supreme Court decided *Mutual Pharmaceutical Co. v. Bartlett*, in which it held that the preemption of failure to warn generic suits against generic manufacturers also applies to design defect claims.<sup>84</sup> In *Bartlett*, the plaintiff was prescribed sulindac,<sup>85</sup> the generic form of Clinoril, for shoulder pain, and thereafter developed an acute case of toxic epidermal necrolysis.<sup>86</sup> At the time, the sulindac warning label did not specifi-

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79. *Id.* at 2573.

80. *Id.* at 2575; see also 21 U.S.C. § 355(j)(4)(G) (2015); 21 C.F.R. §§ 314.94(a)(8)(iii) (2011), 314.150(b)(10) (2014) (approval may be withdrawn if the generic drug's label "is no longer consistent with that for [the brand-name] . . .").

81. *PLIVA*, 131 S. Ct. at 2575–78.

82. *Id.* at 2577–81.

83. *Id.* at 2579 (citations omitted).

84. 133 S. Ct. 2466, 2470 (2013).

85. Sulindac is a nonsteroidal anti-inflammatory pain reliever (NSAID), similar to ibuprofen, naproxen, and Cox2-inhibitors. *Id.* at 2471.

86. *Id.* at 2472. Toxic epidermal necrolysis is a serious side effect of some NSAIDs that occurs in a very small number of patients. Toxic epidermal necrolysis results in the death of skin and mucous membranes. *Id.* "Sixty to sixty-five percent of the surface of [the plaintiff's] body

cally warn of the possibility of toxic epidermal necrolysis, but did warn that the drug could cause “severe skin reactions and [f]atalities.”<sup>87</sup> The plaintiff filed a state law design defect claim against the generic manufacturer of the drug.<sup>88</sup> The manufacturer, like the manufacturer in *PLIVA*, argued that federal law preempted the claim, since generic drug manufacturers could not unilaterally alter drug labels without violating federal law.<sup>89</sup>

In its decision, the Court extended its holding in *PLIVA* to design defect claims under the same reasoning.<sup>90</sup> The Court also rejected the plaintiff’s argument that the generic manufacturer should have simply stopped selling the drug, which would have absolved it of all liability.<sup>91</sup> Preemption doctrine “presume[s] that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility preemption would be all but meaningless.”<sup>92</sup>

After *Wyeth*, *PLIVA*, and *Bartlett*, whether a patient can recover under a failure to warn or design defect claim depends on whether the drug she ingested was brand-name or generic: if the drug was brand-name, the claim is *not* preempted, and the claim may prevail; if the drug was generic, however, the claim *is* preempted, and a claim against the generic manufacturer will *not* prevail.

### E. Case Law Addressing Innovator Liability

The open question after *Wyeth*, *PLIVA*, and *Bartlett* is whether a patient can win a generic suit against the brand-name manufacturer. This concept of holding a brand-name manufacturer liable for the actions of its generic competitors is known as “innovator liability.”<sup>93</sup>

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deteriorated, was burned off, or turned into an open wound. She spent months in a medically induced coma, underwent 12 eye surgeries, and was tube-fed for a year. She is now severely disfigured, has a number of physical disabilities, and is nearly blind.” *Id.*

87. *Id.* (alteration in original) (internal quotation marks omitted).

88. *Id.* *Bartlett* also sued for failure to warn, but the District Court dismissed that claim on other grounds. *Id.*

89. *Id.* at 2470.

90. *Id.*

91. *Id.* at 2477.

92. *Id.* (internal quotation marks omitted).

93. Weeks, *supra* note 9, at 1258 n.9 (citing *Bartlett v. Mut. Pharm. Co.*, 659 F. Supp. 2d 279, 308 n.40 (D.N.H. 2009) (“The vast majority of courts have rejected the notion that the manufacturer of the brand-name drug may be liable for defects in its generic equivalent on a theory of ‘innovator liability.’”)).

### 1. *Rejecting innovator liability*

The vast majority of courts that have ruled on the issue of innovator liability in the pharmaceutical context have rejected it.<sup>94</sup> Courts in Arkansas,<sup>95</sup> Florida,<sup>96</sup> Georgia,<sup>97</sup> Indiana,<sup>98</sup> Iowa,<sup>99</sup> Kentucky,<sup>100</sup> Louisiana,<sup>101</sup> Maryland,<sup>102</sup> Massachusetts,<sup>103</sup> Minnesota,<sup>104</sup> Mississippi,<sup>105</sup> Nevada,<sup>106</sup> New Jersey,<sup>107</sup> North Carolina,<sup>108</sup> Ohio,<sup>109</sup> Oklahoma,<sup>110</sup> Oregon,<sup>111</sup> Pennsylvania,<sup>112</sup> South Carolina,<sup>113</sup> Tennessee,<sup>114</sup>

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94. See James M. Beck, *Innovator Liability at 100*, DRUG & DEVICE L. (July 18, 2014), <http://druganddevicelaw.blogspot.com/2014/07/innovator-liability-at-100.html>.

95. *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1092–93 (8th Cir. 2013) (“[P]laintiffs in Arkansas must introduce sufficient evidence to allow a jury to find that more likely than not their exposure to a particular defendant’s product was a substantial factor in producing their injuries.”); *Fullington v. Pfizer, Inc.*, 720 F.3d 739, 744 (8th Cir. 2013).

96. *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1252 (11th Cir. 2013); *Metz v. Wyeth, LLC, Inc.*, 830 F. Supp. 2d 1291, 1293–95 (M.D. Fla. 2011); *Levine v. Wyeth, Inc.*, 684 F. Supp. 2d 1338, 1344–46 (M.D. Fla. 2010); *Howe v. Wyeth, Inc.*, No. 8:09-CV-610-T-17AEP, 2010 WL 1708857, at \*12 (M.D. Fla. Apr. 26, 2010); *Dietrich v. Wyeth, Inc.*, No. 50-2009-CA-021586 XXX MB, 2009 WL 4924722, at \*11–12 (Fla. Cir. Ct. Dec. 21, 2009); *Sharp v. Leichus*, No. 2004-CA-0643, 2006 WL 515532, at \*2–6 (Fla. Cir. Ct. Feb. 17, 2006).

97. *Moore v. Mylan, Inc.*, 840 F. Supp. 2d 1337, 1344 (N.D. Ga. 2012); *Swicegood v. PLIVA, Inc.*, 543 F. Supp. 2d 1351, 1354–59 (N.D. Ga. 2008); *Reynolds v. Anton*, No. 01A-76719-3, 2004 WL 5000272, at \*14 (Ga. Super. Oct. 28, 2004).

98. *Short v. Eli Lilly & Co.*, No. 49D12-0601-CT-2187, 2009 WL 9867531, at \*19, (Ind. Super. Mar. 25, 2009).

99. *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 378 (Iowa 2014) (plurality opinion).

100. *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 930–34 (6th Cir. 2014).

101. *Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605, 614 (5th Cir. 2014); *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 183–84 (5th Cir. 2012); *Stanley v. Wyeth, Inc.*, 991 So. 2d 31, 34–35 (La. Ct. App. 2008).

102. *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 171 (4th Cir. 1994).

103. *Kelly v. Wyeth*, No. Civ.A.MICV200303314B, 2005 WL 4056740, at \*2–5 (Mass. Super. May 6, 2005).

104. *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 612–14 (8th Cir. 2009); *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342, 352 (Minn. App. 2001).

105. *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 477 (5th Cir. 2014); *Gardley-Starks v. Pfizer, Inc.*, 917 F. Supp. 2d 597, 601–04 (N.D. Miss. 2013); *Washington ex. rel. Washington v. Medicis Pharm. Corp.*, 2013 WL 496063, at \*3–4 (S.D. Miss. Feb. 7, 2013).

106. *Moretti v. Wyeth, Inc.*, 579 F. App’x 563, 565–56 (9th Cir. 2014), *cert. denied*, 1355 S. Ct. 1398 (2015).

107. *Condouris v. Wyeth*, No. ATL-L-1940-10, 2012 WL 2401776 at \*4–5 (N.J. Super. Ct. Law Div. June 26, 2012).

108. *Couick v. Wyeth, Inc.*, 691 F. Supp. 2d 643, 645 (W.D.N.C. 2010); *Stoddard v. Wyeth, Inc.*, 630 F. Supp. 2d 631, 633–34 (E.D.N.C. 2009).

109. *Hendricks v. Pharmacia Corp.*, No. 2:12-CV-00613, 2014 WL 2515478, at \*5–6 (S.D. Ohio June 4, 2014); *Hogue v. Pfizer, Inc.*, 893 F. Supp. 2d 914, 918–19 (S.D. Ohio 2012).

110. *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1285 (10th Cir. 2013).

and Texas<sup>115</sup> have all rejected innovator liability. With some subtle variations, the reason behind these decisions is that a company is not liable for the products made by its competitor.

In *In re Darvocet, Darvon, & Propoxyphene Products Liability Litigation*, the Sixth Circuit opined that the laws of Arkansas, Connecticut, Florida, Georgia, Illinois, Indiana, Louisiana, Maryland, Michigan, Mississippi, Nebraska, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, and Washington do not support innovator liability as a theory of recovery.<sup>116</sup> In addition, an Illinois court predicted that Virginia law would not recognize innovator liability,<sup>117</sup> and a Pennsylvania court predicted that Washington law would not recognize innovator liability.<sup>118</sup>

## 2. Adopting innovator liability

Not all courts that have considered innovator liability have rejected it. Courts in Alabama,<sup>119</sup> California,<sup>120</sup> and Vermont<sup>121</sup> have adopted innovator liability, thus allowing patients who were injured after taking generic drugs to recover from the brand-name manufacturers. In each of these cases, the court held that the brand-name manufacturers were liable on a negligent misrepresentation theory,

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111. *Phelps v. Wyeth, Inc.*, 857 F. Supp. 2d 1114, 1118–19 (D. Or. 2012); *DaCosta v. Novartis AG*, No. CV 01-800-BR, 2002 WL 31957424, at \*8–9 (D. Or. Mar. 1, 2002).

112. *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 549–50 (E.D. Pa. 2006).

113. *Fisher v. Pelstring*, No. 4:09-cv-00252-TLW, 2010 WL 2998474, at \*6 (D.S.C. July 28, 2010).

114. *Strayhorn v. Wyeth Pharm.*, 737 F.3d 378, 396–97 (6th Cir. 2013).

115. *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 477 (5th Cir. 2014); *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674, 678–79 (5th Cir. 2004); *Willis v. Schwarz-Pharma, Inc.*, 62 F. Supp. 3d 560, 564–66 (E.D. Tex. 2014); *Phares v. Actavis-Elizabeth LLC*, 892 F. Supp. 2d 835, 842–43 (S.D. Tex. 2012); *Finnicum v. Wyeth, Inc.*, 708 F. Supp. 2d 616, 620–22 (E.D. Tex. 2010); *Hardy v. Wyeth, Inc.*, No. 9:09CV152, 2010 WL 1049588, at \*2–5 (E.D. Tex. Mar. 8, 2010); *Burke v. Wyeth, Inc.*, No. G-09-82, 2009 WL 3698480, at \*2–3 (S.D. Tex. Oct. 29, 2009); *Cousins v. Wyeth Pharm., Inc.*, No. 3:08-CV-0310-N, 2009 WL 648703, at \*2 (N.D. Tex. Mar. 10, 2009); *Pustejovsky v. Wyeth, Inc.*, No. 4:07-CV-103-Y, 2008 WL 1314902, at \*2 (N.D. Tex. Apr. 3, 2008); *Block v. Wyeth, Inc.*, No. Civ.A. 3:02-CV-1077-, 2003 WL 203067, at \*2 (N.D. Tex. Jan. 28, 2003); *Negron v. Teva Pharm. USA, Inc.*, No. 09-16519, 2010 WL 8357563, at \*1 (Tex. Dist. May 7, 2010).

116. *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 941–54 (6th Cir. 2014).

117. *Colas v. Abbvie, Inc.*, No. 14 C 1452, 2014 WL 2699756, at \*2 (N.D. Ill. June 13, 2014).

118. *Madden v. Teva Pharm. USA, Inc.*, No. 0087, 2012 WL 4757253, at \*7–9 (Pa. Com. Pl. Oct. 1, 2012).

119. *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 664–75 (Ala. 2014).

120. *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 307–21 (Cal. Ct. App. 2008).

121. *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 703–09 (D. Vt. 2010).

whereby it was foreseeable to the manufacturers that the mislabeling of their products could eventually cause consumers of identical generic drugs to be injured. However, these three cases and the reasoning behind their holdings are still the minority.

*F. Lefkowitz: Challenging Generic Substitution Laws*

In 1978, plaintiffs challenged New York's generic substitution law as being unconstitutional under the dormant Commerce Clause and as being preempted under the Supremacy Clause.<sup>122</sup> New York's generic substitution law requires that:

(a) . . . Imprinted conspicuously on every prescription written in this state in eight point upper case type immediately below the signature line shall be the words: "THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS PRESCRIBER WRITES 'd a w' IN THE BOX BELOW". Unless the prescriber writes d a w in such box in the prescriber's own handwriting or, in the case of electronic prescriptions, inserts an electronic direction to dispense the drug as written, the prescriber's signature or electronic signature shall designate approval of substitution by a pharmacist . . . . No other letters or marks in such box shall prohibit substitution . . . .

(b) The prescriber shall inform the patient whether he or she has prescribed a brand-name or its generic equivalent drug product.<sup>123</sup>

The plaintiffs were the Pharmaceutical Society of the State of New York, a pharmacist, a physician, and a patient.<sup>124</sup> They argued that the generic substitution law was unconstitutional under the dormant Commerce Clause because "on its face it creates an excessive burden on interstate commerce by prohibiting the sale of [brand-name drugs] solely because of [their] price."<sup>125</sup> The Second

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122. *Pharm. Soc'y of N.Y., Inc. v. Lefkowitz*, 586 F.2d 953, 955 (2d Cir. 1978).

123. N.Y. EDUC. LAW § 6810(6) (McKinney 2015).

124. *Lefkowitz*, 586 F.2d at 955.

125. *Id.* Under the dormant Commerce Clause, a state law is unconstitutional if it is facially discriminatory against commerce involving other states; if it is facially neutral with regard to commerce involving other states but has a purpose or effect of protecting the economy of the state; or if it is facially neutral with regard to commerce involving other states but has proportionally adverse effects on interstate commerce. See generally *Hunt v. Wash. State Apple Adver. Comm.*, 432 U.S. 333 (1977); *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970); *Philadelphia v. New Jersey*, 437 U.S. 617 (1951).

Circuit rejected this argument. While acknowledging that “the statute could conceivably burden commerce to the extent that the flow of the more expensive brand-name drug prescribed by the doctor would be restricted,” it held that “not every exercise of local power is invalid merely because it affects in some way the flow of commerce between the States. [Plaintiffs] have not shown that the burden here would be ‘clearly excessive’ compared to the benefit.”<sup>126</sup>

The plaintiffs also argued that the Federal Food, Drug, and Cosmetic Act preempted the law.<sup>127</sup> The Second Circuit quickly disposed of this argument, holding that “there is no actual conflict between the federal and state statutes” and that “the federal statute is not so pervasive as to remove the states entirely from the field of drug regulation.”<sup>128</sup>

## II. ANALYSIS

### *A. The Current Drug Regulation Landscape Is Unworkable and Unfair*

The way that the regulation of the drug market has evolved through federal regulations, state laws, Supreme Court decisions, and lower court decisions has created a convoluted system of benefits and drawbacks for consumers, brand-name drug manufacturers, and generic drug manufacturers. Consumers benefit to the extent that generic substitution laws recommend or require physicians to fill prescriptions with generic forms of brand-name drugs, thus saving the consumers money.<sup>129</sup> However, consumers’ interests can be *severely* damaged if they are hurt due to inadequate labeling of the generic drugs. In all but a few jurisdictions, consumers are entirely unable to obtain monetary relief for their injuries, neither from the generic manufacturers, which made the drugs the consumers ingested, nor from the brand-name manufacturers, which pioneered the drugs and were solely responsible for creating and updating the warning labels. The bizarre effect of this situation is that consumers understandably think, with no reason to question otherwise, that there is absolutely no difference between the generic and brand-

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126. *Lefkowitz*, 586 F.2d at 957 (citing *Great Atl. & Pac. Tea Co. v. Cottrell*, 424 U.S. 366, 371 (1976)).

127. Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301-399f (2015)).

128. *Lefkowitz*, 586 F.2d at 958.

129. See ASPE ISSUE BRIEF, *supra* note 10, at 7.

name versions of drugs. While this belief may be true in terms of bioequivalence, it is hardly the case if the drugs injure the consumers.

Brand-name drug manufacturers benefit to the extent that they are not liable in generic suits.<sup>130</sup> The brand-name manufacturers' economic interests are hurt, insofar as generic substitution laws recommend or require prescriptions for brand-name drugs to be filled with generic versions, sometimes even if the patients explicitly request otherwise.<sup>131</sup>

Compared to consumers and the brand-name drug manufacturers, generic drug manufacturers benefit from a win-win regulatory landscape. First, the generic substitution laws of many states recommend or require that pharmacists fill prescriptions with generic drugs, granting an obvious benefit to generic manufacturers, since the vast majority of drugs sold are generics.<sup>132</sup> Second, generic manufacturers are, as a matter of constitutional law, immune from generic suits.

### B. Proposed Solutions

This Note advocates two possible solutions to the issues described above: petitioning the legislature to fix generic substitution laws, and challenging the constitutionality of generic substitution laws as they currently operate. Specifically, this Note seeks not to eliminate generic substitution laws in their entirety, but rather to give consumers more of an informed choice in what drugs they receive. Ultimately, consumers, rather than the legislature, should decide what drugs they want to take and to what risks they want to subject themselves. These solutions would benefit the two groups whose interests are seemingly inapposite: consumers and brand-name drug manufacturers. Consumers would benefit insofar as they would be aware of the potential ramifications of taking a generic drug at the time of dispensing and would therefore be able to make an informed decision. This solution may lead to more consumers choosing brand-name drugs over generic drugs, thereby giving consumers the opportunity to recover in brand-name suits. It may seem at first that brand-name drug manufacturers would suffer because they would be liable in a greater number of potential lawsuits. However, brand-name manufacturers would benefit as well, as a

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130. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2580–82 (2011).

131. *See infra* Part II.B.

132. *GENERIC PHARM. ASS'N*, *supra* note 1, at 15. In 2014, for example, 88% of all prescriptions were filled with generic drugs. *Id.*

greater number of consumers would choose brand-name drugs over generic drugs, thus increasing the profits of the brand-name manufacturers. While the precise risk-versus-reward analysis of how much brand-name manufacturers would lose in brand-name suits compared to how much they would gain from increased sales is outside the scope of this Note, it is sufficient to note that both consumers and brand-name manufacturers have a stake in the elimination or modification of generic substitution laws.

*1. Petition the legislature to change generic substitution laws*

Consumers and other groups should take action to petition their legislatures to change generic substitution laws, get rid of them altogether, or recognize innovator liability. These requests are not impossible, immoral, or impractical; consumers deserve compensation for their injuries, especially when the injuries are so severe as to cause disfigurement, permanent disability, or death.

When viewing the problem in terms of radically unequal bargaining power, it is clear that legislators ought to step in to fight for their constituents. On one side are pharmaceutical companies: corporate titans with armies of lawyers at their disposal and virtually unlimited funding to pump into litigation. For pharmaceutical companies, it is absolutely in their best interests to categorically limit or be free from liability in generic suits. On the other side are consumers, who oftentimes do not have the recordkeeping ability, business savvy, and legal expertise or resources at their disposal to wage an expensive legal battle. And of course for the consumers, it is absolutely in their best interests to receive compensation for their injuries.<sup>133</sup> Unfortunately, perhaps due to the unequal bargaining power between the two parties, pharmaceutical companies have come out on top and have become impervious to generic suits. As such, consumers should petition their legislatures to change the laws.

One possible change would be a requirement that the patient be apprised at the pharmacist's window or at the doctor's office about her right to recourse (or lack thereof) if she were to be injured after taking a generic drug. This appraisal could be a document that the patient must sign, or could be a conspicuous warning on the packaging of the prescription. The appraisal would warn consumers that,

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133. In addition to financial compensation for injuries, compensation also serves as an incentive for the pharmaceutical companies to put the best product on the market with the most complete and accurate warning labels, lest they be sued.

if they are injured after taking a generic drug, they cannot receive compensation from the manufacturers. Consumers would therefore be knowledgeable about the risks they are taking when they ingest generic drugs. It is fundamentally unfair that consumers opt for or are forced into taking generic versions of drugs, correctly thinking that they are saving money for a bioequivalent product, only to be left completely without recourse in the unfortunate event that they are injured because of the manufacturers' failure to warn them of a potential danger. Warning consumers ahead of time about their legal options allows them to make informed decisions regarding to which risks they are willing to subject themselves.

Another possible change to generic substitution laws would be a requirement that the prescribing physician or dispensing pharmacist ask the patient if she would like the brand-name or generic version of the drug along with a brief appraisal, which may be in the form of a pamphlet, of the differences between the two, including the legal implications. This information would empower consumers to choose which medicine they ingest and to which risks they are willing to subject themselves, rather than having a generic substitution law make the determination for them, eliminating any possibility of recovery in a failure to warn or design defect situation.

Most radically, consumers could petition their legislatures to eliminate generic substitution laws altogether, leaving the decision of which medicine to dispense up to the prescribing physician or the consumer herself. However, this solution would be detrimental to consumers as a whole, who undeniably benefit from the greatly reduced cost of generic drugs in comparison to their brand-name counterparts. Additionally, if doctors are in the habit of writing the brand-name of a drug on the prescription, consumers could unwittingly pay much more in the long run.

Alternatively, consumers could petition their legislatures to have their states recognize innovator liability as a theory of recovery in the pharmaceutical context. The intricacies of innovator liability theory and the reasons for and against it are outside the scope of this Note,<sup>134</sup> but if courts recognized it as a theory for recovery, brand-name drug manufacturers would be liable to consumers who are injured after taking the generic equivalent of the drug, thus creating a just result.

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134. See, e.g., Martin A. Ramey, *Conte v. Wyeth: Caveat Innovator and the Case for Perpetual Liability in Drug Labeling*, 4 PITT. J. ENVTL. PUB. HEALTH L. 73 (2010).

## 2. Challenge the constitutionality of generic substitution laws

Another way to attack generic substitution laws and the unintended harm they do to consumers is to challenge the constitutionality of them. Either consumers or brand-name drug manufacturers could make this challenge, arguing that the laws are unconstitutional under the dormant Commerce Clause. This challenge would be similar to the argument made in *Lefkowitz*.<sup>135</sup> While the Second Circuit in *Lefkowitz* found the argument unconvincing in 1978, the outcome may be different if challenged today, given the current regulatory landscape and the size of the modern pharmaceutical industry.

Pursuant to the dormant Commerce Clause, states in some circumstances may not enact legislation that favors intrastate commerce at the expense of interstate commerce.<sup>136</sup> Under the Commerce Clause, “Congress is empowered to regulate and protect [and conversely, under the dormant Commerce Clause, states are prevented from burdensomely regulating] the instrumentalities of interstate commerce, or persons or things in interstate commerce . . . .”<sup>137</sup>

While the dormant Commerce Clause is typically implicated with regard to state laws that protect the economy of the state by facially discriminating against commerce from other states,<sup>138</sup> laws that are facially neutral in terms of their geographic protectionism may still be analyzed pursuant to the dormant Commerce Clause under a doctrine known as the *Pike* balancing test. Under the *Pike* test, a facially neutral state law may be unconstitutional if its advancement of local interests places a “clearly excessive” burden on out-of-state commerce.<sup>139</sup> To determine whether the burden is clearly excessive, courts balance the nature of the local interest against “whether it could be promoted . . . with a lesser impact on interstate activities.”<sup>140</sup> Two colorable arguments may be made that call into question whether generic substitution laws violate the dormant Commerce Clause: one from the brand-name drug manufacturers’ perspective and one from the consumers’ perspective.

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135. *Pharm. Soc’y of N.Y., Inc. v. Lefkowitz*, 586 F.2d 953, 955 (2d Cir. 1978).

136. *See, e.g., United Haulers Ass’n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 338–39 (2007).

137. *United States v. Lopez*, 514 U.S. 549, 558 (1995).

138. *See, e.g., United Haulers Ass’n*, 550 U.S. at 338–39.

139. *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970) (“Where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits.”).

140. *Id.*

In an effort to invalidate or change certain state generic substitution laws,<sup>141</sup> brand-name drug manufacturers may renew the arguments made in *Lefkowitz*, which was decided before the Hatch-Waxman Act paved the way for a dramatic increase in the market share of generic drugs. When *Lefkowitz* was decided, the Second Circuit found that the burden on interstate commerce created by generic substitution laws was not “clearly excessive” when compared to the benefits.<sup>142</sup> However, times have changed. In 1978, when *Lefkowitz* was decided, generic drugs comprised a significantly smaller percentage of the pharmaceutical industry.<sup>143</sup> Today, generic drugs dominate the marketplace.<sup>144</sup> In essence, generic substitution laws may not have placed a “clearly excessive” burden on interstate commerce in the 1970s; should this argument be renewed in 2016, however, at a time when pharmaceutical prescriptions, the vast majority of which are filled with generic drugs, is a massive industry,<sup>145</sup> a court may find the burden on interstate commerce to be clearly excessive.

Generic substitution laws routinely and unilaterally preclude the possibility of consumers from receiving brand-name drugs, undoubtedly a product of interstate commerce, for the sole purpose of saving consumers money at pharmacies, which undoubtedly benefits intrastate commerce. The *Pike* test balances the local interest against whether the goal could be achieved with a lesser burden on interstate commerce.<sup>146</sup> Concededly, saving in-state consumers significant amounts of money is a legitimate local interest; however, it nonetheless benefits intrastate commerce, raising a dormant Com-

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141. Since generic substitution laws differ in terms of their requirements and breadth from state to state, it may well be that one state’s generic substitution law has a better chance of being declared unconstitutional than another state’s. For example, a generic substitution law that *requires* that the prescription be filled with a generic drug, even over the patient’s protests, has more of an adverse effect on interstate commerce than a generic substitution law that merely *recommends* that the prescription be filled with a generic drug.

142. *Pharm. Soc’y of N.Y., Inc. v. Lefkowitz*, 586 F.2d 953, 957 (2d Cir. 1978).

143. While I cannot find data from 1978, in 1984, for example, generic drugs comprised a mere 18.6% of all drugs sold. CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 27 (1998), available at <http://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf>.

144. Generic drugs comprised 88% of all drugs sold in 2014. See *supra* text accompanying note 1.

145. In 2014, total spending on U.S. medicines was \$373.9 billion. Press Release, IMS Inst. For Healthcare Informatics, Highest-Ever Levels of Medicine Spending and Volume of Prescriptions Filled (Apr. 14, 2015), available at <http://www.imshealth.com/en/about-us/news/ims-health-study-2014-a-record%E2%80%93setting-year-for-u.s.-medicines>.

146. *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

merce Clause concern.<sup>147</sup> That end may be achieved by a means more narrowly tailored, such that the burden on interstate commerce is not clearly excessive. Here, the interstate commerce is the sale (or lack thereof) of brand-name drugs and the increased advertising that brand-name manufacturers must do<sup>148</sup> so that consumers ask for brand-name drugs and prescribers prescribe them, which would not be necessary if generic substitution laws did not force prescriptions to be filled with generic drugs as the default.

Just as this Note proposed in the previous “call to action” solution, the goal of generic substitution laws could still be achieved with a lesser burden on interstate commerce. For example, generic drugs could come with a warning label that apprises consumers that they lack recourse if they are injured after taking the drugs. Another way to lessen the impact on interstate commerce would be to require that pharmacists give patients the option between the brand and the generic versions of drugs, placing the decision in the patients’ hands.

Regardless of how it is achieved, any given generic substitution law could have a meaningfully lesser impact on interstate commerce if the law placed the ultimate decision of what drug to take in the hands of the consumer, such that the consumer is *choosing* to reap the benefits of generic drugs, rather than the law *forcing* brand-name manufacturers out of the market. It is a subtle distinction, but a brand-name manufacturer could argue that the distinction is necessary to narrowly tailor the law such that the burden on interstate commerce (the significantly decreased brand-name drug sales and the need for more advertising) is not clearly excessive in comparison to the local interest (saving in-state consumers money).

Alternatively, *consumers* can make a novel argument that generic substitution laws violate the dormant Commerce Clause. Consumers could do this by characterizing the trials that they cannot conduct and the judgments and settlements that they cannot receive as interstate commerce. If a consumer wants to file a generic suit in one of the vast majority of jurisdictions that does not recognize innovator liability, the consumer may argue that the generic substitution law that forced her to take the generic drug, and thus prevented her from receiving compensation for her injuries, violates the dormant

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147. See *supra* note 2 and accompanying text.

148. Brand-name drug manufacturers spend almost \$58 billion each year on advertising. Marc-André Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 PLOS MED. 29, 30 (2008).

Commerce Clause to the extent that the law prevents her from suing and settling or taking the case to trial.<sup>149</sup>

The consumer's argument would go as follows: the generic substitution law of the state in which the plaintiff/consumer resides essentially prevented the pharmacist from filling the plaintiff's prescription with a brand-name drug. Since the state in which this hypothetical lawsuit takes place does not recognize innovator liability, the result is that the plaintiff is powerless to recover from anyone for her injuries. The only situation in which the plaintiff can recover is if she took the brand-name version of the drug, which did not happen (and 88% of the time does not happen)<sup>150</sup> because of the generic substitution law. Therefore, the generic substitution law in effect prevents litigation from occurring. In all likelihood, the injured consumer resides in a different state than where the brand-name drug manufacturer is located.

The effect of this situation is that the generic substitution law, in making it difficult or impossible for the consumer to be prescribed the brand-name drug and thus preventing interstate litigation, prevents the possibility of a settlement crossing state lines, attorneys crossing state lines to conduct depositions, judgments from trials being entered in favor of a citizen of one state and against a company incorporated in another, and the collection of the judgment entered for said citizen and against said company. If one argues that litigation between parties who live in different states is interstate commerce, then the generic substitution laws in effect shut down this interstate commerce in its entirety, thereby violating the dormant Commerce Clause. Especially in this unique and sympathetic context of consumers who are left without recourse after taking a drug that they reasonably thought to be safe injures them, a judge deciding the issue could find that these burdens on interstate commerce are clearly excessive in comparison to the local benefits. And as was described in the previous dormant Commerce Clause argument,

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149. A threshold issue is whether litigation can even be considered interstate commerce in the first place. While there are no cases on point characterizing it as such, it would seem that litigation can indeed be considered interstate commerce, given the "instrumentalities," "persons," and "things" definition of interstate commerce. See *United States v. Lopez*, 514 U.S. 549, 558 (1995). With this broad, encompassing definition, and especially considering that litigation itself and lawsuits are a form of business and commerce for the attorneys and parties involved, it is possible that attorneys and parties crossing state lines to conduct depositions, trials, and meetings are "persons" in interstate commerce, and the verdicts and judgments regarding the rights and liabilities of parties from different states are "things" in interstate commerce.

150. *Supra* note 1.

under *Pike*, this burden on interstate commerce could be meaningfully lessened by having the consumer ultimately choose what drug to take, or by warning the consumer of her lack of available recourse.<sup>151</sup>

#### CONCLUSION

The regulatory landscape that has recently developed and controls the pharmaceutical industry is far from perfect. Consumers who are injured after taking generic drugs are powerless to recover for their injuries under failure to warn or design defect claims. While there are many moving parts to this regulatory landscape, the problem can be traced back to generic substitution laws, which all but force consumers to take generic drugs, thereby eliminating the possibility of recovery. With the market share of generic drugs increasing,<sup>152</sup> it is only fair that a change occurs so that patients can recover in generic suits. Whether it be through collective action to have legislatures change generic substitution laws, or challenging the constitutionality of the laws, these laws – or the effects of them – ought to change, so generic and brand-name drugs truly are the same.

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151. See discussion *supra* Part II.B.2.

152. See *GENERIC PHARM. ASS'N*, *supra* note 1.