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Hidden Risks of Taking Generic Drugs over Brand Name: The Impact of Drug Labeling Regulations on Injured Consumers and the Pharmaceutical Industry

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Hidden Risks of Taking Generic Drugs over Brand Name: The Impact of Drug Labeling Regulations on Injured Consumers and the Pharmaceutical Industry

By Samantha Koopman*

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I. INTRODUCTION

Over 100,000 people in the United States die each year due to “nonerror, adverse effects” of prescription drugs.¹ Most of the prescriptions being filled in the United States are generic. In 2012, eighty-four percent of dispensed prescriptions were generic and the amount of money spent on generic prescriptions increased by \$8 billion.² Because of recent changes in failure-to-warn claims against drug manufacturers, generic drug users who are injured by taking the drug are facing an unfortunate dilemma.

In 1984, federal law changed the way the pharmaceutical markets operate by making prescription drugs more affordable for consumers.³ But affordability comes at another cost. Because of the federal law preemption doctrine and gaps between state and federal labeling requirements, generic drug consumers who are injured by taking the drug are unable to sue the manufacturer for inadequate labeling, even though consumers injured by brand name drugs can sue the brand name manufacturer for the same inadequate labeling.⁴

The 1984 Drug Price Competition and Patent Term Restoration Act (Hatch–Waxman Act) allowed for generic drugs to obtain Food and Drug Administration (FDA) approval by showing that the generic drug is biologically equivalent to the brand name drug and that the labeling of the generic drug is the same as the

* Samantha Koopman is a second year student at Pepperdine University School of Law. Samantha graduated from Gonzaga University with a Bachelor of Business Administration in Accounting and Finance. I would like to thank editors Alice Won, Steve Dixon, and especially Emily Casey for all of their hard work and help to make this comment the best it could be. I also owe a huge thank you to God for an extremely blessed life full of great opportunities, my family for their unwavering belief in me as a student and a writer, my dog Stanley for his constant presence at my side while I wrote, and my fiancé Ryan for loving me, encouraging me, and bringing home Big Gulps and Reese’s on especially rough days. I love you guys!

¹ Barbara Starfield, *Is US Health Really the Best in the World?*, 284 J. AM. MED. ASS’N 483, 484 (2000), available at <http://www.drug-education.info/documents/iatrogenic.pdf>.

² *Id.*

³ 21 U.S.C. § 2(j) (2012).

⁴ PUBLIC CITIZEN, *GENERIC DRUG LABELING* 24 (2013), available at <http://www.citizen.org/documents/2138.pdf>.

approved labeling for the brand name drug.⁵ Many state laws have different requirements for generic and brand name drugs, so preemption issues arise. In *Wyeth v. Levine*, the U.S. Supreme Court held that federal drug regulations do not preempt state law failure-to-warn claims against the brand name manufacturers,⁶ but the Court in *PLIVA, Inc. v. Mensing* later held that federal drug regulations do preempt the same state law failure-to-warn claims against the manufacturers of generic drugs.⁷ In the recent *Mutual Pharmaceutical Co. v. Bartlett* case, the Court held that manufacturers of generic drugs cannot be sued under state law for design-defect claims because the state law is preempted by federal law.⁸

The impact of these cases is great on consumers who choose to take a generic drug over a name brand. Most people who buy prescription medication buy the generic brand when available.⁹ Often a brand name manufacturer will stop selling its drug once the generic brand enters the market.¹⁰ And all states allow the substitution of the generic drug for the brand name, with some states even requiring the substitution.¹¹ These decisions impact administrative law by making it clear that Congress and the FDA need to change the regulations governing manufacturers of generic brands so that consumers have a remedy under state tort law when they choose to save money by purchasing generic brand prescriptions instead of their brand name counterparts. If generic manufacturers are able to unilaterally change their drug labels, they could keep up with new warnings without having to rely on brand name

⁵ See *supra*, note 3.

⁶ *Wyeth v. Levine*, 555 U.S. 555 (2009).

⁷ *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

⁸ *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

⁹ See *Mensing*, 131 S. Ct. at 2584 (citing DEPT. OF HEALTH AND HUMAN SERVS., ASPE ISSUE BRIEF: EXPANDING THE USE OF GENERIC DRUGS 7 (2010), available at <http://aspe.hhs.gov/sp/reports/2010/GenericDrugs/ib.pdf>).

¹⁰ *Id.* (citing Brief for Marc T. Law et al. as Amici Curiae Supporting Respondents at 18, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (No. 09-993)).

¹¹ *Id.* at 2583 (citing Thomas P. Christensen et al., *Drug Product Selection: Legal Issues*, 41 J. AM. PHARM. ASS'N 868, 869 (2001); DEPT. OF HEALTH AND HUMAN SERVS., *supra* note 9, at 7). States that require substitution when possible are Florida, Hawaii, Kentucky, Maine, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, New York, Pennsylvania, Rhode Island, Tennessee, Vermont, and West Virginia. See *infra* note 53.

manufacturers. Such a change would likely prompt the Court to change its position as well.¹²

This comment will explain how claims against drug manufacturers may or may not be preempted depending on whether the drug that caused the injury was a brand name or generic drug, and will suggest several ways that the seemingly incongruous results of these claims can be balanced for injured patients. Part II explains the historical progression of federal drug labeling laws and the differences between state generic substitution laws. Part III describes the federal preemption doctrine and failure-to-warn claims under state law. Part IV examines recent case law from the Supreme Court concerning the applicability of federal drug regulations to brand name and generic drug manufacturers. Part V assesses the innovator liability theory proposed by some courts and the implications of the theory for drug manufacturers. Part VI considers the impact the recent Court decisions may have on generic drug substitution. Part IV proposes various ways that the options for patients injured by prescription drugs can be improved.

II. FEDERAL REGULATORY FRAMEWORK OF THE PHARMACEUTICAL INDUSTRY

A. *Early Drug Regulation—The Food and Drug Administration and the Federal Food, Drug, and Cosmetic Act*

The FDA was created to enhance public health and protect consumers by regulating food and drugs in the United States.¹³ The FDA's regulatory duties began with the Pure Food and Drugs Act, which was passed by Congress in 1906.¹⁴ It provided basic elements of food and drug protection,¹⁵ but did not require any federal

¹² See *infra* Part VII.A–B.

¹³ *History*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm> (last updated May 29, 2013).

¹⁴ *Legislation*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Legislation/default.htm> (last updated July 9, 2012).

¹⁵ *FDA History—Part I*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054819.htm> (last updated June 18, 2009). The 1906 Food and Drug Act banned interstate transport of illegal food and drugs and regulated drug labeling by requiring drugs to be

approval or notification procedures for new drugs prior to their placement in the pharmaceutical market.¹⁶ In 1938, the pharmaceutical market was revolutionized by the passage of the Federal Food, Drug, and Cosmetic Act (FDCA).¹⁷ Enacted in response to the death of 107 people after those people took a legally marketed drug,¹⁸ the FDCA's purpose was to create a notification system where brand name drug manufacturers were required to provide safety data to the FDA in a new drug application (NDA).¹⁹ The FDCA gave authority to the FDA to prevent a new drug from entering the market if the drug's safety was not properly demonstrated.²⁰ The NDA required extensive information from brand name drug manufacturers, including:

- (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use;
- (B) a full list of the articles used as components of such drug;
- (C) a full statement of the composition of such drug;
- (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;
- (E) such samples of such drug and of the articles used as components thereof as the Secretary may require;
- (F) specimens of the labeling proposed to be used for

labeled in accordance with specific standards. *Id.* Food and drug labels were not allowed to be misleading or untrue and certain "dangerous" ingredients had to be listed on the label. *Id.*

¹⁶ 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).

¹⁷ See *Legislation*, *supra* note 14.

¹⁸ *Id.*; see Carol Ballentine, *Sulfanilamide Disaster*, U.S. FOOD & DRUG ADMIN.,

<http://www.fda.gov/aboutfda/whatwedo/history/productregulation/sulfanilamidedisaster/default.htm> (last updated Oct. 7, 2010) (describing the 1937 Elixir Sulfanilamide Incident, in which more than 100 people in fifteen states died from ingesting a sulfanilamide elixir mixed with diethylene glycol, which turned out to be a deadly poison but was not realized before the medication was distributed to patients because food and drug laws at the time did not require safety studies to be done on new drugs).

¹⁹ Kelly, *supra* note 16, at 419.

²⁰ *Id.*

such drug; and (G) any assessments required under section 335c of this title.²¹

Applicants must also describe all of their experiences and observations during all phases of development and ownership, including descriptions and analyses of any information material to the safety and effectiveness of the drug.²²

In 1962, the FDA's regulatory authority was reinforced by the passage of the Keflauer–Harris Amendments,²³ which changed the drug safety review procedure from a simple notification process to a more complex approval system.²⁴ The amendments shifted the burden of proof from the FDA to the drug manufacturers by forcing manufacturers to show that their drugs were safe for use before the drug could be marketed.²⁵ Under the new law, the NDA was “the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S.”²⁶ Application approval required the manufacturer to submit reports showing: (1) that the drug is safe and effective for use; (2) the components and composition of the drug; (3) the methods, facilities, and controls used to manufacture, process, and pack the drug; (4) samples of the drug and its components; (5) examples of the drug's proposed label; and (6) research on pediatric use, if applicable.²⁷ Once the manufacturer submitted its application, the FDA would either approve the drug or give the manufacturer an opportunity for a hearing on whether the application may be approved.²⁸

After the passage of the 1962 Drug Amendments, the FDA implemented numerous procedures governing the approval of generic drugs. Under the updated procedures, a generic drug manufacturer of a pre-1962 brand name drug submitted an abbreviated new drug application (ANDA), which required data demonstrating that the

²¹ 21 U.S.C. § 355(b)(1) (2012).

²² 21 C.F.R. § 314.50(d)(5)(iv) (2014).

²³ See *Legislation*, *supra* note 14.

²⁴ Kelly, *supra* note 16, at 420.

²⁵ 21 U.S.C. § 355(d).

²⁶ *New Drug Application*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/> (last updated Feb. 21, 2013).

²⁷ 21 U.S.C. § 355(b)(1).

²⁸ *Id.* § 355(c)(1).

generic drug was as safe and effective as its brand name counterpart.²⁹ Generic manufacturers of post-1962 brand name drugs had to submit the entire NDA, although the FDA did allow for generic manufacturers to use published scientific literature to demonstrate safety and effectiveness rather than require them to perform their own clinical trials, as was required of the brand name drug manufacturers.³⁰

In 1983, the FDA proposed a new regulation that would allow for generic drug manufacturers of post-1962 brand name drugs to only have to complete the ANDA process. At the same time, the generic drug manufacturers filed a lawsuit against the FDA, hoping to force the FDA to create an ANDA process for all generic drug manufacturers.³¹ Eventually, Congress resolved the controversy surrounding generic drug approval by passing the Hatch–Waxman Act.³²

B. *The Hatch–Waxman Act*

Amid complaints and controversy surrounding the differing procedures for generic drug manufacturers trying to get drugs approved for marketing,³³ Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984³⁴ that “effectively created the modern generic pharmaceutical industry.”³⁵ The Act, commonly known as the Hatch–Waxman Act, was designed to balance two competing interests: to encourage brand name pharmaceutical companies to continue investing in the research and development of new drugs while also increasing competition among

²⁹ Kelly, *supra* note 16, at 420.

³⁰ *Id.*

³¹ *Id.*; see Nat’l Ass’n of Pharm. Mfrs., Inc. v. Heckler, 83 Civ. 4817 (WCC) (S.D.N.Y. 1983). This case was dismissed once the Hatch–Waxman Act was enacted because the Act superseded all prior FDA regulations regarding the generic drug approval process. Kelly, *supra* note 16, at 420.

³² Kelly, *supra* note 16, at 420.

³³ *Id.*

³⁴ 21 U.S.C. § 301 (2012).

³⁵ Matthew Avery, *Continuing Abuse of the Hatch–Waxman Act by Pharmaceutical Patent and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 175 (2008).

generic drug manufacturers in the pharmaceutical market as a way to lower drug prices and costs to consumers.³⁶

A Report by the House Committee on Energy and Commerce analyzed the ANDA procedure and patent term restoration pieces of the Act.³⁷ Congress's goal was to lower the cost of drug prices for consumers by making it easier for generic drugs to enter the pharmaceutical market.³⁸ The House Report remarked that full NDAs, which required human clinical studies, were not valuable or efficient for the generic manufacturer. Instead, the FDA recognized that requiring the manufacturers to repeat the testing would be "unnecessary and wasteful [as well as] unethical because it requires that some sick patients take placebos and be denied treatment known to be effective"³⁹ The Report also acknowledged that most drugs at the time had expired patents but no generic equivalent, demonstrating a need for a process to increase the presence of generic drugs in the market.⁴⁰ Additionally, the Report determined that increased availability of generic drugs would "save American consumers \$920 million over the next 12 years," and would save federal and state governments millions of dollar as well.⁴¹

Congress's other goal of incentivizing research companies to develop new drugs was an effort to "restor[e] some of the time lost on patent life while the product is awaiting pre-market approval."⁴² Although the patent term was seventeen years, the effective patent term was shorter because of the requirements of the regulatory review process.⁴³ Congress adopted the ANDA procedures and patent term restoration in the Act to help solve some of these problems.

³⁶ Kelly, *supra* note 16, at 417. See H.R. REP. NO. 98-857, pt. 1 (1984), for Congress's reasoning in passing the Act. "Congress aimed to increase generic drug entry into the pharmaceutical market in order to drive down drug prices and consumer drug costs. . . . [I]t was not beneficial or efficient for generic drug manufacturers to submit full NDAs," and there was a "need for a streamlined process to increase the number of generic drugs on the market." Kelly, *supra* note 16, at 421.

³⁷ H.R. REP. No. 98-857, pt. 1 (1984).

³⁸ *Id.*

³⁹ *Id.* at 16.

⁴⁰ *Id.* at 17.

⁴¹ *Id.*

⁴² *Id.* at 15.

⁴³ *Id.* at 17.

The Hatch–Waxman Act amended a portion of the FDCA by allowing all generic drug manufacturers to use an ANDA to prove the safety and effectiveness of their drugs.⁴⁴ The ANDA requires generic drug manufacturers to show that their new generic drug

is bioequivalent to the [brand name] drug[,] . . . that the active ingredients of the new drug are of the pharmacological or therapeutic class as those of the [brand name] drug, . . . and the new drug can be expected to have the same therapeutic effect as the [brand name] drug when administered to patients for [the same] condition⁴⁵

Because of the changes Congress put into place, the cost of bringing a generic drug to the market is less than \$2 million, almost a quarter of the typical cost of bringing a brand name drug to market.⁴⁶

Additionally, brand name drug manufacturers must conduct human tests to show that the drug is safe and effective, and must submit those results in an NDA.⁴⁷ However, generic drug manufacturers are no longer required to provide their own clinical trial data to show safety and efficacy, and are able to use the brand name drug’s clinical trial data instead.⁴⁸ This new regulatory system under Hatch–Waxman is designed to guarantee the quality of generic drugs, simplify the approval process, reduce unnecessary time and money sunk into repetitive clinical trial research, and lessen the time to get the drugs on the market.⁴⁹

C. Drug Substitution Laws

In an effort to help consumers save money on prescription drug costs, states have put substitution policies into place that allow

⁴⁴ Avery, *supra* note 35, at 175.

⁴⁵ 21 U.S.C. § 355(j)(2)(A)(iv) (2012).

⁴⁶ DEPT. OF HEALTH & HUMAN SERVS., ASPE ISSUE BRIEF: EXPANDING THE USE OF GENERIC DRUGS 4–5 (2010), available at <http://aspe.hhs.gov/sp/reports/2010/GenericDrugs/ib.pdf>.

⁴⁷ Danielle L. Steele, *The “Duty of Sameness” as a Shield—Generic Drug Manufacturers’ Tort Liability and the Failure of the Need for Label Independence After PLIVA, Inc. v. Mensing*, 43 SETON HALL L. REV. 441, 448 (2013).

⁴⁸ Avery, *supra* note 35, at 176.

⁴⁹ *Id.*

pharmacists to dispense cheaper generic equivalents for brand name drugs; that is, when a physician fills out a prescription, he or she has the option of requiring the brand name be dispensed.⁵⁰ If the physician does not specify that the brand name drug is required, state laws step in to explain when substitution is allowed. Eleven states require express permission for substitution.⁵¹ The other thirty-nine states allow generic substitution unless the physician expressly forbids it.⁵² When substitution is allowed, some states require

⁵⁰ See, e.g., CAL. BUS. & PROF. CODE § 4052.5(b) (West 2013) (“In no case shall a [generic substitution] be made . . . if the prescriber personally indicates, either orally or in his or her own handwriting, ‘Do not substitute’ or words of similar meaning.”); KY. REV. STAT. ANN. § 217.822(1) (West 2013) (“When a pharmacist receives a prescription for a brand name drug . . . he shall select a lower priced therapeutically equivalent drug”); see also *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2583 (2011) (Sotomayor, J., dissenting) (“[A]ll States ‘allow the physician to specify that the brand name must be prescribed, although with different levels of effort from the physician.’”).

⁵¹ Oklahoma forbids substitution of the generic equivalent without the physician’s authority. See OKLA. STAT. ANN. tit. 59, § 353.13(D) (West 2013). Alabama, Delaware, Indiana, Missouri, South Carolina, Utah, and Washington all require physicians to sign on one of two lines to indicate that he or she permits or forbids substitution of the generic equivalent. See ALA. CODE § 34-23-8(4) (2014); DEL. CODE ANN. tit. 24, § 2549(a)(1), (c) (2014); IND. CODE ANN. §§ 16-42-22-6, 16-42-22-8(a)(1) (West 2013); MO. REV. STAT. § 338.056 (2013); S.C. CODE ANN.

§ 39-24-40(b) (2013); UTAH CODE ANN. § 58-17b-605(6)(a) (West 2013); WASH. REV. CODE ANN. § 69.41.120 (West 2013). Maine requires physicians to check a box to indicate that substitution of the generic equivalent is forbidden. See ME. REV. STAT. ANN. tit. 32, § 13781 (2013). New York requires physicians to write “d a w” (meaning “dispense as written”) to prohibit substitution of the generic equivalent. See N.Y. EDUC. LAW § 6810(6)(a) (McKinney 2014). Pennsylvania requires physicians to write “brand necessary” or “brand medically necessary” on the prescription to indicate that substitution of the generic equivalent is forbidden. See 35 PA. CONS. STAT. ANN. § 960.3(a) (West 2014).

⁵² The states that allow generic substitution unless expressly forbidden by the physician are Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming. See, e.g., ARIZ. REV. STAT. ANN. § 32-1963.01(A) (2014) (“If a medical practitioner prescribes a brand name drug and does not indicate an intent to prevent substitution . . . a pharmacist may fill the prescription with a generic equivalent drug.”); MASS. GEN. LAWS ANN. ch. 112, § 12D (West 2014) (“Except in cases where the practitioner has indicated ‘no substitution’, the pharmacist shall dispense a less expensive, reasonably available, interchangeable drug product . . .”).

pharmacists to make the substitution when possible,⁵³ while other states merely allow the pharmacist to make the substitution.⁵⁴ States also differ on what kind and what amount of patient notice is required before substituting a generic drug. Ten states do not require any patient notice before the pharmacist substitutes a generic drug.⁵⁵ In Arizona, the pharmacist does not have to inform the patient of the substitution if a third party reimburses the drug.⁵⁶ In Iowa and Ohio, the pharmacist does not have to inform the patient of the substitution if public funding reimburses the drug.⁵⁷ Five states require patient notice of substitution, but do not give the patient the right to refuse the generic drug.⁵⁸ Twenty-nine states require the pharmacist to

⁵³ The states that require substitution when possible are Florida, Hawaii, Kentucky, Maine, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, New York, Pennsylvania, Rhode Island, Tennessee, Vermont, and West Virginia. *See, e.g.*, FLA. STAT. ANN. § 465.025(2) (West 2013) (“A pharmacist who receives a prescription for a brand name drug shall, unless requested otherwise by the purchaser, substitute a less expensive, generically equivalent drug product . . .”); 35 PA. STAT. ANN. § 960.3(a) (West 2014) (“Whenever a pharmacist receives a prescription for a brand name drug, the pharmacist shall substitute a less expensive generically equivalent drug unless requested otherwise by the purchaser or indicated otherwise by the prescriber.”).

⁵⁴ The states that allow, rather than require, the pharmacist to make substitutions are Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Georgia, Illinois, Indiana, Iowa, Kansas, Michigan, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Mexico, North Carolina, North Dakota, Ohio, Oregon, South Carolina, South Dakota, Texas, Utah, Virginia, Washington, Wisconsin, and Wyoming. *See, e.g.*, ALA. CODE § 34-23-8(1) (2014) (“A licensed pharmacist in this state shall be permitted to select for the brand name drug product . . . a less expensive pharmaceutically and therapeutically equivalent drug product . . .”); DEL. CODE ANN. tit. 24, § 2549(a) (West 2014) (“When a pharmacist receives a prescription drug order from a practitioner for a brand name or trade name drug, the pharmacist may dispense a therapeutically equivalent drug . . .”). The statutes in Idaho, Louisiana, and Oklahoma are unclear. IDAHO ADMIN. CODE r. 27.01.01.185 (2013); LA. REV. STAT. ANN. § 37:1241 (2013); OKLA. STAT. ANN. tit. 59, § 353.13(D) (West 2013).

⁵⁵ The states that do not require patient notification are Alabama, Illinois, Kansas, Maryland, Massachusetts, Michigan, New Mexico, New York, North Carolina, and Wyoming. *See, e.g.*, MD. CODE ANN., HEALTH-GEN. § 15-118(a) (West 2014); WYO. STAT. ANN. § 33-24-148 (West 2013).

⁵⁶ ARIZ. REV. STAT. ANN. § 32-1963.01(B) (2013).

⁵⁷ IOWA CODE ANN. § 155A.32(2)(b) (West 2013); OHIO REV. CODE ANN. § 4729.38 (West 2013).

⁵⁸ CAL. BUS. & PROF. CODE §§ 4052.5(e), 4073(e) (West 2014); COLO. REV. STAT. § 12-42.5-122(3) (West 2014); DEL. CODE ANN. tit. 24, § 2549(a)(2) (West

notify the patient of the substitution, which the patient may refuse.⁵⁹ Maine, Tennessee, and Vermont require the pharmacist to notify the patient of the substitution, which the patient may refuse, but if he refuses the substitution he must pay the additional costs of the brand name drug out-of-pocket.⁶⁰

There are many advantages to allowing generic drug substitution. Generic drugs are just as effective as brand name drugs.⁶¹ Generic drugs are required to have the same dosage, safety, strength, quality, purity, and stability as brand name drugs; generic drugs must work the same, must be taken the same, and must be used the same way as their brand name equivalents.⁶² Generic drug substitution lowers healthcare costs for both insurance companies and patients.⁶³ If substitution for a generic drug happened in every possible situation, costs could be reduced by an estimated \$1.2 billion annually for patients and \$7.7 billion for health care systems.⁶⁴ Another advantage is that generic substitution makes patients more likely to stick with their drug regime; when substitution is not allowed, the chance that a patient will not purchase the drug at all

2014); IND. CODE ANN. § 16-42-22-8(a)(2) (West 2013); VA. CODE ANN. § 54.1-3408.03 (West 2013).

⁵⁹ The states that require patient notification of substitution, which the patient may refuse, 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. *See, e.g.*, GA. CODE ANN. § 26-4-81(f) (West 2013) (“A patient for whom a prescription drug order is intended may instruct a pharmacist not to substitute a generic name drug in lieu of a brand name drug.”); WASH. REV. CODE ANN. § 69.41.130 (West 2013) (“Unless the brand name drug is requested by the patient or the patient’s representative, the pharmacist shall substitute an equivalent drug product . . .”).

⁶⁰ ME. REV. STAT. ANN. tit. 32, § 13781 (2013); TENN. CODE ANN. § 53-10-205(d) (2013); VT. STAT. ANN. tit. 18, § 4605 (West 2013).

⁶¹ *Generic Drugs: Questions and Answers*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm> (last updated Sept. 3, 2013).

⁶² *Id.*

⁶³ William H. Shrank et al., *The Consequences of Requesting “Dispense as Written,”* 124 AM. J. MED. 309, 311 (2011). Patients and their insurance companies spent an average of \$17.90 and \$26.67, respectively, on generic drugs and an average of \$44.50 and \$135.26, respectively, for brand name drugs with a generic equivalent. *Id.*

⁶⁴ *Id.* at 314.

increases by 42% and the chance that a patient will not continue to refill the prescription increases by 61% when compared to situations where generic substitution is allowed.⁶⁵

III. FEDERAL PREEMPTION DOCTRINE AND FAILURE-TO-WARN CLAIMS

The Hatch–Waxman Act caused significant growth in the pharmaceutical market by increasing the number of generic drugs available to consumers.⁶⁶ Prior to the Act, “only 35[%] of the top-selling drugs with expired patents . . . had generic versions available. Today, nearly all do.”⁶⁷ Such success, however, has placed a burden on the FDA to ensure that safety requirements are sufficient to protect consumers.⁶⁸

A. Federal Preemption of State Laws

The Supremacy Clause in Article VI, clause two of the U.S. Constitution gives rise to the doctrine of federal preemption.⁶⁹ Under this doctrine, federal law may expressly or impliedly preempt state law and cause the state law to have no effect.⁷⁰ State law preemption occurs in one of three ways: first, Congress may pass a statute that explicitly defines how it preempts state law;⁷¹ second, Congress may pass a statute that, although lacking expressly preemptive terms, implies its occupation of an entire field of regulation and does not

⁶⁵ *Id.* at 313.

⁶⁶ Steele, *supra* note 47, at 459.

⁶⁷ *Id.* (alteration in original) (quoting CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 17 (July 1998), available at <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/6xx/doc655/pharm.pdf>).

⁶⁸ *Id.*

⁶⁹ U.S. CONST. art. VI, cl. 2 (“This Constitution, and the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”).

⁷⁰ Chamberlan v. Ford Motor Co., 314 F. Supp. 2d 953 (N.D. Cal. 2004).

⁷¹ Abbot v. Am. Cyanamid Co., 844 F.2d 1108, 1111 (4th Cir. 1988); *see, e.g.*, Shaw v. Delta Air Lines, Inc., 463 U.S. 85 (1983) (finding that a New York human rights law was preempted by a federal benefit plan based on the federal law’s plain language, structure, and legislative history).

allow states to regulate any aspect of the area;⁷² and third, Congress may pass a statute that neither expressly nor impliedly preempts state law, but state law is still preempted to the extent that the state law conflicts with the federal law.⁷³ Such conflict occurs when it is impossible to be in compliance with both the state and federal laws,⁷⁴ or when state law hinders the achievement of a federal purpose.⁷⁵

There is, however, a presumption against state law preemption in areas that the states have traditionally occupied.⁷⁶ One such area is the protection of health and safety.⁷⁷ The presumption is that states have the power to regulate matters of health and safety unless the government demonstrates a “clear and manifest purpose” to preempt state law.⁷⁸ Therefore, Congress or the FDA must provide a “clear indication” of an intention to preempt, or the anti-preemption presumption will apply to state products liability claims.⁷⁹

Since the federal requirements as outlined by the Hatch–Waxman Act are different for name brand drug manufacturers and generic drug manufacturers, a manufacturers’ liability case revolves around whether the drug in question is brand name or generic.⁸⁰ This intrinsic struggle between federal regulations and states’ own drug safety laws creates problems, both for manufacturers trying to follow the rules and unassuming consumers.

⁷² *Abbot*, 844 F.2d at 1111; *see, e.g.*, *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947) (holding that an act passed by Congress in a field traditionally occupied by the States preempted Illinois law).

⁷³ *Abbot*, 844 F.2d at 1111.

⁷⁴ *Id.*; *see also* *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963) (“The test of whether both federal and state regulations may operate, or the state regulation must give way, is whether both regulations can be enforced without impairing the federal superintendence of the field, not whether they are aimed at similar or different objectives.”).

⁷⁵ *Abbot*, 844 F.2d at 1111; *see, e.g.*, *Hines v. Davidowitz*, 312 U.S. 52 (1941) (finding that the federal government has superior authority in the field of alien registration, so state regulations cannot “conflict or interfere with, curtail or complement, . . . or enforce additional or auxiliary regulations” in that area).

⁷⁶ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

⁷⁷ *Id.*

⁷⁸ *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985).

⁷⁹ *Id.* at 716.

⁸⁰ Suzanne Kaplan, *Brand Name or Generic? The Choice Determines Your Legal Options When the Drug is Defective*, WESTLAW J. PROD. LIAB. (2013), 2013 WL 3984301, at *1.

B. Failure-to-Warn Claims Under State Law

State law failure-to-warn claims usually look to the Restatement (Second) of Torts for direction.⁸¹ The Restatement applies “where the defective condition of the product makes it unreasonably dangerous to the user or consumer.”⁸² Sellers must provide directions or warnings on product containers to ensure that the products are not unreasonably dangerous.⁸³ Some products—namely drugs—cannot possibly be made safe, even when used in the intended way, but their use may be justified even with the high degree of risk involved.⁸⁴ If the drug is prepared properly and gives adequate warning to its consumer, it is not considered unreasonably dangerous.⁸⁵ Sellers of drugs with proper preparation and warning cannot be held to strict liability for the consequences of taking the drug.⁸⁶

⁸¹ RESTATEMENT (SECOND) OF TORTS § 402A (1965).

⁸² *Id.* at cmt. i. Many food and drug products can never be entirely safe for consumption by all people. An unreasonably dangerous product is one that is “dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.” *Id.* For example, regular butter is not unreasonably dangerous just because its ingestion may cause cholesterol build-up in a person’s arteries and eventually lead to a heart attack. Butter *would* be unreasonably dangerous, however, if it was contaminated with poisonous fish oil. *Id.*

⁸³ *Id.* at cmt. j. Sellers do not have a duty to warn against common allergies, but if the product contains an ingredient that a large number of people are allergic to and the ingredient is either not generally known to be dangerous or not reasonably expected to be found in the product, the seller must warn against it if he has, or should have, knowledge of the ingredient and its danger. *Id.* Sellers do not have a duty to warn consumers about a product or ingredient if it is only dangerous when consumed in excess or over a long period of time, or if the danger is generally known. *Id.*

⁸⁴ *Id.* at cmt. k.

⁸⁵ *Id.*

⁸⁶ *Id.*

IV. LEGAL REMEDIES FOR PRESCRIPTION DRUG CONSUMERS

Three recent Supreme Court cases addressed the issue of federal preemption of state tort liability claims regarding label requirements for brand name and generic manufacturers.⁸⁷

A. Wyeth v. Levine

In April 2000, Diana Levine was at Northeast Washington County Community Health, Inc. (Health Center) to receive treatment for a migraine headache.⁸⁸ Levine suffered nausea as a result of the migraine, so the Health Center administered an intramuscular injection of Phenergan, the brand name drug for an antihistamine manufactured by Wyeth called promethazine hydrochloride.⁸⁹ When the first injection did not provide any relief, the Health Center administered a second injection of Phenergan intravenously.⁹⁰ The drug inadvertently entered Levine's artery and came into contact with her blood.⁹¹ Levine developed gangrene and her right forearm had to be amputated.⁹² Because of the amputation, Levine suffered significant medical expenses and was no longer able to perform as a professional musician.⁹³

The Court in *Wyeth* addressed the issue of whether federal drug regulations applicable to brand name drug manufacturers preempt state law failure-to-warn claims against drug manufacturers for failure to properly warn consumers about the risks of taking the drug.⁹⁴ The Court held in a 6–3 decision that federal drug regulations *do not* preempt state law failure-to-warn claims against brand name drug manufacturers.⁹⁵

Justice Stevens explained that federal law did not preempt Levine's state tort claim because of the two bases of the preemption

⁸⁷ *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011); *Wyeth v. Levine*, 555 U.S. 555 (2009).

⁸⁸ *Levine v. Wyeth*, 944 A.2d 179, 182 (Vt. 2006), *aff'd*, 555 U.S. 555 (2009).

⁸⁹ *Wyeth*, 555 U.S. at 559.

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.* at 563.

⁹⁵ *Id.* at 581.

doctrine.⁹⁶ First and foremost is the purpose of Congress.⁹⁷ Second, in areas where states have traditionally occupied, we must assume that the police powers of the state are not preempted by federal law unless it is Congress's "clear and manifest purpose" to preempt those powers.⁹⁸ In reviewing the history of federal regulation of drug laws and labeling,⁹⁹ the Court found that Congress acted to preserve state law.¹⁰⁰ A provision of the 1962 Keflauer–Harris Amendments to the FDCA suggested that only a conflict between state law and the FDCA would cause the state law to be preempted.¹⁰¹ Under that provision, state tort claims "continued unabated despite . . . FDA regulation."¹⁰² Additionally, in 1976, Congress passed an express preemption provision for medical devices,¹⁰³ but chose not to do so for prescription drugs, indicating that Congress did not intend to preempt state law in that area.¹⁰⁴

The Court rejected Wyeth's argument that it was impossible to comply with both the state and federal laws' labeling requirements.¹⁰⁵ "[T]he FDA's belief that a drug is misbranded is not conclusive," the Court stated, "And the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to the [changes being effected] regulation is difficult to accept"¹⁰⁶ The Court explained that the FDA was not the primary authority responsible for drug labeling; "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times."¹⁰⁷ The manufacturer is the one held accountable for ensuring that a drug's label is, and remains, adequate.¹⁰⁸

The Court also rejected Wyeth's argument that state law obstructs Congress's intent to balance competing interests.¹⁰⁹ The

⁹⁶ *Id.* at 565.

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *See supra* Part II.

¹⁰⁰ *Wyeth*, 555 U.S. at 567.

¹⁰¹ *Id.*

¹⁰² *Id.* (quoting *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 340 (2008)).

¹⁰³ *See* 21 U.S.C. § 360k(a) (2012).

¹⁰⁴ *Wyeth*, 555 U.S. at 567.

¹⁰⁵ *Id.* at 568.

¹⁰⁶ *Id.* at 570.

¹⁰⁷ *Id.* at 570–71.

¹⁰⁸ *Id.* at 571.

¹⁰⁹ *Id.* at 573.

lack of federal remedy for consumers injured by unsafe drugs in the original statute or its amendments suggests that Congress deemed state rights of action to be sufficient relief.¹¹⁰ Congress may have also determined that remedies under state law give consumers more protection by encouraging manufacturers to produce safe drugs with appropriate warnings.¹¹¹ Congress's silence on express preemption, along with its understanding of the state law claims, indicates that it did not intend for the FDA to be the sole governing authority of drug safety.¹¹² "If Congress thought state-law suits posed an obstacle to its objective, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history."¹¹³

After the *Levine* decision, courts routinely held that federal drug labeling regulations did not preempt state law requirements for adequate drug labeling of brand name drugs.¹¹⁴ However, courts were unsure of how to deal with the issue of preemption concerning generic drugs.¹¹⁵ In 2011, the Supreme Court resolved the issue in a 5–4 decision in *Mensing*.¹¹⁶

B. PLIVA, Inc. v. Mensing

Gladys Mensing and Julie Demahy were each prescribed the drug Reglan in 2001 and 2002, respectively.¹¹⁷ Both women received the generic version of Reglan, metoclopramide, from their pharmacists.¹¹⁸ After taking the drug for several years, each woman developed tardive dyskinesia, a severe neurological disorder.¹¹⁹

The majority in *Mensing* addressed the issue of whether federal drug regulations applicable to generic drug manufacturers preempt state law claims.¹²⁰ The Court held that the federal drug

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.* at 575.

¹¹³ *Id.* at 574.

¹¹⁴ Steele, *supra* note 47, at 478.

¹¹⁵ See *Demahy v. Activis, Inc.*, 593 F.3d 428, 431 n.7 (5th Cir. 2010) (showing a split among circuit courts on the question of federal preemption of state law for generic drugs).

¹¹⁶ *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

¹¹⁷ *Id.* at 2573.

¹¹⁸ *Id.*

¹¹⁹ *Id.* at 2572–73.

¹²⁰ *Id.* at 2572.

regulations *do* preempt the same state law claims against generic drug manufacturers.¹²¹ The Court found that, in this case, it was impossible for the metoclopramide manufacturers to meet the requirements of both the state and federal labeling laws.¹²² Justice Thomas explained that state laws required the manufacturers to include a safer label to metoclopramide, but federal law ordered generic manufacturers to include the same label on their drugs as their brand name counterparts.¹²³ Therefore, the generic manufacturers could not have satisfied both the requirements of the state and federal drug labeling laws without additional action, such as asking the FDA to change the label of the brand name drug.¹²⁴

The Court considered whether conflict preemption should take into account possible actions the FDA and brand name drug manufacturers could take to allow the generic drug counterparts to satisfy both state and federal laws without changing the law.¹²⁵ Federal law does not tell generic drug manufacturers what exactly to put on the labels; it merely requires that the generic drug label match the associated brand name drug's label.¹²⁶ Consequently, generic manufacturers could come into compliance with federal law if they could compel the FDA and the brand name drug manufacturer to change the label on the brand name drug to fulfill the state law labeling requirements that the generic manufacturers are subject to.¹²⁷

If the Court were to require generic drug manufacturers to convince the FDA to change brand name drug labels, then it would no longer be impossible for the generic manufacturers to comply with both state and federal labeling laws.¹²⁸ But the Court rejected that proposition: "If 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."¹²⁹ The text of the Supremacy Clause "plainly

¹²¹ *Id.* at 2581.

¹²² *Id.* at 2577–78.

¹²³ *Id.* at 2578.

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.* at 2579.

¹²⁹ *Id.*

contemplates conflict pre-emption” and “suggests that federal law should be understood to impliedly repeal conflicting state law.”¹³⁰

A party establishes preemption when the “ordinary meaning” of the federal law disallows the party from acting independently to accomplish state law requirements.¹³¹ In this case, the generic manufacturers could not meet state law requirements without the “special permission and assistance” of the federal government.¹³² Thus, the claims of the generic manufacturers were preempted.¹³³

The Court acknowledged the fact that it makes little sense, from a consumer’s perspective, to rule that federal regulations preempt in this case but not in *Wyeth*; however, the Court reasoned that it could not disregard the Supremacy Clause simply to please the consumer.¹³⁴ Unlike the generic manufacturers in *Mensing*, the brand name manufacturers in *Wyeth* could have changed their labels to meet state law guidelines without the assistance of the FDA.¹³⁵ Had the injured consumers taken the brand name drug instead of the generic, state law would control; but because their pharmacists substituted the generic drug—an action that is allowed and sometimes required by state law—federal law governs these claims.¹³⁶ Unfortunately for *Mensing*, *Demahy*, and other similarly situated generic drug consumers, federal drug regulations place injured generic drug consumers in the losing position.¹³⁷

The dissenting opinion, authored by Justice Sotomayor, viewed the issue of preemption differently.¹³⁸ She argued that federal preemption could only occur when the manufacturers could not possible follow both state and federal laws and that it was not impossible for the generic manufacturers in this case to comply with both sets of laws.¹³⁹ “[T]he mere possibility of impossibility had not been enough to establish pre-emption,” the dissent said, and generic manufacturers had the burden of proving that the FDA would have

¹³⁰ *Id.* at 2579–80.

¹³¹ *Id.* at 2580.

¹³² *Id.* at 2580–81.

¹³³ *Id.* at 2581.

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ *Id.* at 2582 (Sotomayor, J. dissenting).

¹³⁹ *Id.*

denied the request to change the warning.¹⁴⁰ The dissent did agree with the majority that, under current laws, generic manufacturers are not allowed to unilaterally change their labels,¹⁴¹ but then the dissent argued that the inability to unilaterally change the warning label was not an excuse to do nothing while they believed the label was inadequate.¹⁴² Generic manufacturers, the dissent argued, have a federal duty to monitor the safety of the drug and should propose label modifications to the FDA if the manufacturer believes it is necessary.¹⁴³ The dissent lamented the effect that the majority's ruling would have on the prescription drug industry, maintaining that the holding would decrease demand for generic drugs and create ethical quandaries for prescribing physicians.¹⁴⁴

C. Mutual Pharmaceutical Co. v. Bartlett

In December 2004, Karen Bartlett went to the doctor for treatment of pain in her right shoulder.¹⁴⁵ Her doctor prescribed the drug Clinoril, a non-steroidal anti-inflammatory drug.¹⁴⁶ Bartlett's pharmacist filled the prescription with sulindac, the generic version of Clinoril, which was manufactured by Mutual.¹⁴⁷ In a matter of weeks, Bartlett had to go to the emergency room for skin blisters, a fever, eye irritation, and other symptoms.¹⁴⁸ She was diagnosed with Stevens–Johnson Syndrome (SJS) progressing to toxic epidermal necrolysis (TEN).¹⁴⁹ SJS/TEN causes necrosis of the skin and mucous membranes and is potentially fatal.¹⁵⁰ Bartlett spent three months in the hospital and left with permanent injuries, including blindness.¹⁵¹ At the time that Bartlett received her prescription for sulindac, the label listed SJS/TEN under potential adverse reactions,

¹⁴⁰ *Id.*

¹⁴¹ *Id.* at 2585.

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ *Id.* at 2593.

¹⁴⁵ *Bartlett v. Mut. Pharm. Co.*, 731 F. Supp. 2d 135, 142 (D.N.H. 2010), *aff'd*, 678 F.3d 30 (1st Cir. 2012), *rev'd*, 133 S. Ct. 2466 (2013).

¹⁴⁶ *Bartlett*, 731 F. Supp. 2d at 142.

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

but did not mention SJS/TEN by name under the warnings section.¹⁵² After Bartlett's severe reaction to the drug, the FDA conducted an analysis of the risks and benefits of nonsteroidal anti-inflammatory drugs (NSAIDs), such as sulindac, and recommended changing the labels of all NSAIDs, including sulindac, to explicitly warn against TEN.¹⁵³

The Court in *Bartlett* addressed the issue of whether federal drug regulations preempt state design-defect claims based on the adequacy of the drug's warnings.¹⁵⁴ Justice Alito explained that state law design-defect claims put the manufacturers in a situation where they are in conflict with federal regulations because the only ways for the manufacturers to improve a drug's safety are either to change the drug's composition or change the labeling, both of which are not allowable actions under federal drug regulation laws.¹⁵⁵ The Court held that generic drug manufacturers cannot be sued under state law for injuries caused by their products because the state law is preempted by federal law.¹⁵⁶ This case shows that the Court followed the same line of reasoning used for failure-to-warn claims in *Mensing* to extend federal preemption to design-defect claims.

Although the holding in *Bartlett* is very similar to the Court's holding in *Mensing*, *Bartlett* addressed two issues that *Mensing* left undecided.¹⁵⁷ First, the Court established that impossibility preemption applies to design-defect claims in addition to failure-to-warn claims.¹⁵⁸ Just as generic drug manufacturers are prohibited from changing the labels on their drugs without FDA approval, so too are the manufacturers prohibited from unilaterally altering the design of their drugs.¹⁵⁹ Therefore, it was almost inevitable that the Court would extend the *Mensing* decision to apply to design-defect claims.¹⁶⁰ Second, the majority rejected the "stop-selling" rationale—the theory that the generic manufacturer could escape the impossibility of complying with both federal and state laws by

¹⁵² *Id.*

¹⁵³ *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2472 (2013).

¹⁵⁴ *Id.* at 2470.

¹⁵⁵ *Id.* at 2479.

¹⁵⁶ *Id.* at 2470.

¹⁵⁷ Louis M. Bograd, *Doubling Down on Generic Drug Preemption*, TRIAL, Nov. 2013, at 52.

¹⁵⁸ *Bartlett*, 133 S. Ct. at 2470.

¹⁵⁹ *Id.* at 2477–78.

¹⁶⁰ Bograd, *supra* note 157, at 54.

choosing not to produce the drug at all—as a valid option for manufacturers to avoid impossibility preemption.¹⁶¹ Again, this decision was not surprising given that acceptance of the stop-selling rationale would also effectively overturn the decisions in *Mensing* and other failure-to-warn cases.¹⁶²

The Supreme Court’s recent decisions addressing the issue of federal preemption of state tort liability claims against brand name and generic manufacturers have clearly established the scope of federal preemption in certain types of cases, but have also raised questions about whether the laws that limit the legal remedies available to consumers are appropriate. In *Wyeth*, the Court found that brand name drug manufacturers are not preempted from failure-to-warn claims because they can change the warning labels of their products without FDA approval.¹⁶³ But despite the *Wyeth* Court’s ruling, the Court decided in *Mensing* that federal law *does* preempt generic drug manufacturers from state law failure-to-warn claims because generic manufacturers cannot strengthen their drugs’ warning labels unilaterally.¹⁶⁴ Finally, the Court further restricted consumer remedies against drug manufacturers in *Bartlett* by holding that state law design-defect claims against generic manufacturers are also preempted by federal law because generic manufacturers cannot change the composition of their drugs unilaterally.¹⁶⁵

V. INNOVATOR LIABILITY THEORY

In light of the Supreme Court’s decisions in *Wyeth*, *Mensing*, and *Bartlett*, state courts are grappling with how to provide injured consumers with remedies in state tort law if a generic drug caused the injury. Courts in Alabama, California, and Vermont have adopted the innovator liability theory (also called competitor liability theory), which holds brand name drug manufacturers liable when a consumer is injured after taking the generic version of the drug.¹⁶⁶ The theory

¹⁶¹ *Bartlett*, 133 S. Ct. at 2477.

¹⁶² *Id.* at 2478.

¹⁶³ *Wyeth v. Levine*, 555 U.S. 555, 591 (2009).

¹⁶⁴ *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2578 (2011).

¹⁶⁵ *Bartlett*, 133 S. Ct. at 2470.

¹⁶⁶ *See Wyeth, Inc. v. Weeks*, No. 1:10-cv-602, 2013 WL 135753, at *19 (M.D. Ala. Jan. 11, 2013) (“Under Alabama law, a brand-name drug company may be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture of a brand-name

is based on the belief that a consumer taking a generic drug should be able to reasonably rely on the warnings on the brand name drug equivalent, since the generic and brand name drugs must be bioequivalent and have identical labels.¹⁶⁷ Since the consumer may rely on the brand name drug warnings, the consumer maintains the right to file a failure-to-warn claim against the brand name manufacturer, regardless of whether the consumer actually used and was injured by the brand name drug.¹⁶⁸

When an injured consumer files a failure-to-warn claim, it is a negligence action.¹⁶⁹ In order to prove negligence, the plaintiff must prove that the brand name manufacturer had a duty to warn, that the duty to warn was breached, and that the breach of duty was caused by the brand name manufacturer's failure to warn.¹⁷⁰ The standard of care is that of the average reasonable person.¹⁷¹ Since failure-to-warn is not a claim of a manufacturing defect, liability is not limited to the company who actually manufactured the drug.¹⁷² Therefore, creative attorneys have tried to find ways to subject brand name manufacturers to liability even when the injured plaintiff only took the generic form of the drug.

The Fourth Circuit was the first appellate court to address the innovator liability theory in the pharmaceutical industry.¹⁷³ The court held in *Foster v. American Home Products, Corp.* that the injured plaintiff could not recover from the brand name manufacturer when she was injured by the generic drug.¹⁷⁴ The court found that the brand name manufacturer did not have a duty of care to the plaintiff because the plaintiff was not injured by the manufacturer's drug.¹⁷⁵ In order to prevail against the brand name manufacturer, the

prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company.”); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010); *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (2008).

¹⁶⁷ *Weeks*, 2013 WL 135753, at *4.

¹⁶⁸ *Id.* at *19.

¹⁶⁹ Wesley E. Weeks, *Picking Up the Tab for Your Competitors: Innovator Liability After PLIVA, Inc. v. Mensing*, 19 GEO. MASON L. REV. 1257, 1274 (2012).

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² *Id.*

¹⁷³ *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165 (4th Cir. 1994).

¹⁷⁴ *Id.* at 172.

¹⁷⁵ *Id.* at 171.

plaintiff would have had to show that the defendant actually manufactured the product that caused the injury.¹⁷⁶

Innovator liability claims were previously unsuccessful¹⁷⁷ because courts relied on the ability of generic manufacturers to add or supplement warnings on their drugs.¹⁷⁸ But in 2008, a California appellate court became the first to allow an injured consumer to bring a claim against a brand name manufacturer for injuries caused by the generic version of the drug.¹⁷⁹ In *Conte v. Wyeth, Inc.*, plaintiff Elizabeth Conte took the generic drug metoclopramide for the brand name drug Reglan.¹⁸⁰ After taking metoclopramide for several years, Conte developed a debilitating neurological disorder.¹⁸¹ She filed suit against both the generic and brand name manufacturers, claiming that the drug's label did not adequately warn about the serious side effects of long-term use.¹⁸² The court held that the brand name manufacturer had a duty of care to consumers of the generic drug because it was "eminently foreseeable" that a patient would receive the generic drug based on the representation from the brand name manufacturer about the brand name drug.¹⁸³

In *Kellogg v. Wyeth*, a federal court similarly found that it was "reasonably foreseeable that a physician will rely upon a brand name manufacturer's representations—or the absence of representations—about the risk of side effects of its drug, . . . regardless of whether the pharmacist fills the prescription with a generic form of the drug."¹⁸⁴

Although innovator liability has been claimed in many cases, very few courts have actually followed the lead of *Conte* and *Kellogg* in shifting liability.¹⁸⁵ The *Levine* and *Mensing* decisions, however,

¹⁷⁶ *Id.* at 172.

¹⁷⁷ *See, e.g.*, Fullington v. Pfizer, Inc., No. 4:10CV00236 JLH, 2010 WL 3632747 (E.D. Ark. Sept. 17, 2010); Fields v. Wyeth, Inc., 613 F. Supp. 2d 1056 (E.D. Ark. 2009).

¹⁷⁸ *See, e.g.*, *Foster*, 29 F.3d at 170.

¹⁷⁹ *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (2008).

¹⁸⁰ *Id.* at 95.

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *Id.* at 105.

¹⁸⁴ *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 709 (D. Vt. 2010).

¹⁸⁵ *See, e.g.*, *Smith v. Wyeth*, 657 F.3d 420 (6th Cir. 2011); *Moore v. Mylan, Inc.*, 840 F. Supp. 2d 1337 (N.D. Ga. 2012); *Lashley v. Pfizer, Inc.*, 877 F. Supp. 2d 466 (S.D. Miss. 2012); *Eckhardt v. Qualitest Pharm., Inc.*, 889 F. Supp. 2d 901 (S.D. Tex. 2012); *Metz v. Wyeth*, 830 F. Supp. 2d 1291 (M.D. Fla. 2011).

have brought the option of innovator liability back to light, since the results of these two decisions created two different sets of liability rules for brand name manufacturers and generic manufacturers.¹⁸⁶ Because generic drug users do not have the same options for recovery that brand name drug users do, it is likely that attorneys and courts will be more open to the innovator liability argument.

A. *Duty to Warn*

The general nature of the duty to warn allows it to apply to consumers who relied on the brand name manufacturer's warnings, even if the actual drug ingested by the consumer was a generic version.¹⁸⁷ Brand name manufacturers have a duty to avoid foreseeable harm by properly warning consumers of the drug.¹⁸⁸ Since it is foreseeable that generic manufacturing companies will eventually produce a generic version of the brand name company's drug, that duty extends to the third parties that take the generic version.¹⁸⁹ Although courts previously disregarded foreseeability as stretching the concept too far,¹⁹⁰ the *Mensing* and *Bartlett* decisions made it easily foreseeable that generic drug consumers will rely on brand name drug warnings because that is the only warning allowed.¹⁹¹ Furthermore, since substituting generic drugs for brand name is common practice by pharmacists,¹⁹² it makes it even more foreseeable that generic drug consumers will rely on the brand name drug warnings.¹⁹³

One might argue that a generic manufacturer assumes the risk of inadequate labeling by the brand name manufacturer, but in negligence cases the defendant is only liable if the adopted label was negligently adopted.¹⁹⁴ Since the brand name drug labels must be

¹⁸⁶ *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011); *Wyeth v. Levine*, 555 U.S. 555 (2009).

¹⁸⁷ *Weeks*, *supra* note 169, at 1275.

¹⁸⁸ *Id.* at 1275–76.

¹⁸⁹ *Id.* at 1276.

¹⁹⁰ *See Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 171 (4th Cir. 1994).

¹⁹¹ *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470 (2013); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2576 (2011).

¹⁹² *Mensing*, 131 S. Ct. at 2583–84.

¹⁹³ *Weeks*, *supra* note 169, at 1276.

¹⁹⁴ *Hammons v. Icon Health & Fitness*, 616 F. Supp. 2d 674, 682 (E.D. Mich. 2009).

FDA-approved and the generic drug manufacturers are legally required to adopt the brand name label, it is not negligent for the generic manufacturers to do so.¹⁹⁵

B. Cause of the Harm

In a failure-to-warn case, the harm is caused by an inadequate warning; it is not the drug itself that causes the harm.¹⁹⁶ In order to prevail on a failure-to-warn claim, the consumer must prove factual cause, which means “but for” the inadequate warning, the consumer of the drug would not have suffered harm.¹⁹⁷ Even though, under *Mensing* and *Bartlett*, a manufacturer cannot be held responsible for a warning that it did not create and that it was legally required to put on its product,¹⁹⁸ it is the inadequate warning that causes the harm, not the manufacturing of the drug itself.¹⁹⁹ Any inadequacy in the brand name drug’s original warning will flow down to the generic drug’s warning, causing foreseeable harm to the generic consumer.²⁰⁰ It is direct causation because the generic manufacturer cannot alter the warning in any way.²⁰¹ The only action that a generic manufacturer can take is to choose not to market an inadequately labeled drug or inform the FDA of the inadequate warning.²⁰² In either case, the action is not a superseding cause and therefore does not change the fact that the brand name manufacturer caused the harm with the inadequate label.²⁰³

The learned intermediary doctrine also creates a cause of harm by brand name manufacturers.²⁰⁴ The learned intermediary doctrine states that a brand name manufacturer’s duty to warn is met when a physician relies on the manufacturer’s warning when

¹⁹⁵ Weeks, *supra* note 169, at 1277–78.

¹⁹⁶ *Id.* at 1280.

¹⁹⁷ The harm is not the physical harm done to the consumer, but the fact that, had the consumer been properly informed about the risks of taking the drug, he would have either not taken the drug or taken precautions before ingesting the drug.

¹⁹⁸ See *supra* Part III.

¹⁹⁹ Weeks, *supra* note 169, at 1280.

²⁰⁰ *Id.*

²⁰¹ *Id.*

²⁰² *Id.* at 1280–81.

²⁰³ *Id.* at 1281.

²⁰⁴ *Id.*

prescribing the drug.²⁰⁵ If the doctor relies on an inadequate warning, the harm is done at that time; it does not matter that a pharmacist may later fill the prescription with the generic drug.²⁰⁶

Under current FDA regulations, a generic drug manufacturer cannot alter the warning from the brand name drug.²⁰⁷ Since the generic manufacturer cannot and does not create the warning for the drug that causes harm to a consumer, the generic manufacturer cannot be held liable. A manufacturer cannot be held responsible for a warning that it did not create and that it was legally required to put on its product.²⁰⁸ Another way to look at the issue is that if one particular generic manufacturer exits the market, it will not decrease the harm done to consumers of the generic drug; the pharmacist will just prescribe a generic drug from a different manufacturer (or the brand name drug) and it will have the same inadequate warning.²⁰⁹ The only way for the harm to be avoided is for the brand name manufacturer to change the warning.

C. Implications of Innovator Liability

Innovator liability creates problems for brand name manufacturers. Since the brand name manufacturer is the one who invests time and money into the research and development of the drug, the increased liability reduces the profitability of producing new drugs and allows generic manufacturers to enjoy the benefits of the brand name manufacturer's work without the additional liability.²¹⁰ Even if the brand name drug is removed from the market, the manufacturer is still liable for harm caused by competing generic drugs.²¹¹ Although it may seem unfair, it is still the brand name manufacturer's negligence in labeling that is the cause of the injury and whether or not the manufacturer continues to sell the product has no impact on its duty to consumers who rely on the manufacturer's labeling.²¹²

²⁰⁵ *Id.*

²⁰⁶ *Id.*

²⁰⁷ *See supra* Part III.

²⁰⁸ Weeks, *supra* note 169, at 1281.

²⁰⁹ *Id.* at 1285.

²¹⁰ *Id.* at 1259.

²¹¹ *Id.* at 1286.

²¹² *Id.* at 1286–87.

Innovator liability also creates problems concerning generic drug manufacturing as well.²¹³ Since the generic manufacturers are not at risk for inadequate warnings on their drugs, they are able to sell their drugs to consumers at a low price, but that price is not a true reflection of the cost of selling a potentially harmful drug.²¹⁴ If the drug is indeed inadequately labeled, the harm to society might be increased because more people are able to afford and consume the drug.²¹⁵ The brand name manufacturer would be the one liable for the harm caused to all the injured consumers, and that would disincentivize the brand name manufacturer from researching and developing new drugs at the risk of inadequately labeling the drug.²¹⁶ Overall, innovator liability likely results in less new drug development.²¹⁷

Since current FDA regulations prohibit a generic drug manufacturer from altering the warning label from the brand name drug, the generic manufacturer cannot be held liable for a poorly labeled drug.²¹⁸ Although protecting generic manufacturers against liability for something they cannot control is a correct application of current administrative regulations, it has significant negative implications for brand name manufacturers, prescription drug consumers, and even generic manufacturers.

VI. IMPACT ON DRUG SUBSTITUTIONS

Although the recent Court decisions were a win for generic drug manufacturers, there will likely be some repercussions in the form of decreased numbers of generic drug substitutions.²¹⁹ Decreased numbers of substitutions would happen because physicians would stop allowing substitutions, pharmacists would stop making automatic substitutions, patients would start denying substitutions or requesting brand name drugs, or states would change their substitution laws to deter or eliminate generic substitutions.²²⁰

²¹³ *Id.* at 1288.

²¹⁴ *Id.*

²¹⁵ *Id.*

²¹⁶ *Id.*

²¹⁷ *Id.*

²¹⁸ *Id.* at 1281.

²¹⁹ Daniel Kazhdan, *Wyeth and PLIVA: The Law of Inadequate Drug Labeling*, 27 BERKELEY TECH. L.J. 893, 913–14 (2012).

²²⁰ *Id.* at 914.

Physicians have several motivations for disallowing substitutions.²²¹ One reason is to preserve the patient's right to seek compensation if the generic drug is inadequately labeled.²²² Another reason is to avoid malpractice claims against them for negligently prescribing an inadequately labeled drug.²²³ Patients have the ability to sue multiple sources for their injuries, so a physician could be sued for negligently prescribing the medication that caused the injury.²²⁴ If physicians feel as though inadequately labeled generic drugs may harm their patients, it is likely that physicians will start to prevent substitution more frequently.²²⁵

Perhaps the largest potential cause of decreased drug substitutions would be changes in state laws. Although most changes to drug substitution laws have been in favor of promoting drug substitution,²²⁶ the recent Supreme Court decisions in *Wyeth*, *Mensing*, and *Bartlett* will increase the pressure on states to change their laws to discourage generic substitution. The ten states that allow pharmacists to substitute generic drugs without informing the patient²²⁷ are more likely to seek to change their laws so that patients are not deprived of their rights to sue the manufacturer without notice; studies show that patient consent is correlated to a decrease in generic substitution.²²⁸

²²¹ *Id.*

²²² *Id.* If the patient lives in a state with a court that has adopted the innovator liability theory, then he or she might have the ability to sue the brand name drug manufacturer and be compensated in that way. Otherwise, the patient is without recourse for the injury caused by inadequate labeling.

²²³ *Id.* at 914–15.

²²⁴ *Id.* However, if the patient sues the manufacturing company and receives complete compensation, the patient can no longer sue the physician for the same injury. If partial or no compensation is received from the manufacturing company, then the patient may still sue the physician for the remaining amount of damage. *Id.*

²²⁵ *Id.*

²²⁶ Compare ARIZ. REV. STAT. ANN. § 32-1963.01(D) (2001); 225 ILL. COMP. STAT. ANN. 85/25 (West 2001); KAN. STAT. ANN. § 65-1637(a)(1) (West 2001); ME. REV. STAT. ANN. tit. 32, § 13781 (2001); MD. CODE ANN. HEALTH-GEN. § 15-118(a)(1) (West 2001); MASS. GEN. LAWS ANN. ch. 112, § 12D (West 2001); N.J. STAT. ANN. § 24:6E-7 (West 2001); N.C. GEN. STAT. ANN. § 90-85.28(b) (West 2001); TENN. CODE ANN. § 53-10-204 (West 2001), with the modern versions of the statutes discussed in *supra* notes 50–60.

²²⁷ See *supra* note 55.

²²⁸ William H. Shrank et al., *State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid*, 29 HEALTH AFFAIRS 1383, 1383 (2010).

States are also more likely to change their laws to require physicians to expressly state whether generic substitution is permitted to not, which would force physicians to consider the question each time they prescribed a drug.²²⁹ States have to find a way to balance the financial and compliance benefits of generic substitution with the deprivation of the right to seek compensation that is now a concern in light of the recent Court decisions.

VII. WAYS TO BALANCE OPTIONS FOR PATIENTS HARMED BY BRAND NAME OR GENERIC DRUGS

There are several ways that the differences in treatment between harms caused by brand name drugs and harms caused by generic drugs can be balanced for the consumer. The Court may reverse or limit the holdings from *Wyeth*, *Mensing*, or *Bartlett*, but such action is very unlikely unless the FDA changes its position, because the Court relied on the FDA's regulations and interpretations in coming to its decisions in those cases.²³⁰ Other ways to balance treatment are waiver of the preemption defense by generic manufacturers (either by the manufacturer's own choice or by force by the state), state action that would permit injured consumers to bring an action against the brand name manufacturer (under the innovator liability theory), or congressional action to overrule any of the Court's decisions.²³¹

A. *No Changes*

Under the current post-*Mensing* law, attorneys for clients injured by generic drugs do not have the option to seek damages under state failure-to-warn claims.²³² University of California, Irvine School of Law Dean Erwin Chemerinsky believes that, until a better solution is put into place, attorneys have the responsibility to find alternative ways to litigate on behalf of such clients.²³³ “The

²²⁹ See *Mosley v. Wyeth*, 719 F. Supp. 2d 1340, 1347 n.6 (S.D. Ala. 2010) (explaining how in Alabama, where express authorization by the physician is required for generic drug substitution, such substitution is “less likely to occur”).

²³⁰ *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011); *Wyeth v. Levine*, 555 U.S. 555 (2009).

²³¹ Kazhdan, *supra* note 219, at 917–25.

²³² *Mensing*, 131 S. Ct. at 2582.

²³³ Erwin Chemerinsky, *A Devastating Decision*, TRIAL, Sept. 2011, at 54.

immediate challenge for lawyers representing patients harmed by generic drugs,” Chemerinsky says, “is to develop alternative litigation theories. This may require suing parties other than the makers of generic drugs or devising claims based on grounds other than failure to warn.”²³⁴ Possible alternatives include bringing claims against the prescriber of the injuring drug or taking action against the manufacturer for negligence or fraud.²³⁵

Advocates of the current law argue that Congress’s purpose, as conveyed through the Hatch–Waxman Amendments, is to allow federal preemption for generic drug manufacturers with respect to state failure-to-warn claims.²³⁶ They believe that if Congress had intended an alternative to be available, it would have expressly addressed the issue in the Amendments;²³⁷ in fact, they contend that Congress’s real purpose for sheltering generic manufacturers from failure-to-warn liability is to maintain low costs for prescription drug consumers.²³⁸ More consumers will have access to prescription medications if generic manufacturers can keep their drug costs low in part by avoiding costly litigation.²³⁹

Opponents of the current law maintain that the use of generic drugs will decline because physicians will be more hesitant to prescribe generic drugs or allow for generic substitution, and consumers will be deterred from using generic drugs because of the legal implications.²⁴⁰ They also argue that the current law limits the rights of consumers injured by generic drugs with inadequate labels, allows for a regulatory system that will negatively affect drug safety, and is at odds with Congress’s purpose to make brand name and generic drugs identical.²⁴¹ Congress allowed for an abbreviated approval process for generic drugs because they are bioequivalent to their brand name counterparts.²⁴² This revised process allowed

²³⁴ *Id.* at 56.

²³⁵ *Id.*

²³⁶ *Mensing*, 131 S. Ct. at 2575.

²³⁷ *Id.*

²³⁸ *Id.*

²³⁹ *Id.*

²⁴⁰ *Id.* at 2593.

²⁴¹ *Id.* at 2592–93.

²⁴² *Abbreviated New Drug Application (ANDA): Generics*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedand>

Congress to “provide a safe, effective, low cost alternative to the American public.”²⁴³ Challengers of the *Mensing* decision argue that allowing different levels of state tort liability to apply to generic and brand name drug manufacturers is, in essence, stating that generic and brand name drugs are not equivalents and that only consumers of brand name drugs have to right to bring failure-to-warn claims in state court.²⁴⁴

B. Reverse or Limit the Holdings

The Supreme Court has the authority to reverse or limit its holding in a previous case.²⁴⁵ Although it is unlikely that the Court would choose to reverse or limit any of its holdings of its own accord, it seems more likely if the FDA makes certain changes to its guidelines. In *Mensing*, the Court states “[a]ll relevant events in these cases predate the Food and Drug Administration Amendments Act of 2007. We therefore refer exclusively to the pre-2007 statutes and regulations and express no view on the impact of the 2007 Act.”²⁴⁶ The meaning of this statement is not clear, but there are a few possibilities.²⁴⁷ The first is that the Court believes the amendments granted the FDA the ability to require post-market studies, and such action would cause the Court to come to a different decision in *Mensing*.²⁴⁸ If the FDA requires generic drug manufacturers to perform post-market studies, then those manufacturers might have enough information about the drug that they could be allowed to amend their own labels.²⁴⁹ In that case, state law would not be preempted because the label changes would be allowed and *Mensing* would not be good law.

The Court’s statement may also be in reference to the ability granted by the amendments to the FDA to order label changes.²⁵⁰ Prior to the 2007 amendments, the FDA could suggest a label change

approved/approvalapplications/abbreviatednewdrugapplicationandgenerics/default.htm (last updated July 17, 2013).

²⁴³ *Id.*

²⁴⁴ *Mensing*, 131 S. Ct. at 2592–93.

²⁴⁵ Kazhdan, *supra* note 219, at 917.

²⁴⁶ *Mensing*, 131 S. Ct. at 2574 n.1 (internal citations omitted).

²⁴⁷ Kazhdan, *supra* note 219, at 917.

²⁴⁸ *Id.*

²⁴⁹ *Id.* at 917–18.

²⁵⁰ *Id.* at 918.

to a brand name drug manufacturer but the manufacturer was free to disregard the suggestion; the FDA could choose not to continue to approve a drug with a label that did not include the FDA's suggested changes, but the manufacturer had no obligation to make the suggested changes.²⁵¹ Now, the FDA does not have to try to convince the brand name manufacturer that a change needs to be made; the FDA can just mandate the change.²⁵² In *Mensing*, the claim was brought under pre-2007 rules, so the FDA could not just force the brand name manufacturer to change its label. The generic manufacturer would have had to ask the FDA to suggest a label change, and then the FDA would have had to negotiate with the brand name manufacturer to decide on and implement a new label.²⁵³ Regardless of the amendments, however, the generic manufacturer would still be unable to independently change the labels on its drugs, and that is what the Court relied on to determine the impossibility of the manufacturers' compliance with state and federal law.²⁵⁴ Therefore, it is unlikely that such an interpretation of the Court's statement would have reversed its decision.

C. FDA Change of Position

The most likely method of changing the results of *Mensing* and *Bartlett* is for the FDA to allow generic manufacturers to unilaterally change their drug labels.²⁵⁵ The FDA was the originator of the distinction between brand name and generic manufacturers; the Court just followed suit.²⁵⁶ The FDA's rationale for the distinction was that it wanted brand name and generic drugs to be equivalent so that a consumer could rely on a generic drug to be equivalent to the brand name.²⁵⁷ Consistent labeling, the FDA reasoned, would

²⁵¹ *Wyeth v. Levine*, 555 U.S. 555, 571 (2009).

²⁵² Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901(a), 121 Stat. 823, 924 (2007) (amending 21 U.S.C. § 355(o)(4)).

²⁵³ *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2578 (2011).

²⁵⁴ *Id.* at 2579.

²⁵⁵ *Kazhdan*, *supra* note 219, at 918.

²⁵⁶ *Mensing*, 131 S. Ct. at 2575–69.

²⁵⁷ *Kazhdan*, *supra* note 219, at 918.

minimize confusion and enforce confidence in product equivalency.²⁵⁸

The generic manufacturer, however, argued that the ability to unilaterally change or add to warnings created benefits that outweighed those of consistent labeling.²⁵⁹ If the change proposed by the generic manufacturer is agreed to by the FDA, then the brand name manufacturer would have to change its label as well and there would still be consistency; if the FDA did not agree with the change, the generic manufacturer would return to the brand name label.²⁶⁰ Also, even under the current rules, when a brand name manufacturer changes its label to reflect new warnings, it takes time for the FDA to review the change and for the generic manufacturers the change their labels, so labels are already inconsistent between the brand name and generic drug during that period of change.²⁶¹ If the FDA changed its regulations to allow generic manufacturers to unilaterally change their labels, then it seems likely that the Court would change its position.²⁶²

D. Generic Manufacturer Waiver of Its Preemption Defense

Another option for altering the outcome caused by the Court's decisions is for generic drug manufacturers to waive their preemption defense.²⁶³ Even though it seems counterintuitive for the very companies who fought for federal preemption from failure-to-warn claims²⁶⁴ to waive that defense, it might become a good business

²⁵⁸ *Mensing*, 131 S. Ct. at 2574-75 (citing Brief for the United States as Amicus Curiae Supporting Respondents at 16, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501), 2011 WL 741927).

²⁵⁹ Brief of Petitioners *PLIVA, Inc.; TEVA Pharms. USA Inc.; and UDL Labs, Inc.* at 37-38, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501), 2011 WL 219554.

²⁶⁰ Kazhdan, *supra* note 219, at 919.

²⁶¹ *Id.*

²⁶² *Id.* at 919-20.

²⁶³ *Id.* at 921.

²⁶⁴ See Reply Brief of Petitioners Actavis, Inc. & Actavis Elizabeth, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501), 2011 WL 1059615, at *3; Reply Brief of Petitioners *PLIVA, Inc.; Teva Pharm. USA, Inc.; and UDL Labs, Inc.* at 4, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501), 2011 WL 1059616; Brief of Apotex, Inc. as Amicus Curiae in Support of Petitioners at 14, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501), 2011 WL 288894; Brief of Generic

practice for generic manufacturers if sales of generic drugs decrease due to the decrease in generic drug substitutions.²⁶⁵ Generic manufacturers would face a problem, however, if they attempted to waive their preemption defense.²⁶⁶ Since generic manufacturers are generally not distinguishable as individual companies by consumers, the manufacturers do not advertise their products because doing so would benefit all generic drugs with the same chemical name.²⁶⁷ The same issue occurs if a generic manufacturer decides that it would be beneficial to waive its preemption defense; if one generic manufacturer waives its preemption defense, then all the manufacturers will gain consumer goodwill, even if they do not all allow their consumers to sue.²⁶⁸ Therefore, even though the effect of preemption might be harmful to the generic manufacturers' bottom line, waiving the preemption defense may not work to avoid the problem.²⁶⁹

E. State Action

States do not have the statutory authority to overrule the Supreme Court's decisions, but there are other options that states can pursue.²⁷⁰ Two options are: (1) to require generic manufacturers to waive their preemption defense before allowing that manufacturer's drug to be substituted, or (2) to allow injured patients to bring suits against the equivalent brand name drug manufacturers.²⁷¹

A required waiver would limit generic drug substitution to only drugs from manufacturers that waived their preemption defense.²⁷² The state would maintain a list of generic drug

Pharm. Ass'n as Amicus Curiae in Support of Petitioners at 19, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501), 2011 WL 343069; Brief for Morton Grove Pharm., Inc. & Impax Lab., Inc. as Amici Curiae in Support of Petitioners at 13, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501), 2011 WL 343070.

²⁶⁵ Kazhdan, *supra* note 219, at 921.

²⁶⁶ *Id.*

²⁶⁷ Adam R. Young, *Generic Pharmaceutical Regulation in the United States with Comparison to Europe: Innovation and Competition*, 8 WASH. U. GLOBAL STUD. L. REV. 165, 178 (2009).

²⁶⁸ Kazhdan, *supra* note 219, at 922.

²⁶⁹ *Id.*

²⁷⁰ *Id.*

²⁷¹ *Id.* at 922–24.

²⁷² *Id.* at 922.

manufacturers that had waived their preemption defense and only drugs from those manufacturers would be allowed to be substituted for brand name drugs.²⁷³ Therefore, generic drug manufacturers would have the choice of whether or not they wanted to waive their tort liability. If the manufacturer chose not to waive its preemption defense, then substitution of its generic drug for the equivalent brand name drug would not be allowed in that state.²⁷⁴

One potential problem with required waivers would arise if contractual waivers are not judicially enforceable.²⁷⁵ The First Circuit has held that “[a] statutory right or remedy may be waived when the waiver would not frustrate the public policies of the statute. . . . [But a] statutory right may not be disclaimed if the waiver could ‘do violence to the public policy underlying the legislative enactment.’”²⁷⁶ If allowing state tort claims for inadequate labeling clashes with the policies underlying the Hatch–Waxman Act, then the Court would likely find that state laws requiring generic manufacturers to waive their preemption defense are invalid as “obstacle[s] to the accomplishment and execution of the full purposes and objectives of Congress.”²⁷⁷

The second option for states, to allow suits against equivalent brand name drug manufacturers, would allow injured patients to have some form of recourse against drug manufacturers. The logic behind allowing these types of suits is that the reason the generic drug label was not more accurate was because the brand name had not changed its label to be more accurate.²⁷⁸ Most courts at this time do not allow this argument and require that an injured plaintiff must have taken the defendant manufacturer’s drug, not a bioequivalent drug.²⁷⁹

²⁷³ *Id.*

²⁷⁴ *Id.*

²⁷⁵ *Id.* at 923.

²⁷⁶ *Canal Elec. Co. v. Westinghouse Elec. Corp.*, 548 N.E.2d 182, 187 (Mass. 1990) (quoting *Spence v. Reeder*, 416 N.E.2d 914, 924 (Mass. 1981)).

²⁷⁷ *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 373 (2000).

²⁷⁸ *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2576–77 (2011).

²⁷⁹ See Kenneth Sills, *Liability of Name Brand Drug Manufacturer for Injury or Death Resulting from Use of Prescription Drug’s Generic Equivalent*, 56 A.L.R. 6TH 161 (2010) (containing a collection of cases in which the court considered the liability of brand name manufacturers for injuries or deaths to a patient who took the generic bioequivalent of the brand name drug).

F. Congressional Action

Congress could balance the difference in treatment of claims for injured patients by making the preemption laws uniform for both brand name and generic drugs.²⁸⁰ The Court in *Wyeth*,²⁸¹ *Mensing*,²⁸² and *Bartlett*²⁸³ makes it clear that Congress did not explicitly state whether it wanted preemption or not, and had Congress made the point explicitly, the Court would have accepted and followed that decision. If Congress would either explicitly make preemption laws consistent for both generic and brand name drug manufacturers or allow generic drug manufacturers to unilaterally change their labels, then the decisions in *Mensing* and *Bartlett* would effectively be reversed.²⁸⁴

VIII. CONCLUSION

It is clear from the amount of money spent on prescription drugs in the United States and the increase in spending on generic drugs that the effects of choosing a generic drug over a brand name drug are increasingly important for consumers who might be injured by the drug. The lower cost of generic drugs make substitution an appealing choice, but patients may not know about the hidden risks of choosing generic over brand name. The Supreme Court has

²⁸⁰ Kazhdan, *supra* note 219, at 925.

²⁸¹ *Wyeth v. Levine*, 555 U.S. 555, 574–75 (2009) (“Congress could have applied the pre-emption clause to the entire FDCA. It did not do so’ Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.”) (footnote omitted) (quoting *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327 (2008)).

²⁸² *Mensing*, 131 S. Ct. at 2576 n.5 (“The Hatch-Waxman Amendments contain no provision expressly pre-empting state tort claims. Nor do they contain any saving clause to expressly preserve state tort claims. Although an express statement on pre-emption is always preferable, the lack of such a statement does not end our inquiry. . . . [T]he absence of express pre-emption is not a reason to find no *conflict* pre-emption.”) (original citations omitted).

²⁸³ *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2480 (2013) (“[T]he Court would welcome Congress’ ‘explicit’ resolution of the difficult pre-emption questions that arise in the prescription drug context. . . . In the absence of that sort of ‘explicit’ expression of congressional intent, we are left to divine Congress’ will from the duties the statute imposes.”).

²⁸⁴ Kazhdan, *supra* note 219, at 925.

endured much criticism for its decisions in *Wyeth*, *Mensing*, and *Bartlett* and it acknowledges, the “situation is tragic and evokes deep sympathy,” however, “a straightforward application of pre-emption law” requires that federal law preempts state failure-to-warn and design-defect claims.²⁸⁵ Therefore, the FDA and Congress must work together to resolve the preemption issues arising out of state tort claims by patients injured by generic drugs in order for the Supreme Court to change its stance in the matter.

As the decisions in *Mensing* and *Bartlett* demonstrated, the current preemption laws do not give the Court the ability to allow state tort claims against generic manufacturers. The FDA and Congress have the ability to change the laws so that this imbalance can be righted. Although there are other ways that the states or manufacturers could work to provide a solution to the problem, it should ultimately fall to the FDA and Congress to revise the preemption laws to allow injured patients to bring claims against generic manufacturers. By doing so, the FDA and Congress could bring individual liability to federal drug regulation and the state tort systems where current laws have created unwanted and unnecessary results.

²⁸⁵ *Bartlett*, 133 S. Ct. at 2480.